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**COMPETITION ADMINISTRATION**  
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**INTERNATIONAL DEVELOPMENT**  
**RESEARCH CENTRE**  
**(IDRC)**

**USING COMPETITION LAW TO REGULATE ANTI-COMPETITIVE  
PRACTICES IN THE PHARMACEUTICAL DISTRIBUTION SYSTEM  
IN VIETNAM**

**A REPORT**

**Disclaimer:** This report is prepared by a team of researchers headed by the Competition Administration Department – Ministry of Industry and Trade. The views and analysis provided in the report are on the basis of the team’s finding during the desk and field research process and are not the official viewpoints of the Competition Administration Department.

All quotations of information in this report have to be clearly cited.

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**Project Director**

**Bach Van Mung**

## **ABBREVIATIONS**

AIDS	Acquired Immune Deficiency Syndrome
AFTA	ASEAN Free Trade Area
ARV	Anti-retroviral
ASEAN	Association of South East Asia Nations
ATC/DDD	Anatomical Therapeutic Chemical/the assumed average maintenance <i>dose</i> per <i>day</i> for a <i>drug</i> used for its main indication in adults
BMI	Business Monitor International Ltd.
Co. Ltd.	Company Limited
CR	Concentration Ratio
CUTS	Consumer Unity & Trust Society
M&A	Merger and Acquisition
DAV	Drug Administration of Vietnam
EC	European Commission
ECJ	European Court of Justice
EDL	Essential Drug List (in the Philippines)
EU	European Union
FTC/US FTC	United States' Federal Trade Commission
FDA	Food & Drug Administration (in Thailand)
FDI	Foreign Direct Investment
FIEs	Foreign-invested Enterprises
GDP	Good Distribution Practices
GMP	Good Manufacturing Practices
GPO	Government Pharmaceutical Organisation (in Thailand)
GSO	General Statistics Office
GSP	Good Storage Practices
GSK	GlaxoSmithKline
HCMC	Ho Chi Minh City
IDRC	International Development Research Centre
IMF	International Monetary Fund
IPR	Intellectual Property Right
JSC	Joint-stock Companies

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JVs	Joint-ventures
MCA	Monopoly Control Authority (of Pakistan)
MNCs	Multinational Corporations
MRTPA	Monopolistic and Restrictive Trade Practices Act (of India)
NDP	National Drug Plan (in the Philippines)
NDRC	National Development & Reform Commission (in China)
OECD	Organisation for Economic Co-operation and Development
OFT	Office of Fair Trading (UK)
OTC	Over the Counter
PMPRB	Patented Medicine Prices Review Board (Canada)
R&D	Research and Development
SFDA	State Food and Drug Administration (China)
SMEs	Small and Medium-size Enterprises
SOEs	State-owned Enterprises
STDs	Sexually-transmitted Diseases
TNCs	Transnational Corporations
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UK	United Kingdom
UNCTAD	United Nations' Conference on Trade and Development
UNIDO	United Nations' Industrial Development Organisation
USA	United States of America
VASS	Vietnam Academy of Social Sciences
VCAD	Vietnam Competition Administration Department
VCC	Vietnam Competition Council
VIMAMES	Vietnam Association for Medical Ingredients
VND	Vietnam Dong
VNPCA	Vietnam Pharmaceutical Companies Association
VSIC	Vietnam Standard Industrial Classification
VN	Vietnam
WHO	World Health Organisation
WTO	World Trade Organisation
ZPV	Zuellig Pharma Vietnam

## INTRODUCTION

“The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being.”

*- Preamble to the WHO Constitution*

“The State shall see to [...] create the necessary conditions for all citizens to enjoy health care. [...] It is strictly forbidden for private organisations and individuals to dispense medical treatment, to produce and trade in medicaments illegally, thereby damaging the people's health.”

*- Article 39 of the Constitution 1992 (amended in 2001) of Vietnam*

It is undeniable that access to health care is one of the most basic needs, an inviolable right of every human. It is also recognised by the Constitution of Vietnam. Health care is an intrinsic component of the development process and its quality reflects clearly how the socio-economic development achievements are being translated into increased welfare for the whole society, or, on the other hand, the drawbacks and remaining problems of a market economy, without the regulatory role by the state. Despite the constitutional commitments to provide access to health to the nation's population, there remain a lot of problems in this field, which, sometimes, results in the legitimate rights and interests of patients and Vietnamese people, in general, not being respected and protected.

However, access to health care is not a problem confined to Vietnam and may easily be ranked as a crisis of global dimensions. Over one-third of the world's population lacks access to health care and pays a heavy price, in terms of poor health and elevated mortality<sup>1</sup>. Lack of access to health care also increases poverty, since reduced physical health would adversely affect productivity, whereas additional costs to secure health care aggravated poverty. There is a widely held assumption that health care for the poor is very inexpensive, given their reliance on welfare-driven government institutions. However, in reality, the poor are often compelled to avail of more expensive private services, due to a range of factors, and government hospitals also have many hidden costs.

In developing countries, a large proportion of the population has no access to necessary medicines. In the poorest parts of Africa and Asia, the picture is even worse, with over 50 percent of the population lacking access to even the most basic essential drugs. In Vietnam, we have witnessed several times when prices of medicines are exorbitantly high, which a large part of the population cannot afford. The matter of health care, like most other development issues, is simply so enormous in magnitude that the government alone cannot be expected to provide the perfect panacea to resolve all the issues in the matter. The involvement of the people and relevant industries is essential to transform the paper pledges into reality. Besides, we can also make use of the movements of the free markets effectively to bring medicines and health care to the people.

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<sup>1</sup> Nitya Nanda and Ritu Lodha, *Making Essential Medicine Affordable to the Poor*, Wisconsin International Law Journal, Vol. 20, No. 3, p. 581, 2002.

Access to medicines and health care has five aspects: availability of supply, price, quality, ability to pay and access to proper and affordable consultations. All these aspects are vitiated in our country by a number of factors, which range from poverty and poor infrastructure to corruption, market malpractices and lack of awareness. Competition law would be a good instrument, in addition to other legal instruments, to undertake this solution: promoting effective free market mechanisms, preventing anti-competitive practices or unfair trade practices, protecting the interests of the consumer and improving social welfare.

Anti-competitive practices in the pharmaceutical industry include, amongst others, price-fixing, abuse of dominance, collusive agreements and tied selling. Even practices such as kickbacks to doctors and pharmacists may be deemed as anti-competitive, as they result in depriving patients of best possible medicines and services at the lowest possible prices. The primary effect of anti-competitive practices on the health sector is that medicines and services are rendered costlier.

In the context of Vietnam's integration into the world economies, new concerns arise with respect to access to medicines and health care. Will there be abuse of the monopoly rights of the patent-holder, causing an increase in prices? Will relaxation in price controls lead to rising prices? Will the inevitable increase in MNC presence, post-TRIPS, usher in many anti-competitive practices? Will the current spurt in mergers and acquisitions create market structures, which may result in abuse of dominance? These are a few of the many questions arising in the wake of a series of changes in the pharmaceutical industry related to competition and de-regulation. They need to be closely examined from the perspective of competition law and policy as well as other relevant laws and regulations.

### **Research Objectives**

This report is undertaken within the framework of a project supported by the IDRC, under its grant entitled "Competition Research for Economic Development". The overall objective of the project is to promote public (consumer) welfare in Vietnam, by way of ensuring and enhancing access to medicines and enhancing the efficiency of health delivery systems in the country.

The specific objectives of the project, as well as of the report, are:

- To identify competition concerns in the pharmaceutical sector and health delivery system in Vietnam;
- To examine the scope of competition policy and law in dealing with such concerns in the context of Vietnam, with references to relevant experiences of other countries in the region and the world;
- To suggest an implementation strategy for the competition authorities of Vietnam, alone as well as in co-operation with other relevant government agencies, in particular the sectoral regulators, to address these concerns;
- To build the analytical research of the competition authorities of Vietnam; and

- To disseminate research findings amongst all relevant stakeholders towards promoting compliance and best practices amongst the private sector.

### **Scope and Subject of Research**

Towards the above-mentioned objectives, the project would look into the following matters:

- Market structure, the existence of barriers to entry, market shares of dominant businesses, market entry and exit process;
- The pharmaceutical distribution system in Vietnam, existing players, including enterprises and professional and trade associations;
- The legal and regulatory framework regulating issues related to competition and the manufacturing and distributing of medicines in Vietnam, such as competition law, pharmaceutical law, laws on pricing, taxation, intellectual property rights (IPRs), consumer protection policy and other laws on business and distribution;
- The system of relevant state agencies, including competition authorities and sectoral regulators;
- The real situation regarding competition in the pharmaceutical distribution sector in Vietnam and those behaviours which might violate the competition law and consumer protection policy in Vietnam; and
- The international experiences in similar issues, or relevant laws and regulations, in order to draw the lessons for Vietnam.

Considering all the matters above, the report would provide assessments regarding the competitive environment and competitive activities in the market for pharmaceutical products in Vietnam; draw conclusions on the degree of competition, the potential risks regarding anti-competitive practices and unfair trade practices; and on that basis, propose recommendations to the government, the competition authorities, sectoral regulators as well as the private sector and the consumers.

In this report, we only examine issues related to the final completed pharmaceutical products used for treating or preventing diseases in humans and do not include pharmaceutical ingredients, materials, unfinished products or Vietnamese traditional herbal medicines or oriental formulations. The medicines examined might be manufactured in Vietnam or outside Vietnam and then imported into Vietnam, in accordance with the relevant laws and regulations.

### **Research Methodology**

The methodology adopted for this study comprised of analysis of primary and secondary data.

Primary data utilised for the report consisted of survey results, opinions culled from interviews, legislations, case law, the official data and statistics which have been published in Vietnam. A survey was conducted in two big cities in Vietnam, Hanoi and Ho Chi Minh City.

Secondary data were sourced from books, journals, newspapers, magazine and websites.

## **Chapter I**

### **PHARMACEUTICAL DISTRIBUTION IN VIETNAM:**

#### **THE MARKET STRUCTURE**

##### **1. The Pharmaceutical Distribution Modes and Chains<sup>2</sup>**

Distribution is always considered as the vein of the national economy. It is via these channels that goods are transferred from the manufacturers to the consumers and inputs and outputs reach manufacturers. For a national economy to stay healthy, it is important to have a good and well-functioning distribution system. The efficiency of the distribution system also, directly and indirectly, affects the life and daily routine of the people, as well as social stability, especially when it comes to such sensitive products as essential consumer goods, foods, gas and medicines.

Physical distribution is the set of activities concerned with efficient movement of finished goods from the end-of-the-production operation to the consumer. Physical distribution takes place within numerous wholesaling and retailing distribution channels and includes such important decision areas as customer service, inventory control, material handling, protective packaging, order processing, transportation, warehouse site selection and warehousing.<sup>3</sup>

As provided by the commercial law in Vietnam, distribution is defined to include ‘such activities as wholesaling, retailing, marketing and franchising’.<sup>4</sup>

In the pharmaceutical industry, medicine is a special product, directly related to human health. Therefore, the circulation of medicines has to be in accordance with very specific regulation of the industry. However, medicine is also a type of goods. Therefore, pharmaceutical distribution also has to be in accordance with the rules of demand versus supply and the competitive process in the market.

Article 10 of the Law on Medicines states that “types of business for trading in medicines include manufacturing, exporting, importing, wholesaling, retailing, preservation service and testing services”. Even though this Law specifies quite clearly that:

- Pharmaceutical wholesalers include:
  - Pharmaceutical wholesaling enterprises;
  - Co-operatives, individual households which sell in bulks pharmaceutical ingredients, oriental medicines and herbal medicines; and

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<sup>2</sup> In this part, all words such as “pharmaceutical(s)”, “medicine(s)” or “drug(s)”, etc., are meant to refer to those final finished products which are the subject of research – in order to define the relevant products more clearly.

<sup>3</sup> [http://findarticles.com/p/articles/mi\\_gx5201/is\\_2002/ai\\_n19121452](http://findarticles.com/p/articles/mi_gx5201/is_2002/ai_n19121452)

<sup>4</sup> Section 5, Article 3, Decree No. 23/2007/ND-CP issued on February 12, 2007 by the Government, guiding the implementation of the Commercial Law about sale and purchase of products and other activities directly related to purchase and sale of products by foreign-invested enterprises in Vietnam



- Wholesaling agents dealing in vaccines and medical-biological products;
- Pharmaceutical retailers include:
  - Pharmacists;
  - Medicine stores;
  - Marketing agents for enterprises; and
  - Medicine stores of community clinics.

All other types of economic activities related to medicines, such as manufacturing, exporting, importing and preservation service, have a very close link to the pharmaceutical distribution system in Vietnam. They may easily be part of this whole system. Therefore, in this part, we examine the market structure of the pharmaceutical distribution sector in the context of the overall pharmaceutical industry of Vietnam.

In general, the Vietnamese pharmaceutical industry is considered as having great potential, which can be seen from the following table:

**Table 1 – Pharmaceutical Indexes 2005-2007**

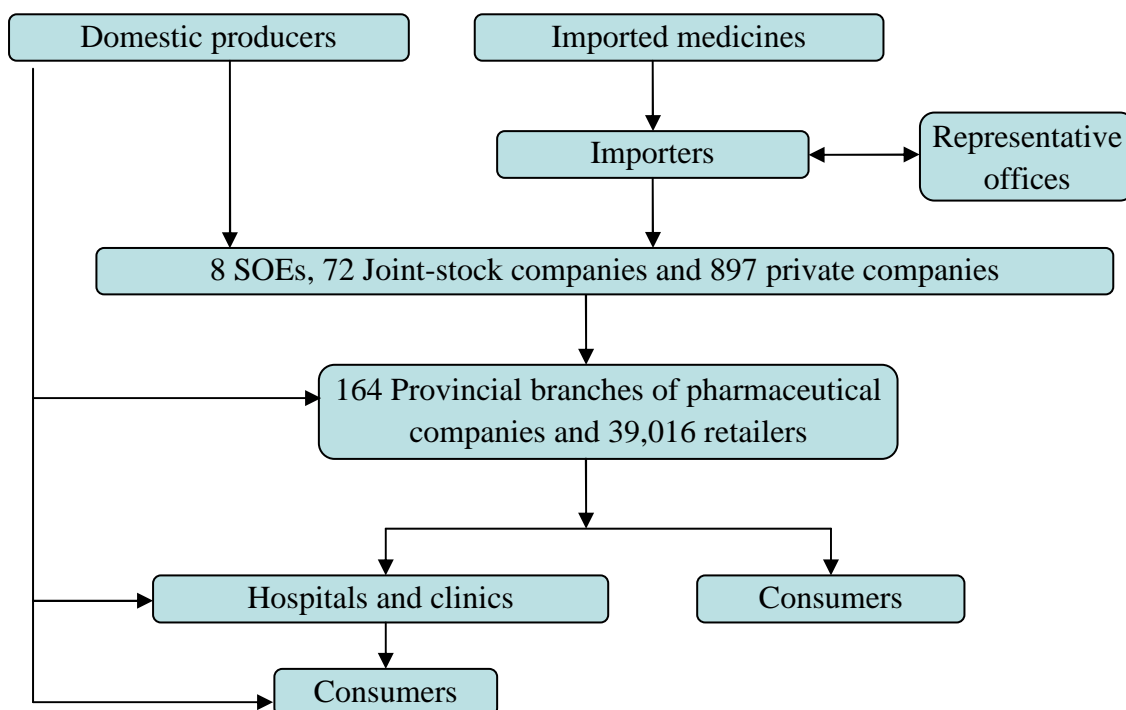
<b>Pharmaceutical Indexes</b>	<b>2005</b>	<b>2006</b>	<b>2007</b>
Total value of medicines used (US\$1,000)	817,396 (original year)	956,353 (increased by 16.99%)	1,136,353 (increased by 18.82%)
Total value of medicines domestically produced (US\$1,000)	395,157 (48.35%)	475,403 (49.70%)	600,630 (52.86%)
Total value of imports (US\$1,000)	650,180	710,000	777,450
Total value of exports (US\$1,000)	17,656	19,744	22,113
Per capita usage (US\$1,000)	9.85	11.23	13.40
The number of effectively registered drugs	12,349	14,097 (increased by 14.15%)	16,626 (increased by 17.94%)

*Source: Drug Administration of Vietnam (DAV).*

The pharmaceutical distribution channel of Vietnam is also considered as quite developed. According to current statistics, there are in total 39,000 pharmaceutical retailers throughout the countries, which should help to ensure that the medicines reach the consumers in a timely manner. Hence, on average, there are one pharmaceutical retailing spot for every 2,000 Vietnamese people.

The following chart provides a bird-eye's view of the pharmaceutical distribution system in Vietnam.

**Figure 1 – The Pharmaceutical Distribution System of Vietnam in 2006**



## 2. Pharmaceutical Distributors

### 2.1. Current Enterprises

Overall, the medicine supply network of Vietnam comprises of the main following components.

- In accordance with the types of business as registered with the relevant State agencies:

**Table 2 – Types of Business as Registered with the Relevant State Agencies**

Type of Business	2005	2006	2007
Domestic pharmaceutical companies	956	1,163	1,330
Foreign-invested enterprises (FIEs)	8	15	22
Provincial branches of pharmaceutical companies	111	127	164
Medical departments and other specialised departments	867	985	977
Medical stores	29,541	39,319	39,016
Community clinics without a medical store	966	932	941

- In accordance with the mode of doing business:

<b>Mode of Doing Business</b>	<b>2005</b>	<b>2006</b>	<b>2007</b>
Pharmaceutical wholesalers	680	800	800
Direct pharmaceutical import/export companies	79	89	90
Pharmaceutical producers (*)	174	178	171
Foreign companies supplying into Vietnam	270	320	370
Pharmaceutical retailers	29,541	39,319	39,016

(\*) *Amongst the 76 producers with GMP certificates, there are about 25 FIEs  
(Source: DAV – Ministry of Health).*

Accordingly, until 2007, there were about 800 companies registered with relevant state agencies in Vietnam for dealing in pharmaceuticals, of which around 370 are representative offices. The most registration comes from South Korean, Indian and French companies.

Pharmaceutical distributors in Vietnam are categorised into two types:

- Previously state-owned enterprises (SOEs), which now mainly deal in authorised importation (for commissions), and other services such as warehousing and delivery; and
- Other enterprises which are specialised in marketing activities and building up distribution networks. These enterprises undertake authorized imports as a service so their turnover is very high (ranging from hundreds of billions to thousands of billions of VND every year). However, most of these turnover figures are actually accounted for by the representative offices in Vietnam and their distributors, so these authorised importers only benefit from a small percentage (1 percent-3 percent) as commissions.

Amongst all, the large members of the pharmaceutical distribution system in Vietnam are:

- 7 domestic companies:
  - Phyto Pharma – based in HCMC,
  - Coduphar – based in HCMC,
  - Sapharco – based in HCMC,
  - Vimedimex II – based in HCMC,
  - Vimedimex I – based in HCMC,
  - Hapharco – based in Hanoi, and
  - Dapharco – based in Danang.
- 26 representative offices of large multinational pharmaceutical producers doing direct

marketing in Vietnam; and

- Other enterprises who are specialised in providing distribution and marketing services for one or many manufacturers. These enterprises are those that are really in control of the whole pharmaceutical distribution sector in Vietnam, with a large system of agents, customers and salesmen, with turnovers reaching one thousand billion VND every year. These enterprises also have high profit level and are considered as having the most significant market power in the whole pharmaceutical industry of Vietnam, being capable of influencing (*i.e., increasing and sustaining in a significant time period, without being subject to the influence of competitors and other market factors*) medicine prices in Vietnam. Most outstanding are three enterprises: Zuellig Pharma, Mega Product and Diethelm.

However, the most crucial factor which leads to the complex nature of the pharmaceutical distribution sector in Vietnam is the duplication of functions between all market players: manufacturing and distributing at the same time. Some large manufacturers also have their own distribution systems (such as Hau Giang Pharmaceutical Co., Domesco, Mediplantex, etc.). The number of enterprises specialised in distribution remains low, while many distributors also manufacture in small scale at small manufacturing sites.

Legally, only Vietnamese enterprises have the right to import, as would be discussed subsequently in the section on the legal and regulatory framework. However, most of these companies are only into authorised imports for commissions. Meanwhile, foreign pharmaceutical companies, or large distributors mentioned above, without the right to directly import, hold the sole distributorships of many foreign pharmaceutical manufacturers having been registered in Vietnam (more on the registration of drug later). Therefore, the latter companies are those that are in control of medicine supply in the market. This state of overlapping and duplication has caused a lot of difficulty for regulators.

Besides, in the pharmaceutical sector in Vietnam, there are the following professional and trade associations being active:

- (i) The Pharmaceutics Association: This is a social professional association which was established first in Vietnam, comprising of all the pharmacists in all types of businesses, the major of them being into retailing (pharmacies).
- (ii) The Vietnam Association of Medical Elements (VIMAMES): This was established in 1999, comprising of institutions (like companies, factories, research institutions, etc.) working in the area of growing, processing, manufacturing, trading, exporting and importing pharmaceutical ingredients and other products (such as oriental medicines, raw and processed herbal medicines and functional foods, etc). In the current low stage of industrial development in Vietnam, VIMAMES is also facing a hard time.
- (iii) The Vietnam Pharmaceutical Companies Association (VNPCA): This was

established in 2001, comprising of all enterprises and manufacturers of medicines. However, because of the weak co-operation amongst members, the role of VNPCA has not been fully developed.

## **2.2. Market Entry and Exit**

### **2.2.1. The process of Entering the Market**

In order to get into the market for pharmaceutical products in Vietnam, all enterprises would have to go through the business registration process (which comprises 3 steps) to begin with at the relevant state agencies responsible for this task, in accordance with the provisions of the Enterprise Law 2005. These provisions are applied equally amongst enterprises of all economic sectors (state-owned, private, domestic and foreign) in order to ensure a level playing field. They have also been simplified and customised to the best extent possible to promote investment. After completing the business registration process, all enterprises would have to apply for sub-licenses from sectoral regulators of the pharmaceutical industry. Barriers to market entry, in most cases, would emerge at this stage, since manufacturing and trading medicines, as well as distribution, is considered a conditional business sector.

<b>Business Registration Procedure</b>
<p><b>Step 1: Application of registration documents to relevant authority for business registration (usually the Provincial Planning and Investment Departments)</b></p> <p>Kinds of documents required vary according to the form of the enterprise to be set up, usually including draft charter of enterprise, list of founders, documents identifying the founder(s), professional certificates of managers for some conditional business sectors, certification of minimum legal capital requirements, if required by specific regulations.</p>
<p><b>Step 2: Considering of registration documents by relevant authority</b></p> <p>The relevant authority has 10 working-days from the date of receipt of all required documents to consider the registration request.</p>
<p><b>Step 3: Issuing registration certificate</b></p> <p>The relevant authority shall issue the business registration certificate no later than the specified dead-line (10 working-days from the date of receipt of complete documents). Where the registration certificate is refused, the founder must be notified in writing, specifying the motivations of the refusal.</p>

According to the Law on Medicines 2005 and the Decree 76/2006/ND-CP guiding the implementation of Law on Medicines 2005, in order to carry out business in this industry, individuals and enterprises have to apply for certifications of satisfactions of conditions for pharmaceutical trading. Certification holder is to act within the conditions and locations as

specified in the certification. The relevant authorities for issuing the certifications are the Ministry of Health or Provincial Departments of Health (depending on the kind of certificate applied for). The conditions to apply for a certification vary according to the kind of trading in question (wholesale, retail-sale, manufacture, storing service, qualification inspecting service, etc.) and cover personnel qualification (pharmaceutical professional certificate of technical managers) as well as the types of medicines to be distributed (ordinary medicines or specially-controlled medicines).<sup>5</sup>

However, the completion of business registration procedures and the obtaining of sub-licenses are only the starting points when an enterprise wants to enter the market. After these points, the enterprises would have to:

- Register their products (medicines);<sup>6</sup>
- Build up the distribution networks or channels of access to consumers (including individual consumers, hospitals and clinics); and
- Undertake advertising and sale promotion.

During these steps, the registration of medicines is mandatory by law (as would be discussed in subsequent parts of the report), while the other steps are considered as part of the strategic plans of businesses to penetrate and compete in the market. During the whole market participation process, there would be several types of entry barriers, which include regulatory barriers, economic barriers and barriers erected because of anti-competitive practices by competitors. We would examine these types of barriers more closely in the next part.

### 2.2.2. Market Entry Barriers

Barriers to entry are factors which prevent or deter the entry of new firms into an industry or a market even when incumbent firms therein are earning excess profits. There are two broad classes of barriers: structural (also called ‘economic’) and behavioural (also called ‘strategic’). It should also be noted that governments can be a source of entry barriers, through licensing and other regulations (legal or administrative).

Structural barriers to entry often include the following:

- Cost advantages independent of scale – Existing competitors in the market usually have certain advantages over newcomers, such as proprietary technology, know-how, favourable access to raw materials, favourable geographic locations and learning curve cost advantages. In the case of the pharmaceutical distribution market in Vietnam, these factors mean available supply (through contracts) from manufacturers, marketing know-how and understanding of the tradition and customs of Vietnamese people, especially in using medicine, good store location and a whole range of agents.

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<sup>5</sup> More details on these conditions would be presented in Chapter II on the Legal and Regulatory Framework for Pharmaceutical Distribution and Competition in the Pharmaceutical Distribution System in Vietnam.

<sup>6</sup> For more details on this, see Chapter II, 2.2. (a).

- Customer loyalty – Large incumbent firms – in this case, large pharmaceutical corporations, owners of several branded medicines – may have existing customers loyal to established products. The presence of established strong brands within a market can be a barrier to entry in this case. A common practice in Vietnam is that when a customer goes to buy medicines at a pharmacy or medical store (with or without prescription), the pharmacist would give them an option between foreign branded medicines (which are usually expensive) and domestically-produced medicines with the same active elements. If possible, the customers usually choose the branded medicines over the domestically-produced ones – even just to keep safe because of lack of knowledge. This popular option leads to the fact that branded medicines still can sell fast at much higher prices, whereas small-scale domestic manufacturers and newcomers in the market would have a hard time finding their ways to the consumers.
- Economy of scale – Large, experienced firms can generally produce goods at lower costs than small, inexperienced firms. In this case, the scale and scope of the distribution network is a clear advantage of existing pharmaceutical distributors over newcomers, who are just in the process of building up theirs.
- Inelastic demand – The demand curve for medicines is inelastic, i.e., not depending on the changes in prices and availability of supply, but rather on doctor's prescription. A strategy of selling at a lower price for sales promotion or rigorous advertising in order to penetrate markets might prove ineffective with price-insensitive consumers.
- Intellectual property – Patent rights often provide companies with large market power. Owning IPRs means enterprises can freely provide exclusive licenses or sole distributorships to some selected distributor or keep it to themselves, making it hard for newcomers. On a related note, in order to be circulated in the market, medicines have to be registered with the relevant agencies. If an enterprise owns a lot of registration numbers of drugs, it would have considerable market power.
- Investment – It is a purely economic factor, related to economies of scale or investment in research and development (R&D), in order to secure first-mover's advantages and IPRs.
- Sunk costs – Sunk costs cannot be recovered, if a firm decides to leave a market. Sunk costs, therefore, increase the risk and deter entry.
- Vertical integration – A firm's coverage of more than one level of production, while pursuing practices which favour its own operations at each level, is often cited as an entry barrier. In the case of the pharmaceutical distribution market in Vietnam, if manufacturers also run their own distribution networks, it would mean high level of vertical integration, making it difficult to enter just the downstream segment of the market (distribution).

Behavioural barriers are those barriers erected by the strategic actions by existing players in the market in order to deter new entry. These strategic actions can be completely in accordance with the law, for example, sale promotion programmes, advertising, or conclusion of sole distributorship agreements with large manufacturers, making use of patent rights or other IPRs, etc. They might also be anti-competitive behaviours which have foreclosure intent. In the case of the pharmaceutical distribution sector, we can cite some of the strategic actions below as behavioural barriers to entry:<sup>7</sup>

- **Predatory pricing:** Existing pharmaceutical distributors, especially with economies of scale and large capital base, can easily lower their prices to below costs in order to attract/secure their customers, creating a barrier to entry. After the new enterprises find it hard to penetrate the market and try to find opportunities elsewhere, the existing distributors again raise the prices to the previously prevailing level, or even higher, to recover the losses they have incurred earlier because of price reduction. Price reduction can be direct or indirect, for example, via the increase of commission to wholesalers or provision of large credit, etc.
- **Boycott or refusal to deal:** An association of distributors can boycott or force their wholesalers or retailers to boycott or refuse to deal with a newcomer, unless the latter agrees to certain concessions or become a member of the association. This is a practice which used to happen in the pharmaceutical market in India.
- **Exclusive dealing:** As mentioned above, existing distributors can enter into exclusive dealing agreements with domestic and foreign pharmaceutical manufacturers so that the latter enterprises would not sell or supply to newcomers. The existing distributors can force independent wholesalers and retailers to refuse to act as agents for the newcomers.
- **Resale price maintenance:** Owners of (the right to distribute) patented medicines might ask their marketing agents to maintain a certain retail or wholesale price level, to create barriers against entry.
- **Abuse of IPRs to restrict competition:** Some practices to deter entry which can be cited here are exclusionary practices against generic medicines or patent pooling.

Finally, as mentioned above, laws and regulations or administrative decisions can also be barriers to entry. For example, some enterprises believe that, in order to satisfy those rules on “Good Distribution Practices”, “Good Pharmacy Practices” or “Good Storage Practices”, they require substantial investment, advanced technologies and infrastructure or ample human resources, which make it difficult to enter the market. The business registration process of Vietnam, even though having been simplified to a great deal, as compared to before, is still

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<sup>7</sup> Specific anti-competitive practices in the pharmaceutical distribution system in Vietnam would be presented in more details in Chapter III of the report on The Status of Competition in the Pharmaceutical Distribution System and Practices Potentially Restricting Competition.



considered as rather unfriendly and cost and time-consuming, which may deter entry. For example, according the World Bank’s “Doing Business 2009” report, an enterprise has to complete 11 procedures (as compared to the average level of 8.6 in the region) and spend 50 days (as compared to the average level of 44.2 days in the region) in order to establish their business in Vietnam. Vietnam, therefore, is ranked 108/181 among countries in term of the business environment.

Article 8 of the Decree 116/2005/ND-CP which guides the detailed implementation of the Competition Law states that:

“*Barriers to entry include:*

1. *Patents, utility models, industrial designs, trademarks, geographical indications in accordance with the law on industrial property rights;*
2. *Financial barriers such as investment into infrastructure, sale promotion or access to finance;*
3. *Administrative decision by state agencies;*
4. *Rules on conditions for trading on products and services and professional standards;*
5. *Import tariff and quota;*
6. *Consumers’ custom; and*
7. *Other barriers to entry.”*

These regulations coincide to some extent with the barriers to entry analysed above.

### 2.2.3. Current Status of Entry and Exit

The analysis of the current status of market entry and exit would be based on the total number of enterprises being registered as active for each year, which include newcomers and those who have terminated their business operations. However, it is hard to find data in this part. Another previous report on competition in the overall pharmaceutical practices provided the following figure, quoted as coming from the General Statistics Office (GSO):

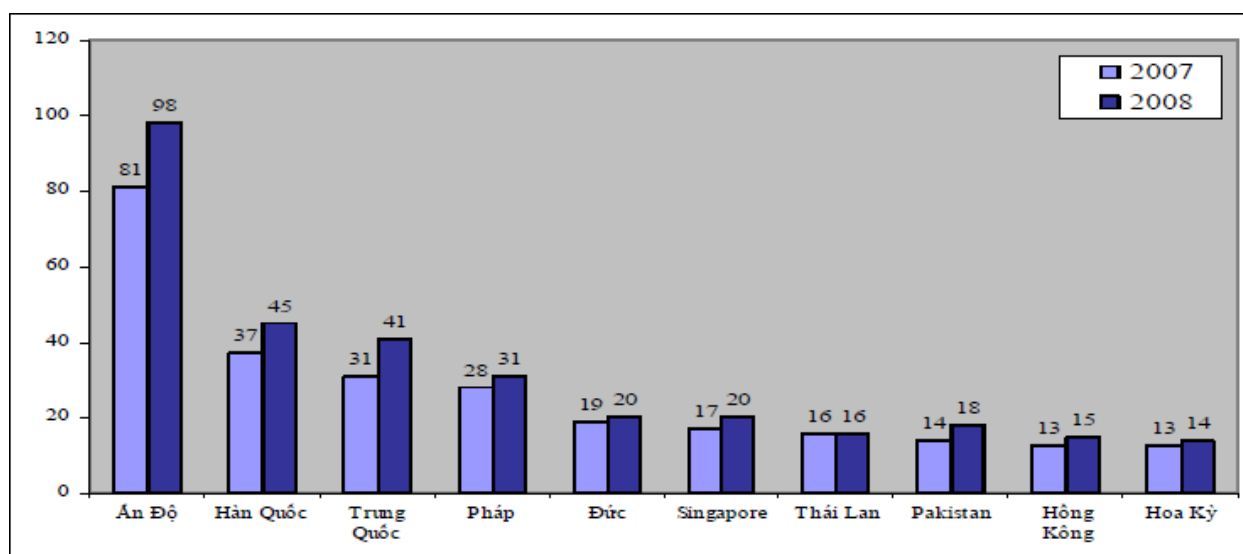
**Table 4 – Total Number of Pharmaceutical Businesses 2001-2005**

Indicators	2001			2002			2003			2004			2005		
	VN	HN	HCM	VN	HN	HCM	VN	HN	HCM	VN	HN	HCM	VN	HN	HCM
<b>Producers</b>	121	24	45	139	31	49	160	33	59	175	38	62	205	40	80
<b>SOE</b>	30	5	5	28	5	4	29	5	6	22	4	3	19	3	3
<b>FDIs</b>	13	1	6	15	1	7	19	1	8	23	3	7	22	1	7
<b>Private</b>	78	18	34	96	25	38	112	27	45	130	31	52	164	36	70
<b>Distributors</b>	492	151	191	646	219	234	729	243	270	1083	376	398	1444	494	574

*Source: Data provided by GSO on special request to the report.*

The Table provides the total number of enterprises being active in the area of HCMC and Hanoi, as well as the increases or decreases, but does not reflect the number of new entries or exits over the years. However, we can say that, overall, the market has become quite crowded over the years, with a 300-percent increase in the number of distributors over the years (2001-2005). Hence, the number of new entries might be considerably large, with some exits. It can be said that the size of the market for pharmaceutical distribution is on the rise, especially in the context that the regulatory barriers are falling down in accordance with Vietnam's WTO accession commitments.

**Figure 2 – The Number of Foreign Enterprises Registered in Vietnam in 2007-08**



#### *2.2.4. Analysing the Trends of Market Entry and Exit*

As mentioned above, despite the lack of data, we can see that there is an increasing trend of new entries into the market for pharmaceutical distribution in Vietnam, while there would be some exits from some stages of the chain (which might not mean complete withdrawal from the market). Besides, we can also look at some factors which might greatly affect market entry and exit relating to barriers. For example:

- (i) *Pharmaceutical industrial development plan of the Government of Vietnam:* In June 2005, the government unveiled a new 10-year industry development plan<sup>8</sup> worth US\$1.5bn, aimed at increasing the domestic sector's market share and quality. Accordingly, the domestic sector's market share should be increased from 40 percent to 60 percent by 2015, with a higher proportion of domestically-produced ingredients usage. The government has outlined plans to invest US\$241mn in eight projects in the local drug manufacturing industry. This will include the construction of four pharmaceutical plants in the next four years.

<sup>8</sup> See Decision No. 108/2002/QĐ-TTg issued on August 15, 2002 by the Prime Minister on the approval of the Strategy for Pharmaceutical Industry Development till 2010.

- (ii) *The average level of consumption of medicines per capita in Vietnam is on the rise:* Vietnam's population is expected to reach the figure of 93 million people in 2015. Population increase, coupled with income rises, would increase the health care expenditures of the population. Besides using medicines for treatment, medicines such as vitamin or others can also be favoured by high-income consumers. According to Business Monitor International (BMI) Ltd, per capita drug expenditure in 2012 would be US\$18.9, which is 45 percent higher than in 2007.
- (iii) *The liberalisation and integration process of Vietnam and, in particular, the pharmaceutical industry:* From January 2007, foreign enterprises would be able to open branches in Vietnam as joint-ventures or 100 percent foreign-owned. Domestic enterprises and foreign enterprises would be treated equally on the basis of national treatment. Protectionism would have to be reduced in accordance with Vietnam's WTO accession commitments. Besides, from January 1, 2009, all FIEs and branches of FIEs would have the right to import directly, without paying for authorised import services. However, foreign enterprises are still not allowed to directly distribute pharmaceuticals in Vietnam. Therefore, they would have to resell to those Vietnamese enterprises that have distributional functions.

Besides, when Vietnam becomes a WTO member, there would be reductions in three (3) tariff lines, at the level of five percent over a period of 3-5 years. Before and after this landmark, Vietnam's import tariff level has always been zero percent for ingredients. This would have not much of an effect on importers of ingredients or those manufacturers relying on imported ingredients. However, it would adversely affect Vietnamese ingredient manufacturers. After Vietnam becomes a full WTO member, there would be reductions in 47 tariff lines, which currently stand at 10-15 percent, over an implementation period of 2-5 years (on average 3). The average level of reduction would be 2-7% (on average 3) for some products, such as antibiotics (18 out of 29 tariff lines), vitamins (4 out of 9), etc. The gradual reduction of tariffs on pharmaceutical products as part of WTO accession will have a positive effect on the prescription drug market, as it will encourage import penetration, helping the sector to develop. The added competition should also force the country's state-owned drug firms to improve efficiency.

- (iv) *Technical barriers:* On April 19, 2007, the Ministry of Health issued Decision No. 27/2007/QD-BYT on the implementation schedule of the rules on "Good Manufacturing Practices" (GMP) and "Good Storage Practices" (GSP). Accordingly, from July 1, 2008, the manufacturing enterprises not meeting the GMP standards, as recommended by the World Health Organisation (GMP-WHO), and the exporters/importers whose warehousing systems do not meet the GSP standards would have to suspend their business.

This would be a complete reshuffle of the Vietnamese pharmaceutical industry. Until 2007, only 31 out of 178 pharmaceutical manufacturers could meet the GMP standards. The rest would have to downscale their product or turn into sub-contractors of those who met the standards.

### 3. The Level of Market Integration and Concentration

#### 3.1. Market Share and How to Calculate Market Share

*“An enterprise’s market share of a certain kind of goods or service means the percentage between sales turnover of this enterprise and the aggregate turnover of all enterprises dealing in such kind of goods or service on the relevant market or the percentage between the purchase turnover of this enterprise and the aggregate purchase turnover of all enterprises dealing in such kind of goods or services on the relevant market on a monthly, quarterly or yearly basis.”* (Section 5, Article 3, Competition Law)

Accordingly, the formula for calculating the market share of a specific enterprise is as follows:

<p><i>Market share of enterprise t</i></p>	$MS_t = \frac{R_t}{\sum_{i=1}^n R_i}$	<p><i>In MS stands for Market Share)</i> <i>R stands for Turnover</i></p>
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This is a simple formula which can be easily used when we have all the data. The important thing is the appropriate and accurate definition of the relevant markets.

According to the Competition Law of Vietnam, the exercise of market definition consists of identifying effective alternative sources of supply for the consumer. A general analysis will have to take into account the economic context, including the objective characteristics of the product; the degree of inter-changeability between the products, having regard to their relative prices and intended use; the competitive conditions; the structure of supply and demand; and the attitudes of consumers and users.

In general market studies, the statistics on enterprises’ turnovers are generally used as pointers for estimating their market share and, on that basis, one can come to some relative conclusion about the market structure prevailing in that industry/sector, for example telecommunications, transportation, steel, electricity, water, etc. This method, however, is problematic, if the relevant markets do not coincide with the boundary of the whole sector/industry. In that case, the estimation of the market structure would be completely incorrect. However, since the studies are only for reference purpose, and not to serve as basis for deciding over specific competition case, this remains the most popular method. In general, the statistics can be obtained from the GSO, based on the different levels of the Vietnam Standard Industrial Classification (VSIC).

However, in this report, this method cannot be applied for approximating the market structure of the pharmaceutical market for the following reasons:

- Un-homogeneity of products and product characteristics: Pharmaceuticals, which comprise of many different types, can be used to treat different diseases. Even when they contain similar active elements or ingredients and treat the same diseases, they may still have different medical effects and can be used only with different specific dosage on different groups of patients. In the world, the most popular method of classification is the ATC/DDD (Anatomical Therapeutic Chemical/the assumed average maintenance *dose* per *day* for a *drug* used for its main indication in adults) system used by the World Health Organisation (WHO). A pharmaceutical enterprise may have a great total turnover, but that comprises of the turnovers of several products. Therefore, the percentage of that particular enterprise's turnover, as compared to the turnover of the whole industry, will not be the same as the market share that enterprise holds in the market for product A or product B. The un-homogeneity of products requires the division of the whole pharmaceutical industry into several small markets, rather than looking at it as a whole.
- Inelasticity of demand: The demand curve for medicines, types and dosage, is not elastic, not depending much on availability of supply, or prices, etc., but rather on doctors' prescriptions (in the case of end consumers) or professional specialisation (in the case of hospitals and clinics). For example, a hospital specialised in heart-related problems will only purchase medicines used for heart-related problems and not any other types, even when the prices of the medicines they need rise or there is shortage of supply. An end consumer, similarly, will not buy paracetamol to treat stomach ache just because the medicines for stomach ache (as per doctors' prescription) are not available in the market or because the latter is too expensive. Therefore, it is difficult to define the substitutability of products on the basis of the end users' reactions towards changes in prices and supply. This inelasticity of demand for pharmaceuticals also dictates the behaviours of distributors. The demand of pharmaceutical wholesalers and traders, for example, is determined by the demand of their customers (e.g., hospitals, pharmacies and other wholesalers), whose demand is itself directly influenced by the prescription of a particular product by doctors. Therefore, it is difficult to pool together different pharmaceutical products as one group of substitutes, or in the same relevant product market.

These peculiarities of the pharmaceutical market suggest that in defining the relevant markets here, the one-product-one-market approach is applicable. An alternative is to base on therapeutic categories. Accordingly, a pharmaceutical enterprise may not have high turnover, but it might still be holding a high market share for one or more specific products. Many market studies in the pharmaceutical industry all over the world have found a high level of concentration in various market segments for different therapeutic categories. Besides, it should also be noted that statistics/data on market share at a specific point of time, as per this method, might not be accurate for long, since market shares and market structure might

change when new products are marketed or when patents expired. This is the problem caused by the dynamicity of the pharmaceutical market, characterised by high innovation content and continued R&D process.

On the other hand, a majority of medicines in circulation in Vietnam are patented products imported for distribution inside the country. Meanwhile, Level 5 of the VSIC (Sector 21001 – VSIC 5 – medicine manufacturing) does not include these imports, or reflects the market shares of those enterprises only specialised in imports and exports and distribution, without manufacturing.

On the basis of the statistics on turnover provided on special request from the GSO, we calculated the market share (based on turnover) of medicine manufacturers in Vietnam as in the above-mentioned formula and came out with the following results:

**Table 5 – Pharmaceutical Manufacturers with Leading Turnover in 2005**

S. No.	Enterprise	Turnover (Million VND)	Market share (%)
1	Domesco	569,380	5.89
2	Nam Ha Pharmaceutical Joint-stock Co.	561,462	5.81
3	Hậu Giang Pharmaceutical Joint-stock Co.	556,189	5.75
4	Bình Định Pharmaceutical and Medical Equipments Co.	388,065	4.01
5	Medipharco	380,851	3.94
Total turnover of all pharmaceutical manufacturers in Vietnam		9,665,100	

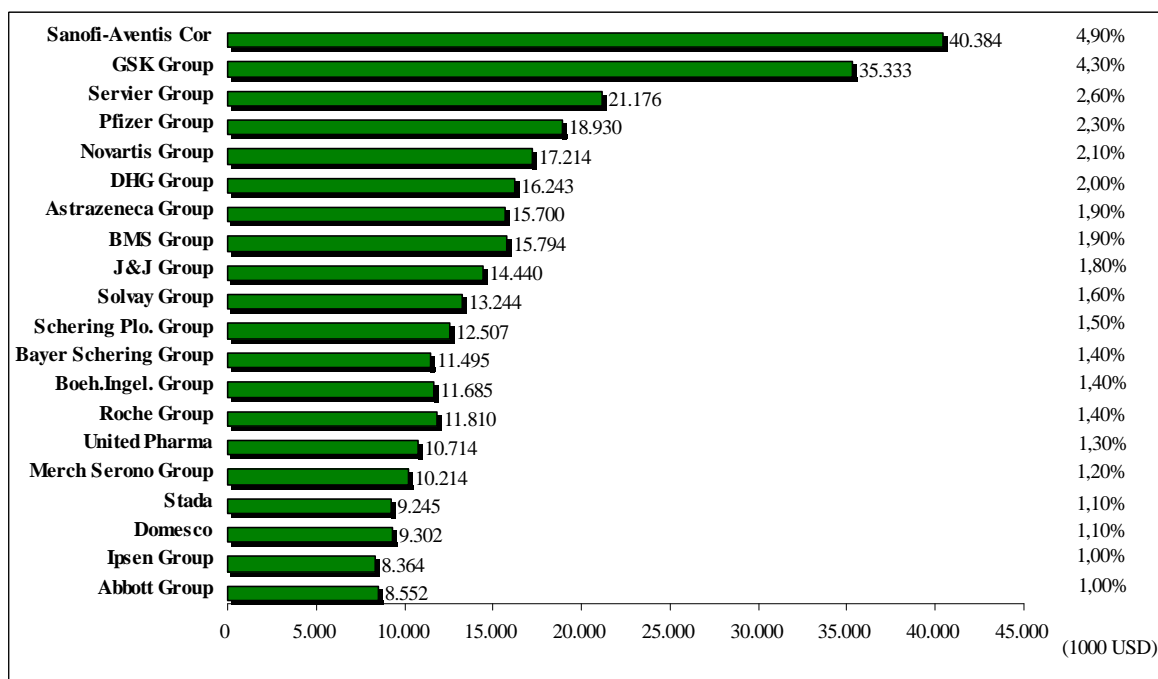
**Table 6 – Pharmaceutical Manufacturers with Leading Turnover in 2006**

S. No.	Enterprise	Turnover (Million VND)	Market share (%)
1	Hậu Giang Pharmaceutical Joint-stock Co.	873,072	9.66
2	Bình Định Pharmaceutical and Medical Equipments Co.	502,513	5.56
3	Mekophar	467,108	5.17
4	Sanofi-Synthelabo Vietnam	386,011	4.27
5	Traphaco	362,591	4.01
Total turnover of all pharmaceutical manufacturers in Vietnam		9,037,406	

**Table 7 – Pharmaceutical Manufacturers with Leading Turnover in 2007**

S. No.	Enterprise	Turnover (Million VND)	Market share (%)
1	Hậu Giang Pharmaceutical Joint-stock Co.	1,337,344	10.34
2	Domesco	1,236,537	9.56
3	Imexpharm	769,714	5.95
4	Bình Định Pharmaceutical and Medical Equipments Co.	603,216	4.66
5	Mekophar	546,526	4.23
Total turnover of all pharmaceutical manufacturers in Vietnam		12,933,493	

**Figure 3 – 20 Enterprises with Leading Turnover in Quarter III/2008**



(Source: IMS Q3/2008).

The Tables and figure above show that, calculating by turnover, the market share levels of pharmaceutical enterprises in Vietnam are quite low, even the market share of the largest enterprise in the third-quarter of 2008 is not beyond five percent. This may point to a great level of competition in the pharmaceutical market in Vietnam.

However, the existence of many sources of data with different figures in Vietnam has resulted in the fact that there are many different results for market shares (on the basis of total turnover) by pharmaceutical enterprises. For example, the VNPCA provides the following data:

**Table 8 – Ten Enterprises with Leading Turnover in 2007**

<b>S. No</b>	<b>Enterprise</b>	<b>Turnover in 2007 (billion VND)</b>	<b>Market share</b>
1.	Hậu Giang Pharma Joint-stock Co.	1,269	14.13%
2.	Mekophar	540	6.02%
3.	Sanofi-Synthelabo	466	5.18%
4.	Imexpharm	430	4.79%
5.	Domesco	420	4.68%
6.	Bình Định Pharma & Medical Equipments Joint-stock Co.	400	4.46%
7.	Cửu Long Pharma Joint-stock Co.	350	3.90%
8.	Hà Tây Pharma Joint-stock Co.	320	3.57%
9.	Traphaco	305	3.40%
10.	Thanh Hóa Pharma & Medical Equipments Joint-stock Co.	207	2.31%
Total turnover of the whole industry		8,980	

Regarding imports, the DAV–Ministry of Health provides the following data:

**Table 9 – Pharmaceutical Import Structure in 2007**

<b>S. No.</b>	<b>Enterprise</b>	<b>Import value<sup>9</sup></b>
1	Phytopharma	29.20%
2	HCMC Pharma Co.	10.10%
3	Vimedimex	8.40%
4	Vimedimex Joint-stock Co.	7.30%
5	Pharbaco I	5.60%
6	Pharbaco II	5.50%
7	Hà Đông Pharma & Medical Equipments Joint-stock Co.	4.50%
8	Đà Nẵng Pharma & Medical Equipments Joint-stock Co.	2.50%
9	Mediplantex	1.80%
10	Others	25.10%

However, as mentioned above, due to the peculiarities of the pharmaceutical market, having low market shares (based on turnover) does not mean that an enterprise is incapable of restricting or distorting competition in the market (by restrictive business practices or unfair competition practices). By our estimates, the turnover of those enterprises which only import medicines for distribution (without manufacturing), especially foreign companies such as Zuellig Pharma or Diethlem, etc., is very low (since their turnover is actually being booked by the authorised importers). However, these enterprises possess very large market power. Their market power lies in four main points:

<sup>9</sup> As percentage (%) of the total value of pharmaceutical imports of Vietnam in 2007.



- Product characteristics – As analysed above, the subjects in this case are medicines used for human beings. They are un-homogeneous products and the demand for them is inelastic. Therefore, if an enterprise holds control over some specific products, these products are hardly substitutable.
- IPRs – This is the factor which invigorates the exclusivity and un-substitutability of the subject products.
- Barriers to entry – Some enterprises have secured exclusive contracts or sole distributorships for patented medicines with the parent companies overseas. There have been circumstances where the parent companies refuse to deal with Vietnamese enterprises without the participation of some specific enterprises (their sole distributors) in the deals.
- Countervailing power of other competitors in the market – Vietnamese importers, wholesaler and retailers of pharmaceutical products do not have access to these above-mentioned exclusive contracts for patented medicines and cannot secure alternative supply. Therefore, they have to depend completely on foreign companies.

It should be noted again that even though the authorised importers, such as Phytopharma or Vimedimex I & II, have very high turnover (by import value, as in Table 9), they have very low profit and do not have control over supply. Therefore, they do not possess any market power. In the complex pharmaceutical distribution system of Vietnam, they are just like the marketing agents and do not have control over product pricing.

### **3.2. Monopoly Power in Pharmaceutical Distribution**

*“An enterprise shall be considered to hold monopoly position if there is no enterprise competing on the goods or services dealt in by such enterprise on the relevant market.”*  
(Article 12 of the Competition Law)

Accordingly, assuming that the relevant geographical market is the whole country of Vietnam, a pharmaceutical distributor would be considered a monopoly if it is the only supplier (by manufacturing or importing) of a medicine (unsubstitutable), or the whole therapeutic category of medicines. (This assumption does not include provincial monopolies, when an enterprise is the only supplier of medicines within a certain geographical-administrative unit or the only supplier to all hospitals and clinics in that area. This can happen in real life, especially in remote areas, cut off from the national roadway system or islands).

According to Decision No. 3121/2001/QĐ-BYT issued by the Ministry of Health on July 18, 2001, on the “Regulations for Registration of Drug”, enterprises can only trade in, import, export or manufacture pharmaceutical products which have been registered with the DAV (for a term of five years). Theoretically, if there is only one or a few medicines registered within a therapeutic category or all the registered medicines in one therapeutic category are

controlled by one single enterprise, the market structure in that particular segment is either monopoly or oligopoly.

**Table 10 – Number of Registered Drugs by Therapeutic Categories**

S. No.	Therapeutic Category	No. of Registered Drugs
1	Others	2,239
2	Anti-infection	1,975
3	Pain-relief and others	1,017
4	Vitamin and tonics	955
5	Respiratory medicines	362
6	Stomach ache and others	354
7	Heart-related	204
8	For skin and venereal diseases	168
9	Anti-allergy	162
10	Blood-related	156
11	Eye-related	113
12	Hormone and hormonal structures	113
13	Mental diseases	77
14	Liver-related	75
15	Special liquids	57
16	Cholinesterase-related	47
17	Dental-related	32
18	Urinal-related	25
19	Epileptics-related	23
20	Antiseptics	12
21	Migraine-related	8
22	Detoxication	7
23	Anaesthetics	2
24	Anti-retrovirals	2
25	Globulin serum	1
26	Anti-malaria	1
27	Cancer-related	1

From the Table, the last three categories are those where there is only one type of drug registered. In practice, however, it is said that these and some others are specialised products, which are not widely traded in the market. They are mainly imported by the Government for special use, which is the reason why there is only one registered product – and that should not be considered as a case of monopoly. From another angle, we can say that this is a buyer’s monopoly.

The issue of monopoly in distribution is also related to the problem of sole distributorship mentioned above. This often originated from other countries, where most patented products are in the hands of the large pharmaceutical manufacturers. These MNCs, however, only

authorise certain companies to be the distributors of their products, leading to a situation where these distributors have monopoly power over supply in Vietnam.

### **3.3. *Dominant Positions of Pharmaceutical Distributors***

*“1. Enterprises shall be considered to hold dominant position on the market if they have market shares of 30 percent or more on the relevant market or are capable of restricting competition considerably.*

*“2. Groups of enterprises shall be considered to hold the dominant position on the market if they take concerted action to restrict competition and fall into one of the following cases:*

*a/ Two enterprises having total market share of 50 percent or more on the relevant market;*

*b/ Three enterprises having total market share of 65 percent or more on the relevant market; and*

*c/ Four enterprises having total market share of 75 percent or more on the relevant market”*

*(Article 11 of the Competition Law)*

Even though we cannot calculate which specific enterprises on the market are holding a market share of 30 percent or more on the relevant market (due to the unavailability of data for defining the relevant markets, as mentioned above) and even though no enterprises in Vietnam are now considered as dominant in terms of turnover, according to Section 1 of the above-mentioned article of the Competition Law, we may still be able to identify the dominant businesses if they *“are capable of restricting competition considerably”*.

According to Article 22 of the Decree 116/2005/ND-CP:

*“The capability to restrict competition considerably on the relevant market can be established on the basis of the following criteria:*

- 1. The financial strength of the enterprise;*
- 2. The financial strength of the organisations and individuals who set up the enterprise;*
- 3. The financial strength of the organisations and individuals who have the control over the activities of the enterprise in accordance with the law or in accordance with the charter of the enterprise;*
- 4. The financial strength of the parent companies;*
- 5. The technological strength;*
- 6. Industrial property rights or license to use such properties from the rights owners;*

*and*

7. *The scope of the distribution networks.*”

Going by the last criteria, some enterprises mentioned above, such as Zuellig Pharma, Diethelm or Mega, can be considered as holding dominant positions in the pharmaceutical distribution market in Vietnam. In practice, there have been cases of abuses of such dominant positions (which would be discussed further in subsequent parts of the report) in order to increase prices above the competitive level and maintain such prices for a sufficiently long period of time, independent of the reactions of their competitors. This shows that they have considerable market power.

Regarding groups of enterprises holding dominant positions in the market, going by the letters of Article 11 of the Competition Law, we can only identify them in specific cases. This is because, in addition to defining the relevant markets, we also have to establish/prove that they are taking “*concerted action to restrict competition*”.

**3.4. *Three-firm and Five-firm Concentration Ratios (CR3-CR5) in the Pharmaceutical Distribution Market in Vietnam***

- CR3 is the total of the market shares of three firms with largest shares on the relevant markets.

$CR3 = CR_{i1} + CR_{i2} + CR_{i3}$	<i>In which <math>CR_{ik}(k=1,2,3) = \max CR_i</math></i>
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- CR5 is the total of the market shares of five firms with largest shares on the relevant markets.

$CR5 = CR_{i1} + CR_{i2} + CR_{i3} + CR_{i4} + CR_{i5}$	<i>In which <math>CR_{ik}(k=1,\dots,5) = \max CR_i</math></i>
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In this case, we cannot calculate CR3 and CR5 on the relevant markets (since we cannot define the relevant markets). If we use turnover figures as a pointer, these indexes in the pharmaceutical industry of Vietnam are not high (25.33% for CR3 and 34.48 for CR5, as per Table 8). Similarly, for importers: 47.7 for CR3 and 60.6 for CR5 (as per Table 9).

However, in the distribution sector, these indexes may take on different meanings, depending on the relationship among these large enterprises, or between these enterprises and the dominant business (based on the scope of the distribution network), i.e., whether they are vertically integrated or not. Vertical integrations between large enterprises in the same market can act as very effective barriers to entry. In the case of the pharmaceutical distribution sector in Vietnam, it is necessary to have further data to come to the final conclusion.

In summary, from the analysis above, we can say that the structure of the pharmaceutical distribution sector in Vietnam is quite competitive, with robust market participation and no enterprises with significantly outstanding turnover. The level of concentration, hence, is low.

However, in the sector, there are currently some enterprises with high market power, which are capable of restricting competition considerably, through exclusive contracts with large multinational pharmaceutical companies. Besides, these enterprises also have large-scale distribution networks, in some cases, beyond the borders of Vietnam, whereas other competitors are quite dependent on them for supply. This leads to a high degree of vertical integration, which might deter new entry and market development. It is necessary to consider the application of the Competition Law 2004 on this issue, since the Law is still limited in terms of flexibility and applicability for vertical agreement-related issues. More information would be given in the next part on the legal and regulatory framework of the report.

## **Chapter II**

### **THE LEGAL AND REGULATORY FRAMEWORK FOR PHARMACEUTICAL DISTRIBUTION ACTIVITIES AND COMPETITION IN VIETNAM**

In this section, we would examine and assess current legal regulations over competition in the pharmaceutical distribution sector in Vietnam.

At present, competition amongst pharmaceutical distributors in Vietnam is regulated by various separate legal normative documents. These documents can be classified as follows:

- (i) The Competition Law 2004 and its implementation regulations;
- (ii) The Law on Medicines 2005 and its implementation regulations; and
- (iii) Other relevant laws and regulations.

#### **1. The Competition Law 2004 and Its Implementation Regulations**

The Competition Law was promulgated by the National Assembly of Vietnam on December 2, 2004 and has been effective since July 1, 2005.<sup>10</sup> It provides for anti-competitive practices, unfair competition practices, procedures for handling competition cases as well as remedies and fines to be applied in cases of violation.<sup>11</sup> Its scope of regulation covers all organisations and individuals doing business in Vietnam, which includes all manufacturers and suppliers of goods and services, utilities, enterprises operating in state-monopolised sectors, foreign-owned enterprises and trade and professional associations in the country.<sup>12</sup> Therefore, competition amongst enterprises of all types in the area of pharmaceutical distribution in Vietnam is directly regulated by this Law.

The Competition Law takes precedence in case of difference between the regulations of this law and those of other laws, when it comes to anti-competitive practices and unfair competition practices.<sup>13</sup> This affirms the specialty of the Competition Law in regulating competitive practices in all markets. Therefore, in order to ensure coherence, all other legal normative documents have to be drafted and revised in order to be in accordance with the provisions of this Law. Following analyses on the Law on Medicines and other laws and regulations would be providing some assessment on their compatibility with the provisions of the Competition Law.

The promulgation of the Competition Law was a landmark in regulating competitive behaviours in Vietnam. Prior to this, all unfair competition practices and especially anti-competitive practices were not regulated adequately and effectively. Scattered amongst

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<sup>10</sup> Competition Law, Article 122.

<sup>11</sup> Competition Law, Article 1.

<sup>12</sup> Competition Law, Article 2.

<sup>13</sup> Competition Law, Article 5(1).

various legal normative documents, these regulations only prohibited, in general, illegal competitive practices and unfair competition practices. These old regulations did not provide for procedures to deal with these practices as well as a specialised enforcement agency either.<sup>14</sup> This led to the fact that these regulations remained “paper tigers”, without any real enforcement values.<sup>15</sup> This is one of the main reasons why the National Assembly of Vietnam decided to promulgate the Competition Law 2004.<sup>16</sup>

The following sub-section would provide a brief overview of the requirements for enterprises doing business in the area of pharmaceutical distribution in Vietnam, as per the Competition Law.<sup>17</sup> Specifically:

### ***1.1. Prohibited Anti-competitive Behaviours***

According to the Competition Law, pharmaceutical distributors in Vietnam are prohibited from the following two types of anti-competitive behaviours:

#### **(a) Restrictive Business Practices**

Restrictive business practices are defined by the Law as those practices which “reduce, distort or restrict competition in the market, including competition-restricting collusive behaviours, abuses of dominance positions, abuses of monopoly and economic concentration.”<sup>18</sup>

Competition-restricting collusive practices include eight specific types listed in Article 8 of the Law. These collusive practices are clearly explained in Article 14-21 of Decree No. 116/2005/ND-CP of the Government issued on September 15, 2005, which stipulates the detailed implementation of the Competition Law. Accordingly, the Law prohibits all agreements amongst enterprises which “prevent and restrict other enterprises from entering

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<sup>14</sup> For example, Article 8 of the Commercial Law 1997 only stipulates the prohibition of illegal competitive practices in commercial activities and lists some specific signs of such unfair trade practices. See the analysis and concrete assessment of the legal and regulatory framework prior to the adoption of the Competition Law 2004 in Tang Van Nghia (2007), *Problems and Solutions for Effective Enforcement of the Competition Law*, Research study at ministerial level No. 2005-78-012, Hanoi, p. 55-58.

<sup>15</sup> Dang Vu Huan (2004), *Laws and Regulations on Anti-monopoly and Unfair Trade Practices in Vietnam*, National Political Publishing House, Hanoi, p. 190; or Central Institute for Economic Management (2002), *Legal and Institutional Issues regarding Competition Policy and Regulation of Monopolies*, Transportation Publishing House, Hanoi, p. 93-99.

<sup>16</sup> See the Official Submission of the Government No. 487/CP-PC dated April 9, 2004, on the Competition Law project, p. 1-3; or Alice Pham, *The Development of Competition Law in Vietnam in the Face of Economic Reforms and Global Integration* (2005) *Northwestern Journal of International Law and Business* 547; or Le Danh Vinh, *Building Competition Law in Vietnam to Meet the Need of Regulating Market Economy and in the Light of Trade Liberalisation and International Economic Integration* (2003), Presentation at the ASEAN Conference on Competition Law and Fair Trade Policy in the ASEAN Free Trade Area (AFTA), Bali from 5 to 7 March 2003, [www.jftc.go.jp/eacpf/01/vietnam\\_p.pdf](http://www.jftc.go.jp/eacpf/01/vietnam_p.pdf) at 20/10/2008.

<sup>17</sup> In this part, we only introduce the Competition Law 2004 of Vietnam in brief, with regard to those provisions which are directly related to competition and the competitive environment in the pharmaceutical distribution system in Vietnam. Comprehensive assessment and evaluation of the effectiveness of the Law is beyond the scope of this paper. There are two reasons for this: (i) the Competition Law has just been adopted very recently and implemented for a short time (three years), which is not sufficient for evaluation yet; and (ii) this Report is not meant to evaluate the effectiveness of the Competition Law.

<sup>18</sup> Competition Law, Article 3(3).

the market or expanding their business”, which “are meant to exclude from the market those enterprises who are not party to the agreement”, and which “are meant to help one or more parties to the agreement win tenders for supplying goods and services”.

The analyses in the following sections of this report also show that pharmaceutical supply tenders by large hospitals constitute a major distribution channel in Vietnam. The Competition Law prohibits all bid-rigging practices amongst pharmaceutical distributors. The legal consequences of such violation, as per the Competition Law, are much more stringent than administrative fines towards violations in tendering. However, administrative fines provided towards violations in tendering by other legal normative documents are still in effect.<sup>19</sup>

Towards the following practices, the Competition Law prohibits those enterprises, whose combined market share<sup>20</sup> in the relevant markets<sup>21</sup> exceeds 30 percent, from:

- (i) Jointly fixing the prices of goods and services, directly or indirectly;
- (ii) Jointly dividing the consumption markets or supplies of goods and services;
- (iii) Jointly restricting or controlling the number, quantity of goods and services produced or traded;
- (iv) Jointly restricting scientific and technological advances and investment; and
- (v) Jointly imposing on other enterprises pre-conditions for entering into contracts or jointly forcing other enterprises to accept obligations which are not directly related to the subject of the contract.

Therefore, from July 1, 2005, those pharmaceutical distributing enterprises with large market shares (exceeding the cumulative level of 30 percent) in Vietnam would have to adjust their strategies and business plans to comply with the above-mentioned provisions. These enterprises would not be able to enter into agreements which fix prices of medicines or divide

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<sup>19</sup> Current regulations prescribing administrative fines for violations in bidding at very low level (20,000,000 VND to 50,000,000 VND), as compared to the level of fines prescribed by the Competition Law. See Decree No. 58/2008/ND-CP issued on May 5, 2008, by the Government guiding the implementation of the Law on Bidding and the selection of bidders in accordance with the Construction Law, Article 65(2); Decree No.53/2007/ND-CP issued on April 4, 2007, by the Government prescribing the level of administrative fines in the area of planning and investment, Article 13(7-8).

<sup>20</sup> Combined market share is understood as the total market share of all enterprises party to the agreement. “An enterprise’s market share of a certain kind of goods or service means the percentage between the sales turnover of this enterprise and the aggregate turnover of all enterprises dealing in such kind of goods or service on the relevant market or the percentage between the purchase turnover of this enterprise and the aggregate purchase turnover of all enterprises dealing in such kind of goods or service on the relevant market on a monthly, quarterly or yearly basis.” See Competition Law, Article 3 (5-6)

<sup>21</sup> Relevant markets, as stipulated by the Competition Law, “mean relevant market of products and relevant geographical market. Relevant market of products means a market of goods, services which are interchangeable in terms of characteristics, uses, purposes and prices. Relevant geographical market means a specific geographical area in which exist goods and services which are interchangeable under similar conditions of competition and which are considerably differentiated from neighbouring areas.” See Competition Law, Article 3(1) and more detailed explanation at the Decree No. 116/2005/ND-CP, Article 4-8.



supplies or consumers (for example, dividing hospitals or geographical territories for medicinal supply). These enterprises would not be able to impose unreasonable conditions which are not related to those distribution contracts that they have with retailers, etc.

Abuses of dominant positions and monopoly are stipulated in Article 13-14 of the Competition Law and clearly explained in Article 23-33 of the Decree 116/205/ND-CP. Accordingly, an enterprise or a group of enterprises having a dominant position in the market would be prohibited from:

- (i) Selling goods, providing services at prices lower than the aggregate costs in order to eliminate competitors;
- (ii) Imposing irrational buying or selling prices of goods or services or fixing minimum re-selling prices causing damage to customers;
- (iii) Restricting production, distribution of goods, services, limiting markets, preventing technical and technological development, causing damage to customers;
- (iv) Imposing dissimilar commercial conditions in similar transactions in order to create inequality in competition;
- (v) Imposing conditions on other enterprises to conclude goods or services purchase or sale contracts or forcing other enterprises to accept obligations which have no direct connection with the subject of such contracts; and
- (vi) Preventing new competitors from entering the market.

It is clear that only distributors with substantial market power can engage in the above mentioned practices, without paying any attention to customer switching to their rivals. Abuses of dominant positions such as predatory pricing, resale price maintenance causing damages to customers or asking customers not to deal with other distributors in order to exclude them from the market are all strictly prohibited by the Competition Law.

In addition to the practices prohibited when an enterprise holds a dominant position in the market, monopolists<sup>22</sup> are also prohibited from (i) imposing unfavourable conditions on customers; and (ii) abusing the monopoly position to unilaterally modify or cancel the contracts already signed without plausible reasons.

Certain acts of economic concentration are also prohibited by the Competition Law (Article 18), which is further explained by Article 34-35 of the Decree 116/2005/ND-CP. Accordingly, the Law prohibits mergers<sup>23</sup>, acquisitions<sup>24</sup>, consolidations<sup>25</sup> and joint

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<sup>22</sup> An enterprise shall be considered to hold monopoly position if there is no enterprise competing on the goods or services dealt in by such enterprise on the relevant market. See Competition Law, Article 12.

<sup>23</sup> Merger of enterprises means an act whereby one or several enterprises transfer all of its/their property, rights, obligations and legitimate interests to another enterprise and, at the same time, terminate the existence of the merged enterprise (s). See Competition Law, Article 17(1).

ventures<sup>26</sup> amongst enterprises in possession of more than 50 percent share of the relevant markets, except for those exempted as per Article 19 of the Law or except the case when, after economic concentration, the merging parties can still be classified as small and medium enterprises (SMEs), as defined by law.<sup>27</sup>

### **(b) Unfair Competition Practices**

Unlike restrictive business practices, unfair competition practices are defined on the basis of such criteria as “business ethics” or having the intent to harm the legitimate interest of specific targets. As per Section 4, Article 3 of the Competition Law, unfair competition practices mean “competition acts performed by enterprises in the process of doing business, which run counter to common standards of business ethics and cause damage or can cause damage to the state's interests, legitimate rights and interests of other enterprises or consumers”. This type of definition, using unquantifiable criteria such as “common standards of business ethics”, may cause difficulty in the application and interpretation of the Law. However, Article 40-48 of the Law has tried to list and describe specific aspects of those prohibited unfair competition practices, including:

- (i) Misleading indications;
- (ii) Infringements upon business secrets;
- (iii) Constraints in business;
- (iv) Discrediting other enterprises;
- (v) Disturbing business practices of other enterprises;
- (vi) Advertising for the purpose of unfair competition;
- (vii) Sales promotion for the purpose of unfair competition;
- (viii) Discrimination by associations; and
- (ix) Illicit multi-level sale.

Besides, Section 10 of Article 39 of the Competition Law authorises the Government to prescribe other unfair competition practices on the basis of the criteria described above. However, Decree 116/2005/ND-CP does not guide or further stipulate other unfair

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<sup>24</sup> Acquisition of enterprises mean an act whereby an enterprise acquires the whole or part of property of another enterprise sufficient to control or dominate all or one of the trades of the acquired enterprise. See Competition Law, Article 17(3).

<sup>25</sup> Consolidation of enterprises means an act whereby two or more enterprises transfer all of their property, rights, obligations and legitimate interests to form a new enterprise and, at the same time, terminate the existence of the consolidated enterprises. See Competition Law, Article 17(2).

<sup>26</sup> Joint venture between enterprises means an act whereby two or more enterprises jointly contribute part of their property, rights, obligations and legitimate interests to the establishment of a new enterprise. See Competition Law, Article 17(4).

<sup>27</sup> Competition Law, Article 18.

competition practices.

### **1.2. Exemption, Notification and Notification Procedures**

Exemptions are available for some restrictive business practices and economic concentration cases when they satisfy certain requirements stipulated by the Competition Law. The Law, however, does not provide for any exemption for abuses of dominant positions, abuses of monopoly or unfair competition practices.

For restrictive business practices stipulated by Section 1-5 of Article 8 of the Law, pharmaceutical distributors can be exempted for a definite term, if these practices are meant to reduce costs to benefit consumers by:

- (i) Rationalising the organisational structure and business model and raising business efficiency;
- (ii) Promoting technical and technological advances and raising goods and service quality;
- (iii) Promoting the uniform application of quality standards and technical norms of products of different kinds;
- (iv) Harmonising business, goods delivery and payment conditions, which have no connection with prices and price factors;
- (v) Enhancing the competitiveness of small- and medium-sized enterprises; and
- (vi) Enhancing the competitiveness of Vietnamese enterprises on the international market.<sup>28</sup>

For economic concentration cases, the merging parties would be exempted if they meet one of the following conditions:

- (i) One or more of the participants in economic concentration is/are in danger of dissolution or bankruptcy; and
- (ii) The economic concentration has an effect of expanding export or contributing to socio-economic development and technical and technological advance.

The above-mentioned exemptions reflect the industrial and socio-economic development policy of Vietnam. In order to qualify for exemptions, the enterprises which are parties to restrictive business practices or economic concentration cases need to submit notification dossiers to the Vietnam Competition Administration Department (Ministry of Industry and

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<sup>28</sup> Competition Law, Article 10(1).

Trade). At present, the VCAD is the lead state agency for receiving exemption dossiers<sup>29</sup> and preparing the positions to be submitted to the relevant authority<sup>30</sup> for decision on whether to grant the exemption applied for or not.

Besides the notification procedures for exemptions, the Competition Law also provides for notification before an economic concentration act is consummated. This mandatory notification mechanism applies for those economic concentration cases where the merging parties have a combined market share of 30-50 percent on the relevant markets, except when the merging parties, after economic concentration, can still be classified as SMEs as per the law.<sup>31</sup> Economic concentration cases can only be completed after receiving written approval by the VCAD that the economic concentration is not prohibited.<sup>32</sup>

### **1.3. Fines and Remedies**

The Competition Law provides for heavy fines and remedies towards violations. Specifically, monetary fines can amount to 10 percent of the total turnover of the financial year preceding the violations by organisations and individuals. Regarding unfair competition practices, monetary fines range from 5,000,000 VND to 100,000,000 VND, depending on the types and levels of violation.<sup>33</sup> It is important to note that pharmaceuticals are considered as an important product, therefore leading to aggravation of the fines imposed by the Competition Law.<sup>34</sup> If parties to an economic concentration case fail to notify the relevant agencies, as provided for by the Law, they could be fined an amount equivalent to one percent to three percent of the total turnover of these parties in the financial year preceding the economic concentration.<sup>35</sup> Enterprises engaging in restrictive business practices/agreements or prohibited economic concentration, before having obtained an approval for exemption from the relevant agencies, would be fined an amount of 30,000,000 VND to 50,000,000, though not beyond three percent of the total turnover of the financial year preceding the violation.<sup>36</sup>

Besides monetary fines, the Competition Law also provides for specific remedies in order to restore the competitive conditions distorted by the violation or prevent repetition of violation. These remedies include:

- (i) Restructuring the enterprises having abused their dominant position on the market;

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<sup>29</sup> See Decree No. 06/2006/ND-CP issued on January 9, 2006 by the Government on the functions, assignments, authority and organisational structure of the Competition Administration Department.

<sup>30</sup> The Minister of Industry and Trade has the authority to grant exemption for restrictive agreements and economic concentration cases when one or more parties to the economic concentration are in danger of dissolution or bankruptcy; whereas the Prime Minister would decide whether to grant exemption in all other cases. See Competition Law, Article 25.

<sup>31</sup> Competition Law, Article 20(1).

<sup>32</sup> Competition Law, Article 24.

<sup>33</sup> Competition Law, Article 118; Decree No. 120/2005/ND-CP issued on September 30, 2005, by the Government on fines and remedies in the competition law.

<sup>34</sup> Decree No. 120/2005/ND-CP, Article 10(2a), Article 11-24 (2), Article 30, Article 35 and 36 (2a).

<sup>35</sup> Decree No. 120/2005/ND-CP, Article 29.

<sup>36</sup> Decree No. 120/2005/ND-CP, Article 41.

- (ii) Dividing or splitting the merged or consolidated enterprises to force the resale of the acquired enterprise parts;
- (iii) Making public corrections;
- (iv) Removing illegal provisions from the business contracts or transactions; and
- (v) Other necessary measures to overcome the competition restriction impacts of the violation acts.<sup>37</sup>

Depending on the specific violations, the relevant state agencies may decide to impose one of the remedies mentioned below.<sup>38</sup>

#### **1.4. Procedures for Investigating and Handling Competition Violations**

In order to ensure that the provisions of the Competition Law are abided by in practices, this Law and all the subordinate regulations provide for specific procedures for investigating and handling breaches of the Law. Accordingly, certain practices may be investigated on the basis of complaints made by those whose interests are damaged by these practices or investigations may be initiated by the VCAD themselves if there are notable signs that the Law is being violated.<sup>39</sup> The investigation process comprises of two stages: preliminary investigation and official investigation.<sup>40</sup> For unfair competition practices, the VCAD would solely decide the fines and remedies.<sup>41</sup> For restrictive business practices, the VCAD would refer the case dossiers to the Vietnam Competition Council (VCC) for consideration.<sup>42</sup> The Chairman of the VCC would decide whether to form an *ad hoc* Council for handling specific cases. The *ad hoc* councils would come out with their decision over the case after hearings.<sup>43</sup>

#### **1.5. Other Provisions of the Competition Law**

Besides stipulating prohibited anti-competitive practices, the procedures for handling violations, the establishment and structure of the investigative and adjudicative agencies to deal with violations, the Competition Law also provides for two other important matters, which is very characteristic of the Vietnam context:

First, state management agencies are prohibited from engaging in certain practices which have the effects of preventing competition on the market. As stipulated in Article 6 of the Law, the following practices are prohibited: (i) forcing enterprises, organisations or individuals to buy and sell goods and provide services to enterprises which are designated by these agencies, except for goods and services in the state-monopolised domains or in

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<sup>37</sup> Competition Law, Article 117(3).

<sup>38</sup> Decree No. 120/2005/ND-CP provides detailed explanation on remedies which would be applicable for each type of violations.

<sup>39</sup> Competition Law, Articles 58 and 89.

<sup>40</sup> Competition Law, Articles 86-90.

<sup>41</sup> Competition Law, Article 49 (2d).

<sup>42</sup> Competition Law, Article 54(3).

<sup>43</sup> Competition Law, Article 98.

emergency cases prescribed by law; discriminating between enterprises; forcing professional associations or enterprises to align with one another with a view to precluding, restricting or preventing other enterprises from competing on the market; or any other acts that prevent lawful business activities of enterprises.

Secondly, the Competition Law also provides for a control system for the enterprises operating in the state-monopolised domains, enterprises producing and supplying public-utility products and services. As per Article 15, the state would keep a check over these enterprises by deciding on the buying prices and selling prices of goods and services in the state-monopolised domains and deciding on the quantities, volumes and scope of the market of goods and services in the state-monopolised domains.<sup>44</sup>

At present, products such as vaccines and services such as transportation and supply of essential medicines which are listed for use at hospitals and clinics (as prescribed by the Ministry of Health) and antibiotics such as Oxytetracycline, Ampicilline, Tylosin and Enrofloxacin for use by ethnic minorities and people living in remote areas are classified as public-utility products.<sup>45</sup> Enterprises trading or distributing these products would be controlled by the state through the above-mentioned measures. Therefore, competition amongst distributors of these products would be substantially influenced by the controlling measures of the state.

## **2. The Law on Medicines 2005 and Its Implementation Regulations**

The Law on Medicines was promulgated by the National Assembly of Vietnam on June 14, 2005, and took effect from October 1, 2005.<sup>46</sup> The Law regulates the trading of pharmaceuticals, their registration and circulation, the supply and use of medicines, provision of information and advertisements on medicines, clinical test of medicines, management of addictive medicines and medicines for mental problems, ingredients for producing medicines and radioactive medicines, quality standards and laboratory tests for medicines, etc.<sup>47</sup> This Law applies to all organisations and individuals within and outside Vietnam.<sup>48</sup> Therefore, the Law and its implementation regulations will directly regulate the activities of trading, distributing, circulating and advertising medicines by enterprises of all economic sectors in Vietnam. This section would examine and evaluate some provisions of this Law on Medicines and its implementation regulations to see whether they have any direct or indirect implications on competition in the market for pharmaceutical distribution. This includes provisions on the prerequisites for distributing pharmaceuticals, requirements for quality control, pricing of distributed medicines, advertisements and promotional sale during the

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<sup>44</sup> For more information see Decree No. 31/2005/ND-CP issued on March 11, 2005, by the Government on the production and supply of utilities and public goods,

<sup>45</sup> Decree No. 31/2005/ND-CP, List B and C; Decree No. 170/2003/ND-CP issued on December 25, 2003, by the Government guiding the implementation of some provisions of the Ordinance on Prices, amended by Decree No. 75/2008/ND-CP issued on June 9, 2008 by the Government, Article 2.

<sup>46</sup> Law on Medicines, Article 72.

<sup>47</sup> Law on Medicines, Article 1(1).

<sup>48</sup> Law on Medicines, Article 1(2).

whole process of pharmaceutical trading and distribution.

### **2.1. Prerequisites for Entering the Market for Pharmaceutical Distribution**

Medicine trading, including pharmaceutical distribution by all means, is classified as a conditional business.<sup>49</sup> In order to enter this market, enterprises need to obtain a certificate proving that they are qualified for dealing in medicines. Pharmaceutical distributors are only to do business in those areas and scopes as stated in their certificates.<sup>50</sup> These certificates would be granted by the provincial Department of Health for each distributor.<sup>51</sup> Conditions for the issuance of certificates depend on the mode of distribution (bulk, retail or importation) and the types of medicines which are being distributed (ordinary medicines or specially-controlled medicines).

#### **(a) Conditions for Wholesalers**

In order to be recognized as wholesale pharmaceuticals,<sup>52</sup> any enterprise must meet the two following conditions:

- (i) Have a professional manager with pharmacists' certificates<sup>53</sup> which are suitable to each type of wholesale business structure; and
- (ii) Have the infrastructure and human resources meeting the requirement of Good Distribution Practices (GDP)<sup>54</sup> which are being implemented as per schedule.<sup>55</sup>

In order to meet the first condition, the professional manager has to meet the following conditions:

- Be a university graduate in medicines; in the case of trading in vaccines or medical-biological products, be a university graduate in medicines or medical practices or biology; in case of enterprises, co-operatives or individual households dealing in pharmaceutical ingredients, oriental medicines or herbal medicines, be a university/college graduate in medicines or be a university/college graduate in traditional medicines or hold other equivalent certificates in medical practices, pharmaceuticals or traditional herbal medicines;<sup>56</sup> in the case of an agent dealing in

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<sup>49</sup> Law on Medicines, Article 11(1).

<sup>50</sup> Law on Medicines, Article 20(2).

<sup>51</sup> Law on Medicines, Article 11(3b).

<sup>52</sup> Pharmaceutical wholesalers include: (i) pharmaceutical enterprises, (ii) co-operatives, or individual households which produce and trade in pharmaceutical ingredients, oriental medicines and other medicines from pharmaceutical ingredients, (iii) marketing agents for vaccines and medical-biological products. See Law on Medicines, Article 21.

<sup>53</sup> Pharmacists' certificates would be granted by the Ministry of Health to those individuals who are registered for trading in medicines with foreign-invested capitals and by the provincial Department of Health for the rest of the cases. See Law on Medicines, Article 13(3).

<sup>54</sup> Good Distribution Practices.

<sup>55</sup> Decree No. 79/2006/ND-CP issued on August 9, 2006, by the Government guiding the implementation of some provisions of the Law on Medicines, Article 22.

<sup>56</sup> All types of certificates related to medical profession, medical materials or traditional formulations and professionalism in traditional and herbal medicines would be granted by the Minister of Health, in accordance

vaccines or medical-biological products, be a college/university graduate in medicines or medical practices or biology;

- Have practical experiences of at least three years working at a legal pharmacists or two years at enterprises, co-operatives or individual households dealing in pharmaceutical ingredients, oriental medicines and herbal medicines or agents dealing in vaccines or medical-biological products;<sup>57</sup>
- Have professional ethics; and
- Be of good health to be able to practice<sup>58</sup>.

In order to meet the second condition mentioned above, the enterprises have to have infrastructure and human resource meeting the requirements laid out in the code of “Good Distribution Practices”, which is being implemented as per the schedule set by the Ministry of Health. At present, the rules in the code of “Good Distribution Practices” have been issued by the Ministry of Health in accordance with the Decision No. 12/2007/QD-BYT on January 24, 2007.<sup>59</sup> Wholesale pharmaceutical enterprises have to have a management structure, processes, human resources, storing facilities, transportation means and all equipments, etc., meeting the requirements of the Decision No. 12/2007/QD-BYT. Regarding the schedule, the Decision stipulates that, from Jan 1, 2011, all pharmaceutical distributors have to meet the requirements of the “Good Distribution Practices”, as prescribed by this Decision. After this Decision takes effect, all newly-established pharmaceutical wholesalers have to meet the requirements of “Good Distribution Practices” in order to obtain a Certificate for having met the requirements for dealing in medicines. From Jan 1, 2008, all certified pharmaceutical wholesalers have to meet the requirements of the “Good Distribution Practices” in order to extend the term of their certificate.<sup>60</sup>

In general, the conditions set for the professional manager, as well for the infrastructure and the human resource in the code of “Good Distribution Practices”, are quite high. They may constitute entry barriers for enterprises which would like to start in the pharmaceutical wholesaling market in Vietnam. However, these entry barriers are necessary in order to

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with the socio-economic conditions and the demand of the people in each province in specific time periods. At present, these certificates are regulated by Circular No. 02/2007/TT-BYT issued on January 24, 2007, by the Ministry of Health guiding the implementation of some provisions on the conditions for doing business in the pharmaceutical sector in accordance with the Law on Medicines and Decree No. 79/2006/ND-CP issued on August 9, 2006, by the Government guiding the implementation of some provisions of the Law on Medicines, Section II, Article 6. See also the Decree No. 79/2006/ND-CP, Article 15(1).

<sup>57</sup> Legal pharmacists are those pharmacists who are established in accordance with the law, including: (i) establishment trading in medicines; (ii) the pharmaceutical department of hospitals and clinics; (iii) schools for training pharmaceutical professionals; (iv) pharmaceutical research institutes and institutions and centres which undertake clinical tests of medicines; (v) relevant state agencies in the pharmaceutical sector; (vi) representative offices of foreign businessmen operating in the pharmaceutical sector in Vietnam; and (vii) other pharmaceutical establishments as prescribed by law. See Decree No. 79/2006/ND-CP, Article 2(1).

<sup>58</sup> Law on Medicines, Article 13(1); Decree No. 79/2006/ND-CP, Article 15(3).

<sup>59</sup> Decision No. 12/2007/QD-BYT, which is supplemented by Decision No. 29/2007/QD-BYT issued on May 11, 2007 by the Ministry of Health.

<sup>60</sup> Decision No. 12/2007/QD-BYT, Section II (1).



ensure that medicines reach the consumers timely, adequately and having the expected quality.

**(b) Conditions for Pharmaceutical Retailers**

In order to qualify as a pharmaceutical retailer,<sup>61</sup> an enterprise has to meet the following conditions:

- (i) The owner of a retailer has to be a certified pharmacist, suited to the organisation structure of the retailing business; and
- (ii) The infrastructure and human resource of the retailing business have to be in accordance with the standards of Good Pharmacy Practices (GPP).<sup>62</sup>

In order to meet the first condition, the owner of the retail business has to have professional ethics and good health for practicing medicines and meet the following criteria:

- The owner of a pharmacist based at municipal cities as well as provincial cities and towns has to be a university graduate in medicines and has to have at least five years' experience of practicing at a legal pharmacy; for other areas, the owner has to be a university graduate in medicines and has to have at least two years of practicing experience at a legal pharmacy;
- The manager of a pharmacist has to hold at least a college degree in medicines and have at least two years' experience of practice at a legal pharmacy;
- The owner of a business retailing agent has to be a certified assistant pharmacist and has to have at least two years' experience of practice at a legal pharmacy;
- The manager of a clinic has to be at least a certified assistant pharmacist and has to have at least two years' experience of practice at a legal pharmacy; and otherwise at least hold a certified nursing degree.<sup>63</sup>

In order to meet the second condition, the retailing business has to have infrastructure and human resource satisfying the standards of "Good Pharmacy Practices", issued by the Ministry of Health in accordance with the Decision No. 11/2007/QD-BYT on January 24, 2007,<sup>64</sup> including the basic principles and standards for professional practices at pharmacies by pharmacists and assistants. This Decision prescribes different schedules for various types of pharmaceutical retailers. For example, from January 1, 2011, all large pharmacies in Vietnam have to meet the standards and criteria of "Good Pharmacy Practices" as prescribed by the Decision No. 11/2007/QD-BYT. However, for small-scale pharmacies, this deadline is

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<sup>61</sup> Pharmaceutical retailers include pharmacies, pharmaceutical retailing stores, marketing agents of enterprises, and the medicine stores of clinics. See Law on Medicines, Article 24(1).

<sup>62</sup> See Decree No. 79/2006/ND-CP, Article 23.

<sup>63</sup> Law on Medicines, Article 13(1) and Article 25; Decree No. 79/2006/ND-CP, Article 15(4).

<sup>64</sup> Decision No. 11/2007/QD-BYT, which is supplemented by Decision No. 29/2007/QD-BYT issued on May 11, 2007, by the Ministry of Health.

extended until January 1, 2013.<sup>65</sup>

Similarly, as in the case of pharmaceutical wholesalers, retailers have to meet the stringent requirements of the Law in order to be certified as having the necessary conditions for pharmaceutical practices. These are necessary requirements in order to ensure the safety of pharmaceutical consumers.

### **(c) Conditions for Pharmaceutical Importers**

Vietnamese enterprises manufacturing and/or distributing medicines in bulk, after being certified as having the necessary conditions for pharmaceutical practices and standardised storing facilities (as in Good Storage Practices GSP),<sup>66</sup> will be allowed to import medicines, as per the law, the decisions of the Ministry of Health and other relevant regulations.<sup>67</sup>

It is important to note that direct pharmaceutical import licences are only given to Vietnamese enterprises without foreign capital contribution. Foreign-invested enterprises (FIEs), after having been certified as having the necessary conditions for pharmaceutical practices, would be allowed to directly import or authorise imports of *pharmaceutical ingredients* in order to serve manufacturing needs, as prescribed in their investment permit. FIEs are not allowed to directly import and distribute medicines in Vietnam and can only import and distribute medicines via Vietnamese enterprises having pharmaceutical import licences (unless otherwise prescribed by Vietnamese law).<sup>68</sup> If foreign-owned companies want to import medicines into Vietnam, they have to obtain a permit for dealing in medicines and pharmaceutical ingredients in Vietnam. And, they can only provide medicines and pharmaceutical ingredients to Vietnamese pharmaceutical importers, as per the scope of business prescribed in their permits.<sup>69</sup> Regarding pharmaceutical ingredients, excipients, follicular cover and package, which is directly attached to imported medicines, foreign suppliers do not need to have permit for dealing in medicines and pharmaceutical ingredients in Vietnam. Foreign-owned companies having a permit for dealing in medicines and pharmaceutical ingredients in Vietnam are allowed to supply registered medicines and

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<sup>65</sup> Decision No. 11/2007/QĐ-BYT, Chapter III, Section I. However, this schedule is applied earlier in the case of pharmacies, pharmaceutical retailing stores and retailers of oriental medicines and medical materials from hospitals. For example, the pharmaceutical departments of hospitals would have to meet the requirements of Good Pharmacy Practices since January 1, 2009. Newly-established pharmacies in cities like Hanoi, Ho Chi Minh City, Da Nang and Can Tho would have to meet these requirements since January 1, 2010. See Decision No. 24/2008/QĐ-BYT issued on July 11, 2008, by the Ministry of Health on the organisation and operations of hospital pharmacies.

<sup>66</sup> Good Storage Practices.

<sup>67</sup> Decree No. 79/2006/NĐ-CP, Article 24(1).

<sup>68</sup> Circular No. 06/2006/TT-BYT issued on May 16, 2006, by the Ministry of Health guiding the exportation, and importation of medicines and cosmetics, Section I, Article 3.1 and 3.2.

<sup>69</sup> Circular No. 06/2006/TT-BYT, Section I, Article 3(7). The procedures for registering business in the pharmaceutical sector in Vietnam for foreign enterprises are stipulated in Circular No. 17/2001/TT-BYT issued on August 1, 2001, by the Ministry of Health guiding the registration of business by foreign enterprises for operations related to medicines and pharmaceutical materials in Vietnam. The procedures for registration of business relating to vaccines and medical-biological products in Vietnam by foreign enterprises are stipulated by Circular No. 10/2003/TT-BYT issued on December 16, 2003, by the Ministry of Health guiding the registration of business by foreign enterprises for operations related to vaccines and medical-biological products.

pharmaceutical ingredients (which are authorised by the manufacturers for registration by Vietnamese enterprises) to Vietnamese enterprises or Vietnamese importers who are qualified for direct importation.<sup>70</sup>

It is clear that the regulations on the right to import and distribute medicines are discriminatory between 100 percent Vietnamese-owned enterprises, FIEs and foreign-owned companies. This discrimination may go against the objective of promoting a level playing field by the Competition Law 2004. However, it reflects the industrial policy objective of promoting the domestic sector of the pharmaceutical sector in Vietnam.<sup>71</sup> It should also be noted that pharmaceutical distribution is exempted from the list of industries/sectors to be liberalised under Vietnam's accession commitments to the World Trade Organisation (WTO).<sup>72</sup> This means that, in the future, whether foreign-owned companies or FIEs can participate in pharmaceutical distribution sector or not solely depend on Vietnam's policy decision.

Principles and standards of "Good Storage Practices" are issued by the Ministry of Health in accordance with Decision No. 2701/2001/QD-BYT on June 29, 2001. Accordingly, GSP includes specialised measures, which are suitable for storage and transportation of ingredients and products at all stages of manufacturing, preservation, storage, transportation and distribution of medicines, in order to ensure that the final pharmaceutical products have the expected quality for being used by consumers.

The schedule for implementing the Good Storage Practices is prescribed by Decision No. 27/2007/QD-BYT issued by the Ministry of Health on April 19, 2007.<sup>73</sup> Accordingly, from July 1, 2008, all pharmaceutical businesses which have been, and are, dealing in importation of medicines need to have storing facilities meeting the GSP qualifications in order to continue importing. Since this Decision has taken effect, all pharmaceutical businesses which are applying to have import licences (for both pharmaceutical ingredients and final products) ought to have storing facilities meeting the GSP qualifications. From January 1, 2011, all businesses which deal in, store and maintain medicines, all pharmaceutical departments of hospitals, all research institutions and clinics have to start the implementation of GSP.<sup>74</sup>

GSP might act as entry barriers for enterprises which want to import medicines for distribution in Vietnam. However, these are necessary conditions to ensure that imported

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<sup>70</sup> Circular No. 06/2006/TT-BYT, Section I, Article 3(7).

<sup>71</sup> For more information, see the Strategy for Pharmaceutical Industry Development till 2010, approved by the Prime Minister in Decision No. 108/2008/QD-TTg dated August 15, 2008.

<sup>72</sup> The Report of the Working Group on the Accession of Vietnam to the World Trade Organisation dated October 27, 2006, Section II – Schedule for specific commitments on services and List of MFN exemptions according to Article II, p. 37.

<sup>73</sup> For more information, see Decision No. 47/2007/QD-BYT issued on December 24, 2007, by the Ministry of Health on the application of principles and standards regarding "Good Manufacturing Practices", "Good Medical Testing Practices", "Good Storage Practices" and "Good Distribution Practices" for manufacturers, clinical testing houses, traders, distributors, exporters and importers, logistics service providers with regard to vaccines and medical-biological products.

<sup>74</sup> Decision No. 27/2007/QD-BYT, Article 1 (2c, d, and dd).

medicines are stored and maintained for good quality, to serve the needs of consumers. Besides, the Law on Medicines also allows those enterprises which do not meet the qualifications for direct importation to be able to authorise imports by other qualified businesses.<sup>75</sup> This authorisation would be undertaken in accordance with the provisions of the Commercial Law on authorised imports.<sup>76</sup>

#### **(d) Conditions for Distributors of Specially-controlled Medicines**

For specially-controlled medicines such as addictives, mental medicines and ingredients, radioactive medicines, in addition to the above mentioned conditions, pharmaceutical distributors also have to meet some other specific conditions. For example, for radioactive medicines,<sup>77</sup> the distributors need to have a permit on “ensuring radioactive safety”, issued by the Ministry of Science and Technology and the person in charge of ensuring radioactive safety needs to undergo proper training programmes jointly organised by the Ministry of Science and Technology and the Ministry of Health and have to be able to obtain the required certificates in this regard.<sup>78</sup> For mental medicines, addictives and ingredients, the distributors have to meet some conditions prescribed by the Decree No. 80/2001/ND-CP, issued by the Government on November 5, 2001, which provides guidance on how to control legal activities related to drugs in Vietnam and the Decree No. 58/2003/ND-CP issued by the Government on May 29, 2003, which stipulates the control of importation, exportation and goods in transit in Vietnam of drugs and ingredients, addictives and mental medicines, as well as other relevant regulations.<sup>79</sup>

### **2.2. Regulations over Pharmaceutical Distribution Activities**

After entering the market, distributors have to comply with various conditions set by the Law on Medicines and its implementation regulations regarding the products to be distributed, pricing and advertisement and sales promotion of medicines. This can be considered as a barrier against business expansion and development, since the compliance would involve certain costs. However, these requirements stem from the special status of the products to be distributed and serve the ultimate objective of protecting the health and life of consumers. Therefore, what should be carefully considered is whether these requirements are discriminating amongst the distributors in order to create unfair competitive edges or not. Besides, we might also consider whether the restrictions created by these requirements upon

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<sup>75</sup> Law on Medicines, Article 19(1).

<sup>76</sup> *Ibid.* See also the Commercial Law 2005, Article 155-156; the Decree No. 12/2006/ND-CP issued on January 23, 2006, by the Government guiding the implementation of the Commercial Law regarding international purchase and sale of products and other activities related to purchasing, selling, sub-contracting of goods in transit, Article 17-20.

<sup>77</sup> In order to be granted permits on radioactive safety, enterprises have to meet the requirements set in Decree No. 50/1998/ND-CP issued on July 16, 1998, by the Government guiding the implementation of the Ordinance on Radioactive Safety and Control, and the Circular No. 05/2006/QD-BKHHCN issued on January 11, 2006, by the Ministry of Science and Technology guiding the procedures for registration and granting of permits for activities related to radioactivity.

<sup>78</sup> Decree No. 79/2006/ND-CP, Article 33.

<sup>79</sup> Decree No. 79/2006/ND-CP, Article 32(2).

business development are of an appropriate level or not.

**(a) Regulations on Medicines Legally Circulated**

In order to be circulated in Vietnam, the medicines have to ensure the following requirements are met:

- (i) They have to be of the quality previously registered;
- (ii) They have to be properly labelled, as prescribed by law;
- (iii) The materials used for packaging and the packaging formats must ensure the quality of the medicines are not adversely affected;
- (iv) The medicines need to have a registration number (or ‘visa’); or in case of no registration yet, need to have been imported, as prescribed by Point a-b, Section 2, Article 20 of the Law on Medicines; and
- (v) The prices of the medicines have to be registered as per the provisions of the Law on Medicines, which means that, in case of imported medicines, the importing prices cannot be higher than those in other countries in the region which are at the similar stage of development as Vietnam regarding the health sector or economic activities, during the same period of time.<sup>80</sup>

Henceforth, in order to circulate medicines, pharmaceutical distributors or manufacturers need to register the medicines with the Ministry of Health. Based on the results of clinical tests on the effectiveness and safety of the medicines, except for those exempted from clinical tests, as per Article 55 of the Law on Medicines, and the technical documents on medicines and national pharmaceutical policy, the Ministry of Health will provide the enterprises with a registration number (or also called in Vietnam, a ‘visa’ number).<sup>81</sup> Enterprises have to follow the procedures set out by Decision No. 3121/2001/QD-BYT issued by the Ministry of Health on July 18, 2001, on the promulgation of “Procedures for Drug Registration”. For vaccines and medical-biological products, enterprises have to follow the procedures set out by Decision No. 4012/2003/QD-BYT issued by the Ministry of Health on July 30, 2003, on the promulgation of “Procedures for the registration of vaccines and medical-biological products”. Accordingly, foreign enterprises, after being permitted by the Ministry of Health to do business on pharmaceuticals in Vietnam, can start the registration process at the Ministry, either for normal medicines or vaccines and medical-biological products.<sup>82</sup> Therefore, regulations on drug registration do not discriminate against enterprises of any particular economic sector, as in the case of pharmaceutical importation, as discussed above.

Regarding labelling, as per Article 37 of the Law on Medicines and the Circular No. 04/2008/TT-BYT issued by the Ministry of Health on May 12, 2008, on pharmaceutical

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<sup>80</sup> Law on Medicines, Article 36(1).

<sup>81</sup> Law on Medicines, Article 35(1).

<sup>82</sup> Decision No. 3121/2001/QD-BYT, Article 2(1); Decision No. 4012/2003/QD-BYT, Article 3(2).

labelling, certain information has to be given on the labels of any medicine, including the name of medicines, active elements, content and concentration level, packaging procedures; specification and usage, anti-specification; formulation, registration number or import permit number, manufacturing batch, manufacturing date, expiry date and storage conditions; important notices; name and address of the institutions or individuals who are responsible for the medicines; origin; and usage specifications.<sup>83</sup> For domestically-manufactured pharmaceutical products, the manufacturers are responsible for labelling, not the distributors. Importers have to make additional labelling (if the original labelling of the products is not appropriate for use in Vietnam), in addition to the original labelling, before putting the medicines in circulation.<sup>84</sup> These regulations apply equally to enterprises of all economic sectors, which are qualified for pharmaceutical distribution, as mentioned above.

Medicine is a special product, which has to be placed under strictest quality control. The Law on Medicines strictly prohibits the distribution of medicines of unknown origins, fake medicines, bad-quality products, expired products, medicines prohibited from imports, medicines under clinical tests, medicines not authorised for circulation yet, sample products used for registration or for marketing with doctors.<sup>85</sup> The quality of medicines has to be as registered and not lower than the national standards on the quality of medicines.<sup>86</sup>

#### **(b) Regulations on Pricing**

As mentioned above, medicine is a special product and consumers do not have a wide range of substitutes to choose from. Therefore, the pricing of medicines is also regulated by state agencies. Section 1, Article 5 of the Law on Medicines stipulates that, “the State regulates the pricing of medicines on the principle of allowing manufacturers, exporters, importers and traders to set their own prices, compete on prices and be solely responsible over the prices set, however retain the right to stabilise the prices on the market in order to fulfil the obligations of ensuring public health”.

Currently, as per the Law on Medicines and the Decree No. 79/2006/ND-CP, before being put into circulation, the prices of medicines have to be registered by the manufacturers and importers. In case of change, the prices have to be re-registered with relevant state agencies, to ensure that the prices are not higher than those in countries in the region which are at similar stages of development as Vietnam, with regard to the health sector and commercial

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<sup>83</sup> For some special cases of labelling, such as labels for materials, labels on medicine bars, labels on direct covers of small-size, labels on formulations as per prescriptions, and labels on medicines for use in national medical programmes, there is some other mandatory information which is to be provided. See further in Circular No. 04/2008/TT-BYT, Section II.B

<sup>84</sup> Circular No. 04/2008/TT-BYT, Section I.9

<sup>85</sup> Law on Medicines, Article 9(3)

<sup>86</sup> Law on Medicines, Article 66(2). The national standards for quality of medicines are prescribed in the Vietnam Pharmaceutical Encyclopaedia. This is the code of standards prepared by the Pharmaceutical Committee for approval and promulgation by the Minister of Health. It is important to note that pharmaceutical distributors can use the standards prescribed overseas or in international pharmaceutical encyclopaedia as registered by these distributors and approved by the Ministry of Health. See further at Decree No. 79/2006/ND-CP, Article 10(4)

conditions.<sup>87</sup> Wholesale prices and retail prices have to be listed as per regulations.<sup>88</sup> All enterprises have to be solely responsible for the prices set, registered and listed.<sup>89</sup> During the process of doing business, manufacturers and importers of medicines cannot sell at prices higher than those registered. In case of selling prices higher than registered prices, the enterprises have to re-register and explain to the relevant state agencies before applying the new prices.<sup>90</sup> In case the selling prices are lower than registered prices, enterprises have to comply with legal regulations on anti-dumping.<sup>91</sup> Relevant state agencies in charge of regulating pharmaceutical pricing<sup>92</sup> will update and make public all the registered prices on the health sector's website, magazines and other mass media, to provide the base to which consumers, clinics and hospitals can refer when purchasing medicines, as well as to wield state control and administration over pharmaceutical pricing.<sup>93</sup>

In general, the regulations over pricing of medicines set by the Law on Medicines and its implementation regulations help to ensure the transparency and information dissemination over the prices of medicines being distributed in Vietnam. The Law allows enterprises to set their own prices on competitive basis, but the enterprises have to register with the relevant state agencies and prices are to be publicly listed. This level of control is completely appropriate for this sensitive product.

The Law on Medicines also strictly prohibits the abuse of monopoly power in pharmaceutical trading, in order to accrue illegitimate rents, predatory pricing or excessive pricing.<sup>94</sup> As compared to the Competition Law, this regulation reflects the general principle of prohibiting the abuse of monopoly power to set excessive prices to harm consumers or to use "predatory pricing" tactics to harm other competitors. In general, Articles 13 and 14 of the Competition Law provide an overview of the prohibited practices by the Law on Medicines.

It is important to note that Vietnam's anti-dumping law<sup>95</sup> only provides for dumping of prices in the case of imported products. It does not apply when an enterprise sells below the normal

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<sup>87</sup> Countries in the region which are at similar stages of development as Vietnam with regards to the pharmaceutical industry and other commercial conditions are those countries with the following statistics similar as Vietnam's: (i) Gross Domestic Products per capita per annum, (ii) Parity Purchasing Power per capita per annum, (iii) the network which supply healthcare services. See Decree No. 79/2006/ND-CP, Article 10(4).

<sup>88</sup> The style, format, timing and content for medicine price listing; and the procedures for registration and re-registration of medicine prices are prescribed at the Inter-Ministerial Circular No. 11/2007/TTLT-BYT-BTC-BCT between the Ministry of Health, the Ministry of Finance and the Ministry of Industry & Trade dated August 31, 2007 guiding the implementation of State administration over medicine prices for human use.

<sup>89</sup> Law on Medicines, Article 5(2), Decree No. 79/2006/ND-CP, Article 8-11

<sup>90</sup> Handling of violations related to medicine price registration and listing is stipulated at Decree No. 169/2004/ND-CP issued on September 22, 2004 by the Government on administrative fines in pricing, Article 1; Article 14 of the Decree No. 120/2004/ND-CP issued on February 12, 2004 on the State administration of prices of medicines for human use; Decree No. 45/2005/ND-CP issued on April 6, 2005 by the Government on administrative fines in the health sector.

<sup>91</sup> Decree No. 79/2006/ND-CP, Article 10(3)

<sup>92</sup> Drug Administration of Vietnam (DAV) - Ministry of Health. See Law on Medicines, Article 13

<sup>93</sup> Decree No. 79/2006/ND-CP, Article 10(5)

<sup>94</sup> Law on Medicines, Article 9(7)

<sup>95</sup> See the Ordinance on Anti-dumping of imported goods into Vietnam; and the Decree No. 90/2005/ND-CP issued on July 11, 2005 by the Government guiding the implementation of some provisions of this Ordinance.

prices of the products or below the registered prices. Besides, Section 1, Article 13 of the Competition Law only prohibits enterprises from abusing their dominant positions or monopoly to set prices below total manufacturing prices. Therefore, the regulations in cases where enterprises sell below registered prices are not exhaustive. This is one point which needs to be considered for revision.

### **(c) Regulations on Advertisement**

In addition to general legal provisions on advertising and sales promotion, enterprises also have to comply with specific regulations on pharmaceutical promotion and advertising stipulated by the Law on Medicines and its implementation regulations. Notably, there are two important provisions as follows:

- (i) It is prohibited to use tangible benefits or abuse the name and reputation of organisations and individuals, mails and letters or clinical test results unrecognised by the Ministry of Health and other similar tactics for the purpose of advertisement.<sup>96</sup>
- (ii) The scope of pharmaceutical advertising is restricted as follows: prescribed medicines cannot be publicly advertised by any means; and over-the-counter (OTC) medicines can be advertised on advertising media.

In case where OTC medicines are being advertised on the mass media (such as radio or television), the medicines have to:

- Contain active elements which are listed as ‘advertisable’ on radio and television by the Ministry of Health; and
- Be effectively and currently registered in Vietnam.<sup>97</sup>

At present, the list of active elements that can be advertised as such is provided in Decision No. 45/2007/QD-BYT issued by the Ministry of Health on December 18, 2007, regarding the issuance of the list of active elements which can be advertised on radio and television. Accordingly, the types of medicines which can be advertised on the television are quite restrictive. For example, only those medicines which are being used for treating common diseases or sickness or can be used by the patients themselves without consulting or visiting doctors, without remarkable consequences, can be registered for advertisements.<sup>98</sup>

Besides the Law on Medicines, the Regulations on information and advertisements<sup>99</sup> regard medicines as a special product which can directly affect human health. The Regulations also provide for “scientific” content in advertisements on medicines.<sup>100</sup> The content of the advertisements have to be in accordance with the usage specification leaflets examined and

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<sup>96</sup> Law on Medicines, Article 52(2).

<sup>97</sup> Law on Medicines, Article 53.

<sup>98</sup> Decision No. 45/2007/QD-BYT, Section I.1.3 & 1.5.

<sup>99</sup> Issued together with Decision No. 2557/2002/QD-BYT on July 4, 2002, by the Ministry of Health.

<sup>100</sup> Decision No. 2557/2002/QD-BYT, Article 4.



approved by the Ministry of Health or relevant state agencies of the same level of the country (in which the medicines are legally manufactured and circulated). And, the content of the advertisements also has to be in accordance with the research entry on the medicines in subject in the National Pharmaceutical Encyclopedia, or other documents internationally recognised.<sup>101</sup> The regulations classify pharmaceutical advertising into two types: advertising to health workers and advertising to the public. The Ministry of Health (Drug Administration of Vietnam DAV) would be able to censor the content of the advertisements before the pharmaceutical distributors can put the advertisements into use or before the advertising agencies can undertake the advertisements. Accordingly, in order to advertise any type of medicine, enterprises would have to submit an application to the DAV. After 15 working days from the day of the receipt of the application, if the DAV does not request changes or revisions in writing, the enterprises can put the advertisements into use, as per the content submitted. If they are asked to make changes or revisions, the enterprises have to do the needful and then re-submit the application (with the changes/revisions incorporated) to the DAV. The enterprises can put the new advertisements into use, if, after five working days from the day of receipt of the revised application, the DAV does not have any express opinion.<sup>102</sup>

From the perspective of competition, these stringent rules on pharmaceutical advertising would involve additional costs and time for firms, affecting the business and, therefore, may restrict the business development process. However, these rules are put in place in order to protect the legitimate interests of the medicine users. They are absolutely essential, provided that they are applied equally and fairly amongst all competitors.

The Law and regulations on medicines and the Competition Law converge when it comes to incorrect and misleading advertisement. The Law on Medicines and the Regulations on Pharmaceutical advertising do not prohibit other unfair acts regarding advertisements and sale promotion, as prescribed by the Competition Law (for example, comparative advertising). Regarding the accuracy of the advertisement, however, the law and regulations on medicines are more detailed than the Competition Law. For example, whereas the Competition Law only prohibits incorrect and misleading advertising (Point a, Section 3, Article 45), Article 26 of the Regulations on Pharmaceutical advertising also prohibit the use of sentences, words, images or sounds which might impress upon the public that using the advertised medicines is the best solution or the medicines do not have any negative effects, etc.

However, when it comes to fines and remedies for incorrect and misleading advertising and information, Decree No. 45/2005/ND-CP issued by the Government on April 6, 2005, on administrative fines in the health sector does not provide any fines for incorrect and misleading advertisement and information.<sup>103</sup> This would be quite a gap if the sectoral administration does not co-operate with the competition authorities in order to use the fines

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<sup>101</sup> Decision No. 2557/2002/QD-BYT, Article 12.

<sup>102</sup> This procedure is stipulated in details at Decision No. 2557/2002/QD-BYT, Article 42.

<sup>103</sup> See Article 39.

and remedies provided for unfair competition acts (including misleading advertising) by the Competition Law and the Decree No. 120/2005/ND-CP.

### **3. Other Relevant Laws and Regulations**

In addition to the Law on Competition, the Law on Medicines and its implementation regulations, the competitive process in the pharmaceutical distribution sector in Vietnam is also regulated by other relevant laws and regulations such as regulations on investment, the establishment and management of enterprises; regulations on commercial activities; regulations on prices; regulations on taxation and intellectual property rights (IPRs), etc. Here below is an overview of the general legal framework which regulates and may affect the competitive process amongst pharmaceutical distributors in Vietnam.

#### **3.1. *The Investment Law 2005***

At present, besides the specific regulations of the pharmaceutical sector, all new investments or expansion of current investment projects are directly regulated by the Investment Law 2005 and its implementation regulations.<sup>104</sup>

The Investment Law 2005 regulates and specifies the general policy of the Government of Vietnam on investment. Accordingly, investors are allowed in all sectors/industries which are not restricted by law; they can make their own decisions and undertake their investments in accordance with the laws; the state would treat investors of all economic sectors, domestic or foreign, equally; and the state would promote and facilitate all investments.<sup>105</sup> This policy is completely in line with the policy to promote and maintain a level playing field and fair competition amongst all enterprises by the Competition Law.

The Investment Law prohibits investors from manufacturing medicines used for human beings, vaccines and medical-biological products which are yet permitted for usage in Vietnam.<sup>106</sup> However, the Law encourages investors to manufacture pharmaceutical ingredients and medicines for treating sexually-transmitted diseases (STDs); vaccines; medical-biological products; herbal medicines; and oriental, traditional medicines which are permitted for usage in Vietnam.<sup>107</sup> In addition, the Law also reflects the investment policy in the pharmaceutical sector. Accordingly, those investment projects which have the objective of developing the pharmaceutical industry into a spearheading scientific and technically advanced industrial sector, such as applying advanced technology to produce medicines or pharmaceutical ingredients, essential medicines or import-substituting medicines, etc., would be entitled to preferential treatment regarding taxation, capital and land-use rights, etc.<sup>108</sup> Besides the preferential treatments given to certain areas of investment, the Law also

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<sup>104</sup> The Investment Law 2005 was passed by the National Assembly on November 29, 2005, effective from July 1, 2006. See the Investment Law, Article 89.

<sup>105</sup> Investment Law 2005, Article 4(1-2).

<sup>106</sup> Decree No. 108/2006/ND-CP issued on September 22, 2006 by the Government guiding the implementation of some provisions of the Investment Law, Annex D.

<sup>107</sup> Decree No. 108/2006/ND-CP, Annex A.

<sup>108</sup> Law on Medicines, Article 3(1); Decree No. 79/2006/ND-CP, Article 4(1).

provides preferential treatments based on geographical location of projects.<sup>109</sup>

The question is whether the preferential treatments given for certain projects in certain areas of investment and regions might give undue competitive favour to certain investors at all or not. It is clear whether the investors doing business in the areas and regions listed for preferential treatment may benefit from some advantages over those not doing business in those areas and regions. However, from the perspective of competition, the enterprises not investing in the same areas or geographical regions may not be direct competitors. Therefore, the preferential treatments might not result in unfair competitive edges. Besides, these preferential treatments are also being given to all investors without discrimination (except those cases stated below) and, hence, enterprises can always decide which areas and regions to invest in.

The Investment Law stipulates that investment into the distribution sector, including pharmaceutical distribution, is a conditional business sector for foreign investors.<sup>110</sup> As mentioned above, neither the Law on Medicines nor Vietnam's WTO accession commitments liberalise the pharmaceutical distribution sector fully for the participation of foreign investors. This may adversely affect the competition between domestic players and foreign companies in the pharmaceutical distribution sector.

Regarding the rights and obligations of investors, the Investment Law is centred upon the principle of non-discrimination amongst all investors. All rights of access to capital, public utilities or rights to advertise, etc., are non-discriminatory amongst investors. However, this principle does not include the right to import and authorise imports,<sup>111</sup> where there remains differential treatment between domestic and foreign companies.

Regarding the form of investment, the Investment Law provides for many types from which investors can choose. As mentioned above, distribution is a conditional business sector for foreign companies. Therefore, the choice on form of investment available to foreign investors in this sector would be more restricted, as compared to those forms available to domestic investors. Regarding the forms of investment which lead to economic concentration and affect the market structure, such as joint-ventures, stock purchase, mergers and acquisitions, the Investment Law only stipulates the formats and procedures for investment and refers to the Competition Law and other relevant laws for specifying the conditions which are necessary for the undertaking of mergers and acquisitions.<sup>112</sup> However, according to Article 17 of the Competition Law, all joint-ventures and mergers are considered as economic concentration activities. The Investment Law does not provide that, in order to enter into a joint-venture or undertake a merger, the merging parties have to ensure that their undertaking is not prohibited by the Competition Law.<sup>113</sup>

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<sup>109</sup> See Decree No. 108/2006/ND-CP, Annex B.

<sup>110</sup> Decree No. 108/2006/ND-CP, Annex C.

<sup>111</sup> Investment Law 2005, Article 15(1).

<sup>112</sup> Investment Law, Article 25; Decree No. 108/2006/ND-CP, Article 10(2).

<sup>113</sup> Decree No. 108/2006/ND-CP, Article 6 & 8.

Regarding the procedures for undertaking investment, the Investment Law 2005 has eliminated, to a significant extent, all the complicated and unnecessary steps. Essentially, depending on the business sectors and the level of capital, the investors would have to register their projects or undergo certain controlling measures. For the projects in the area of pharmaceutical distribution, foreign investors are subject to the regulations of whether to liberalise the market or not, as per the Law on Medicines and relevant international treaties. The improvement of investment procedures has contributed to improving the competitive environment, since the improvement helps enterprises to enter the markets or expand their business more easily.

### **3.2.        *The Enterprise Law 2005***

The establishment, organisation and undertakings of enterprises of all types (limited liability companies, joint-stock companies, joint ventures and private companies of all economic sectors) are subject to the purview of the Enterprise Law 2005 and its implementation regulations.<sup>114</sup> However, state-owned enterprises (SOEs)<sup>115</sup> are still subject to the purview of the Law on State-owned Enterprises 2003 and its implementation regulations until they are completely transformed into limited liability companies or joint-stock companies.<sup>116</sup>

The promulgation of this Law is a great landmark in Vietnam's efforts to create a level regulatory playing field for all economic entities. Except for the transition phase reserved for SOEs, as mentioned above, the public sector is also subject to the same regulations as the private sector and foreign entities, in terms of establishing, organising and managing their business. This is the very reason why this Law is said to have contributed to the promotion of a level playing field by the Competition Law.

As compared to the Enterprise Law 1999, the 2005 Law has been greatly improved in terms of the procedures to be completed for the establishment of enterprises. For example, the Law stipulates that the state agency responsible for the registration of business has to examine applications and issue Certificate of Incorporation within 10 working days from the date of the receipt of the application.<sup>117</sup> It also combines the registration of business with the registration of investment projects (the Certificate of Incorporation is also the Certificate of Investment).<sup>118</sup> This means that entry market barriers, including those in the pharmaceutical distribution sector, have been significantly reduced. However, as mentioned above, whether an investor can successfully enter the market for pharmaceutical distribution or not depends,

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<sup>114</sup> Enterprise Law 2005, Article 1. The Enterprise Law 2005 was passed by the National Assembly in November 29, 2005, effective from July 1, 2006. See Enterprise Law 2005, Article 171(1).

<sup>115</sup> State-owned enterprises are those enterprises completely owned by the State, established, operating, having the organizational structure and being registered under the Law on State-owned Enterprises. SOEs are normally organized as independent public enterprises or general State corporations. See the Law on SOEs 2003, Article 3(1)

<sup>116</sup> See the Enterprise Law 2005, Article 166. Accordingly, the transition phase would expire 4 years after the Law took effects at the latest.

<sup>117</sup> Enterprise Law 2005, Article 15(2). See also the Decree No. 88/2006/ND-CP issued on August 29, 2006 by the Government on Registration of Business.

<sup>118</sup> Enterprise Law, Article 20

to a great extent, on his ability to meet the requirements set out by the Law on Medicines.<sup>119</sup>

Regarding competitive behaviours of enterprises, the Enterprise Law and its implementation regulations provide for some conditions and procedures for undertaking some economic concentration activities and the control of business activities of large Economic Groups. Specifically:

First, regarding merging of enterprises, Section 3, Article 152 of the Enterprise Law 2005 states that *“for merger cases where merging parties have a combined market share of 30 percent up to 50 percent in the relevant markets, the legal representatives of the merging parties have to notify the competition-managing agency before the merger is affected, unless the laws and regulations on competition stipulate otherwise. Merger cases, in which merging parties have a combined market share of beyond 50 percent in the relevant markets, are prohibited, unless the laws and regulations on competition stipulate otherwise.”* The same regulation and prohibition applies in the case of acquisitions, as per Section 3, Article 153 of the Law.<sup>120</sup>

Secondly, Sections 3 and 4, Article 17 of the Decree No. 88/2006/ND-CP stipulate the registration of enterprises after mergers and acquisitions. Accordingly, the state agency responsible for registration of enterprises does not require the enterprises to provide written documents proving that they are exempted from the purview of the Competition Law by the relevant level of authority (in cases where the combined market share of the parties to the merger/acquisition is from 30 percent up to 50 percent in the relevant markets) or written documents proving that they are not prohibited by the Competition Law to merge, issued by the competition authorities (in cases where the combined market share of the parties to the merger/acquisition is beyond 50 percent in the relevant markets). The obligation of notifying the competition authorities or obtaining exemption falls on the parties to the economic concentration case. However, in order to ensure that the Competition Law is complied with and minimises the cost of enforcement, it is necessary to have a clear mechanism for co-operation between the competition authorities and the state agency responsible for registration of enterprises.

Thirdly, Article 26 of the Decree No. 139/2007/ND-CP issued by the Government on September 5, 2007, regarding the implementation of the Enterprise Law assigns the task of guiding the control of Economic Groups and their members, as well as the relationship between the parent companies and the offspring in the implementation of the regulations on restrictive agreements and abuse of dominant positions and monopoly, to the Ministry of Industry and Trade. However, until now, this guiding document has not been issued.

### **3.3. *The Commercial Law 2005***

The Commercial Law 2005 was promulgated by the National Assembly of Vietnam on June

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<sup>119</sup> See more for requirements of conditional businesses at the Enterprise Law 2005, Article 7(2).

<sup>120</sup> Enterprise Law 2005, Article 152(1).

14, 2005, and took effect from January 1, 2006.<sup>121</sup> This is a general law governing all commercial activities, including the distribution of medicines in Vietnam.

The Commercial Law recognises the basic principles in the dealing of businessmen, which affirms that businessmen of all economic sectors are equal before the law in their dealings.<sup>122</sup> This is one of the most important principles which ensures fair competition amongst all economic entities.

Regarding competitive behaviours, the Commercial Law 2005 is quite consistent with the Competition Law, in that it prohibits all unfair competition practices. Specifically, Section 5, Article 100 and Sections 6, 7 and 9, Article 109 of the Commercial Law 2005 prohibit all unfair sales promotion and advertising practices. The Commercial Law also refers the handling of these practices to the Competition Law.<sup>123</sup>

### **3.4. *Laws and Regulations on Prices***

The regulation over prices has already been mentioned partly above during the discussion of the Law on Medicines 2005 and its implementation regulations. Besides, the regulation over prices in Vietnam is also prescribed by the Ordinance on Prices (No. 40/2002/PL-UBTVQH10 issued on April 26, 2002) issued by the President of Vietnam in his Order No. 10/2002/L-CTN on May 8, 2002. In addition, the regulation over pharmaceutical prices is also prescribed in details by Decree No. 120/2004/ND-CP issued by the Government on May 12, 2004, on the administration of the prices of medicines used on human beings.

The regulation over prices, in accordance with the Ordinance on Prices, is based on the same set of principles as the Law on Medicines 2005, which means that enterprises have full autonomy in pricing and compete over prices, but in compliance with the laws. In addition, the state would use appropriate measures to stabilise prices in order to protect the legitimate interests of businesses, consumers as well as the state.<sup>124</sup> On that basis, the state administers the prices of all important assets and natural resources, the prices of those products and services which are important to the welfare of the people and the national economy or those products and services supplied by monopolies by means of such measures as price estimation, price negotiation, price check, control over monopolistic prices, prohibitions on predatory pricing, requirement on public listing of prices, promulgation of legal normative documents on prices, collection of information, forecasting market trends, as well as dispute settlement. Accordingly, medicine is an important product for the welfare of the people and the national economy, hence subject to the administration and regulation by the state.<sup>125</sup> Besides, in case

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<sup>121</sup> Commercial Law 2005, Article 323.

<sup>122</sup> Commercial Law 2005, Article 10.

<sup>123</sup> See Article 28 and 29(10), and 32 of the Decree No. 06/2008/ND-CP issued on January 16, 2008 by the Government on administrative fines applicable for commercial offences.

<sup>124</sup> Ordinance on Prices (No. 40/2002/PI-UBTVQH10 dated April 26, 2002), Article 2.

<sup>125</sup> Governmental Decree No. 170/2003/ND-CP issued on December 25, 2003, guiding the implementation of some provisions of the Ordinance on Prices – Article 2(1), amended by Article 2(1), Governmental Decree No. 75/2008/ND-CP dated June 9, 2008, amending some provisions of the Decree No. 170/2003/ND-CP. Accordingly, medicines for human use, which are listed as essential medicines to be used at hospitals and

there are signs of abuse of monopoly or price-fixing agreements, relevant state agencies can take necessary measures. All businesses and individuals, when receiving the orders from the relevant state agencies in such cases, have the obligation to provide in a timely manner all the necessary information and data regarding the costs of production, circulation, the prices of monopolised products/services to these state agencies.<sup>126</sup> State agencies shall have the authority to give cease and desist orders; ask the parties to the price-fixing agreements to set the prices at the level prevailing before the agreements come into practice; declare a specific price;<sup>127</sup> or impose administrative fines or criminal prosecution, or damage compensation.<sup>128</sup>

These regulations are deficient in a very important aspect, which is that they only look at the process of setting monopolistic prices as the accumulation of all types of costs (production and circulation) as well as the prices set by the products/services providers. They have not taken into consideration the competitive conditions and the structure of the markets, which play quite important roles in the formation of monopolistic pricing.<sup>129</sup> This is an important aspect in the pharmaceutical distribution sector in Vietnam. This leads to quite short-term and case-specific remedies being applied, which does not help to solve the problems at hand in an exhaustive manner. Even after revision,<sup>130</sup> these regulations only touch slightly upon the issue of “elements affecting pricing” (including price estimation methodologies, the conditions for circulating products, financial statements and other documents) and not market conditions or special traces of the dealings.

Besides, as per Article 8(1c) of Decree No. 170/2003/ND-CP, which guides the implementation of the Ordinance on Prices, the Minister of Finance would have the authority to decide the retail prices for some essential medicines for use on human beings. This has been amended by Article 5 of Decree No. 75/2008/ND-CP. Accordingly, the Minister of Health, in collaboration with the Ministers of Finance, Industry and Trade and relevant state agencies, would provide detailed guidance on the estimation and listing of maximum prices for the medicines covered by the state budget and social welfare. Therefore, the regulation over prices in this aspect has overlooked several important stages of the distribution system, for example, import prices or general retail prices, which are often abused by monopolies.

As per Article 3(4b) of the Decree No. 75/2008/ND-CP, price-stabilising measures would be applied when the enterprises involved have engaged in anti-competitive agreements, abuses

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clinics, as prescribed by the Ministry of Health, would be subject to state administration in terms of pricing. Besides, Article 7 of Decree No. 75/2008/ND-CP, amending Article 7 of Decree No. 170/2003/ND-CP, stipulates that medicines for human use covered by state budget and medical insurance schemes would also be subject to state administration, in terms of pricing. This authority to decide the prices is reserved for the Minister of Health, in collaboration with the Ministry of Finance and the Ministry of Industry and Trade, as prescribed in Article 5 of Decree No. 75/2008/ND-CP.

<sup>126</sup> Ordinance on Prices, Article 20.

<sup>127</sup> Ordinance on Prices, Article 21.

<sup>128</sup> Ordinance on Prices, Article 38.

<sup>129</sup> Governmental Decree No. 170/2003/ND-CP dated December 25, 2003, guiding the implementation of some provisions of the Ordinance on Prices, Article 21(2).

<sup>130</sup> Governmental Decree No. 75/2008/ND-CP, Article 10, adding sub-sections a), b), and c) to Article 22 of Decree No. 170/2003/ND-CP.

of dominant positions and monopolies, as per the provisions of the Competition Law, resulting in damages to the consumers or other enterprises. Price-fixing agreements, as defined by Article 20 of Decree No. 170/2003/ND-CP, are the agreements between enterprises or individuals to set the prices at a certain level in order to control the market or expand their market shares beyond the threshold stipulated by law, harming the interests of other enterprises, the consumers and the state. These include practices such as:

- (a) “Agreements between enterprises and individuals to fix prices, control prices, change the prices of products and services in order to restrict competition, harming the legitimate interests of other enterprises, individuals or consumers;
- (b) At the same point of time, some enterprises and individuals suddenly selling/buying the same products/services at the same price levels (identical or similar);
- (c) Agreements between enterprises and individuals to induce scarcity by restricting the production, distribution, transportation and supply of products and services; destroying the products; or price speculation;
- (d) Agreements between enterprises and individuals to set similar conditions for buying/selling or after-sales conditions, affecting the prices of products and services; and
- (e) Agreements between enterprises and individuals to change the selling/buying prices of products and services in order to exclude or force other enterprises to join the agreement or become of a branch of one of the parties.”

These regulations are quite detailed and specific, which allow the imposing of fines and remedies on the monopolistic practices to increase the prices of medicines excessively. However, they are deficient in two important aspects. Firstly, these monopolistic practices would be handled by the Ministry of Finance and provincial departments of finance.<sup>131</sup> This would lead to overlapping of authority with the competition authorities. Secondly, similarly as the Competition Law, these regulations do not have extra-territorial jurisdiction, which means they cannot be applied to foreign entities being based outside Vietnam, but supplying medicines to Vietnamese companies via imports, whereas these entities should be considered a part of the pharmaceutical distribution chain.<sup>132</sup>

There is a small conflict regarding the territorial jurisdictional application between the implementation regulations of the Competition Law and those of the Ordinance on Prices, i.e., the Government’s Decree No. 120/2004/ND-CP on May 12, 2004, on the administration of prices of medicines used on human beings; and the Inter-ministerial Circular between the Ministry of Health, the Ministry of Finance, the Ministry of Industry and Trade No. 11/2007/TTLT-BYT-BTC-BCT on August 31, 2007, which guides the state administration of

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<sup>131</sup> Decree No. 170/2003/ND-CP, Article 21.

<sup>132</sup> Circular No. 06/2006/TT-BYT issued on May 16, 2006, by the Ministry of Health on the exportation and importation of medicines and cosmetics – Article 3(7).



prices of medicines used on human beings. Both the latter provide that their subjects of application include domestic and foreign enterprises and individuals who have obtained permits for manufacturing, importing and trading (in wholesale or retail) medicines used on human beings, as well as all the hospitals and clinics in Vietnam.

Decree No. 120/2004/ND-CP also provides for the administration of medicine prices on the same principles as the Ordinance on Prices and its implementation regulation (as mentioned above) and the Law on Medicines 2005 do. Accordingly, the administration of medicine prices would be classified into three categories: the group of medicine prices ordered and set by the state (in this case the prices would be set by the Ministry of Health or the provincial people's committees)<sup>133</sup>; the group of medicine prices bought by hospitals and clinics to provide for those using free-of-charge treatment, those whose treatments are covered by social welfare, those whose part of the treatments are free-of-charge, and those whose treatments are covered by medical insurance (in this case, the bidding prices as well as the bid-winning prices have to be lower than the common retail prices of the same types of medicines prevailing on the market at that point of time)<sup>134</sup>; and the group of medicine prices not belonging to the above-mentioned two groups and allowed for circulation in the markets in Vietnam (in this case the prices are set by the enterprises or the individuals)<sup>135</sup>. For the third group:

- The manufacturers have to base their marketing prices on the production costs and contributions to the state budget, but the prices *cannot be higher than the prices for the same types of medicines prevailing in those countries which are at the same level of development of the health sector and commercial conditions as Vietnam*. The manufacturers have to register their wholesale prices when registering the products with the relevant State agencies.
- The importers have to base their marketing prices on the import costs and contributions to the state budget, but the prices *have to be fully registered together with the prices for the same types of medicines prevailing in some countries in the region, as well as the expected retail prices when registering medicines manufactured elsewhere rather than Vietnam* (including those importers who have not registered in Vietnam) with the relevant state agencies.
- Pharmaceutical wholesalers would *base their marketing prices on the prices at which the medicines have been purchased and which are written on the receipts issued by the Ministry of Finance and the wholesale surplus, as stipulated by the Ministry of Finance*. These enterprises would have to comply fully with the regulations on the use of tax receipts and supporting documents for all the products put into circulation, as stipulated by the relevant state agencies.

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<sup>133</sup> Decree No. 120/2004/ND-CP, Article 7.

<sup>134</sup> Decree No. 120/2004/ND-CP, Article 8.

<sup>135</sup> Decree No. 120/2004/ND-CP, Article 9.

- Pharmaceutical retailers would base their marketing prices *on the prices at which the medicines have been purchased and which are written on the receipts issued by the Ministry of Finance and the retail surplus, as stipulated by the Ministry of Finance.* These enterprises would have to comply fully with the regulations on the use of tax receipts and supporting documents for all the products put into circulation, as stipulated by the relevant state agencies. They can only sell the medicines on the basis of prescriptions by doctors, unless in the case of medicines which could be sold over the counter, as stipulated by the Ministry of Health.<sup>136</sup>

Besides, Decree No. 12/2004/ND-CP also provides for such issues as stabilisation of medicine prices (at Article 10), public listing of wholesale prices (at Article 11) and retail prices (at Article 12) and the regular checks by state agencies and the handling of violations (at Articles 13 and 14, applying such administrative measures as monetary fines, revocation of trading and professional permits, etc). The Inter-ministerial Circular No. 11/2007/TTLT-BYT-BTC-BCT provides in more details for the registration of medicine prices (which include import prices, wholesale prices and retail prices), public listing of medicine prices (at the site of trading, hospitals and clinics), besides the handling of violations. It also delineates the division of responsibilities and provides for co-operation between the relevant state agencies.

However, as mentioned above, the regulations are still geared towards making the pricing in the markets more transparent. They have not been able to solve the roots of the problems, which lead to the current excessive level of medicine prices in the market (which are competitive conditions in the market). Besides, the administrative measures to be applied (to be specific, monetary fines) are still of very low levels and do not have deterrent and remedying effects. For example:

“Monetary fines ranging from 500,000 VND to 2,000,000 VND would be imposed on those violations regarding registration of prices where the quantity in subject is less than 10 percent of the total number of medicines in the enterprises.

Monetary fines ranging from 2,000,000 VND to 5,000,000 VND would be imposed on those violations regarding registration of prices where the quantity in subject is more than 10 percent of the total number of medicines in the enterprises. Remedies such as forced application of the orders of the relevant state agencies would also be imposed.

Monetary fines ranging from 5,000,000 VND to 10,000,000 VND would be imposed on the violations regarding incorrect imposition of pricing framework and surplus set by the relevant state agencies. Additional fines include revocation of trading and professional permits for a definite term for those violations which happen only once a year; and revocation of trading and professional permits for an indefinite term for those violations which happen twice a year.

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<sup>136</sup> Decree No. 120/2004/ND-CP, Article 9.

Monetary fines ranging from 10,000,000 VND to 20,000,000 VND would be imposed on the violations regarding monopolistic price-fixing. Additional fines include revocation of trading and professional permits for a definite or indefinite term for those violations which happen twice or more than twice a year.”<sup>137</sup>

### **3.5. Law on Intellectual Property Rights**

According to Vietnamese laws, enterprises dealing in the manufacturing, importing of medicines and cosmetics and enterprises authorising or being authorised to import medicines and cosmetics would be held liable for any matters regarding intellectual property rights (IPRs) of the medicines and cosmetics manufactured, exported, imported and authorised for imports and exports by themselves.<sup>138</sup>

IPRs (patents, trademarks and trade names) of medicines manufactured and circulated in Vietnam are protected in accordance with the Law on IPRs No. 50/2005/QH11. Accordingly, the industrial property rights over patents, industrial designs and layouts, trademarks and geographical indications are established on the basis of written approval by relevant state agencies, as per the registration rules set by the IPRs Law or recognition by international treaties of which Vietnam is a member. For famous trademarks, possession of rights is established on the basis of usage, not the basis of registration.<sup>139</sup> The term for protection over patent rights is 20 years for industrial designs and five years for layouts (which can be extended for two consecutive terms, each of which is for five years) and 10 years for registered trademarks (which can be extended for many consecutive terms, each of which is for 10 years)<sup>140</sup>. Besides, upon becoming a member of the WTO, Vietnam has committed to protecting clinical testing data in all drug registrations for five years. In addition, the owners of the patents have the obligation to manufacture (or put into manufacturing) the protected products or applying the manufacturing process protected for the purpose of national defence, security, prevention and treatment of diseases for the public or other essential needs of the society. When such circumstances arise and the owners of the patent rights do not fulfil the obligation, the relevant state agencies can authorise compulsory licensing.<sup>141</sup> Owners of trademarks also have the obligations to use the subject trademarks continuously. In cases trademarks are not used continuously for five years, the owners would no longer have possession over the rights conferred by the trademarks.

Besides these matters of general nature, there are three issues of utmost importance, when it comes to protection of IPRs in the manufacturing and trading of medicines: (i) drug registration, in relation to IPRs, (ii) parallel imports of medicines, and (iii) compulsory licensing.

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<sup>137</sup> Decree No. 120/2004/ND-CP, Article 14.

<sup>138</sup> Circular No. 06/2006/TT-BYT issued on May 16, 2006 by the Ministry of Health on the exportation and importation of medicines and cosmetics – Article 4(4).

<sup>139</sup> Law No. 50/2005/QH11 on Intellectual Property Rights – Article 6.

<sup>140</sup> Law No. 50/2005/QH11 on Intellectual Property Rights – Article 93.

<sup>141</sup> Law No. 50/2005/QH11 on Intellectual Property Rights – Article 136.

Previously, according to the Regulations on Drug Registration (issued together with Decision No. 3121/2001/QĐ-BYT), for patented medicines, the registration dossiers have to contain documentary proof that there is no similarity or certificate of patent issued by the Department of Industrial Property Rights. When required, the registering enterprises would have to check the overall trademarks and industrial designs at the Department of Industrial Property Rights (under the Ministry of Science, Technology and Environment). For foreign drugs already authorised for circulation, when required, the enterprises would have to check the trademarks and designs at the Department.<sup>142</sup> However, recently, the Department of Industrial Property Rights has decided to stop the checking of industrial property rights, including patent, which makes it difficult for enterprises to prove to the DAV that registering the drug does not violate the patent of any other medicines already in circulation in Vietnam. In order to overcome this problem, the DAV has asked all the enterprises which hold patent rights over medicines in Vietnam to provide the DAV with information and documents which prove that they are the legitimate owner of the patent rights, the current state of protection, the level of protection over the medicines so that the DAV can inform other enterprises which manufacture and register medicines of the same active elements in Vietnam. Upon receipt of this information, the DAV would examine and then upload the information on the DAV's website for access by all pharmaceutical companies in Vietnam. For those manufacturing and registering their medicines in Vietnam, the DAV asks them to proactively check for information on the website of the Department of Industrial Property Rights as well as the website of the DAV regarding the active elements of the medicines planned for manufacturing and circulating in Vietnam, in order to avoid disputes over IPRs after a registration number has been issued. When submitting a registration dossier for a medicine which contains an active element being protected in Vietnam, the registering enterprise has to include a letter of commitment pledging that it is not violating the patent rights of the relevant medicines and that it would be held solely liable in case of disputes and complaints. The DAV would provide its decision on the basis of the opinions expressed by relevant State agencies on IPRs.<sup>143</sup>

Regarding compulsory licensing, the IPRs Law provides for certain circumstances in which the state can authorise compulsory licensing, which include:

- a) When the patents must be used for public, non-commercial use, for the sake of national defence, security, prevention and treatment of diseases for the public and other essential needs of the society;
- b) When the patent owners do not fulfil the obligations of utilising the patents, as prescribed by the Law, after four years from the day of submission of registration dossier for patent and after three years from the day of issuance of Certificate of Patent;

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<sup>142</sup> Regulations on the Drug Registration, Article 4.

<sup>143</sup> In accordance with the Official Letter No. 3734/QLĐ-DK of the DAV – Ministry of Health guiding the implementation of the Regulations on Drug Registration with regards to intellectual property rights, dated May 2, 2008.

- c) When those who would like to use the patent(s) cannot reach a licensing agreement with the patent owners after a reasonable time of negotiation on reasonable prices and terms; and
- d) When patent owners engage in anti-competitive practices prohibited by the Competition Law.<sup>144</sup>

Accordingly, compulsory licensing could be imposed in cases of national defence, security, prevention and treatment of diseases for the public and other essential needs of the society (especially regarding essential medicines or epidemics) and in cases where patent owners engage in anti-competitive practices prohibited by the Competition Law.

Finally, in order to ensure sufficient supply of medicines and stabilise the markets, the Ministry of Health has decided to allow parallel imports of medicines into Vietnam.<sup>145</sup>

Parallel imports of medicines means the importing of patented medicines which have been registered in Vietnam from other countries where the prices are lower. Specifically:

- (i) It is possible to import patented medicines which have been registered in Vietnam from various manufacturers of the same company or group. These medicines could be supplied by the manufacturer or another supplier. For example: If both manufacturers A & B of the same company or group produce Product S. Product S of Manufacturer A has been registered in Vietnam and is being sold in the Vietnam market at Price G1. Product S of Manufacturer B has not been registered in Vietnam and is being sold elsewhere outside Vietnam at Price G2. If  $G2 < G1$ , a Vietnamese importer can buy Product S from elsewhere outside Vietnam and sell in Vietnam at Price G3 which is lower than G1.
- (ii) It is possible to import patented medicines which have been registered in Vietnam by the same manufacturer of the same country of manufacturing origin from supplier outside the country of manufacturing origin. For example: Manufacturer X produces Product S, which has been registered in Vietnam and is being sold in the Vietnam market at Price G1. Product S of Manufacturer X has also been sold into Country A at Price G2. If  $G2 < G1$ , a Vietnamese importer can buy Product S from Country A and sell in Vietnam at Price G3 which is lower than G1.

Enterprises have to fulfil certain conditions to be able to undertake parallel imports of medicines, which include: (i) the foreign suppliers have to be a legitimate pharmaceutical business and can ensure the quality of the medicines imported into Vietnam; (ii) the Vietnam

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<sup>144</sup> Law No. 50/2005/QH11 on Intellectual Property Rights – Article 145.

<sup>145</sup> See the Regulations on Parallel Imports of Medicines for Human Use (issued together with Decision No. 1906/2004/QĐ-BYT dated May 28, 2004 by the Minister of Health) available at [http://www.dncustoms.gov.vn/Data/CV\\_nganh\\_khac/QD\\_kem--1906-2004-QĐ-BYT-28-05-04.htm](http://www.dncustoms.gov.vn/Data/CV_nganh_khac/QD_kem--1906-2004-QĐ-BYT-28-05-04.htm)

importers can ensure the quality of the medicines being imported as parallel imports into Vietnam; and (iii) the wholesale and retail prices set by the parallel importers have to be lower than the wholesale and retail prices of the patented medicines currently being set at an excessive level in Vietnam.

According to some experts, these regulations on parallel imports are still deficient in some aspects and these deficiencies might be abused. They should be revised in order to ensure competition in the market for pharmaceutical distribution. For example, Article 1 of the Regulations on Parallel Imports of Medicines for use on human beings (issued together with Decision No. 1906/2004/QĐ-BYT by the Minister of Health on May 28, 2004) states that:

“Medicines having the same name, same active elements, same *dosage* and same formula as patented medicines already registered with the Ministry of Health in Vietnam, but are *not being supplied by manufacturer/supplier, or are being insufficiently supplied, or being supplied at an excessive level as compared to the retail prices of the same medicines in the country of manufacturing origin, or other countries which are at the same level of economic development as Vietnam.*”

Whereas, Section 2, Article 23 of the Law on Medicines provides that pharmaceutical wholesalers have to “*maintain in whole the cover of the medicines and cannot change the cover and label of the medicines.* In case of changes of the label or cover of registered products, the enterprises have to be authorised by the manufacturers and permitted in writing by the Ministry of Health.”

The objective of allowing parallel imports is to ensure the competitiveness of the pharmaceutical distribution sector. However, such regulations can be abused by multinational pharmaceutical corporations and sole distributors of these corporations in Vietnam. For example, Product X can contain active element A and a dosage of 100mg, 200mg and 300mg. If Product X is registered in Vietnam only with a dosage of 300mg of active element A, it would be difficult for parallel importers to bring Product X with dosages of 100mg or 200mg of active element A into the Vietnam market. The multinational pharmaceutical corporations and their sole distributors in Vietnam may agree to register Product X under different trade names or cover in the Vietnam market. If the covers and labels cannot be changed, parallel imports would be illegal for circulation in the Vietnam markets.

The European experience shows that parallel import is the sole responsibility of the parallel importers. Therefore, covers can be altered. Accordingly, Vietnam might want to consider amending these regulations to be more suited to the objectives set out at the beginning.

### **3.6. *Regulations on Taxation***

After becoming a member of the WTO, Vietnam is committed to reducing the import tariffs of 47 important products, including vaccines (18 products) and vitamin (four products) from 10-15 percent to 3-13 percent, with the average reduction of three percent. The average tariff would be 2.5 percent after five years from the day Vietnam becomes a full member of the

WTO. Reduction of import tariff may become a huge challenge for domestic manufacturers in competing with foreign products.

The tariff for imported ingredients for medicine manufacturing would be reduced to zero percent, which helps to reduce costs. But, this would also adversely affect some manufacturers of pharmaceutical ingredients in Vietnam.

### **3.7. Regulations on Consumer Protection**

In 1999, the Standing Committee of the National Assembly of Vietnam promulgated the Ordinance on the Protection of Consumer Interests, which provides for the rights and obligations of consumers and business entities as well as complaint and denunciation rights of consumers. Furthermore, Decree No. 69/2001/ND-CP was issued by the Government of Vietnam for detailed guidelines on the implementation of the Ordinance, then Decree No. 29/2004/ND-CP authorised the Ministry of Trade of Vietnam to take charge of state management of consumer protection issues, as stipulated by law. In addition, Vietnamese consumers are protected by regulations in legal documents such as the Civil Code, the Criminal Code, the Commercial Law, the Law on Public Health Protection, the Law on Environmental Protection, the Ordinance on Goods Quality, the Ordinance on Measurement, the Ordinance on Food Hygiene and Safety, etc. Most recently, the legal corridor for consumer protection has been improved with the provisions of the Competition Law 2004 and Decree No.55/2008/ND-CP, which has superseding power over Decree No. 69/2001 for detailed guidelines on the Ordinance 1999.

According to the Ordinance 1999, it is prohibited to manufacture or trade in fake or prohibited goods; manufacture, trade in or consume goods which may seriously pollute the environment, endanger human life or contravene national traditions; undertake incorrect and misleading advertising and information; and undertake other deceptions to harm consumers.<sup>146</sup> This can be applied to all areas of trade, including medicines. Specifically, Article 26 of the Ordinance 1999 clearly states that, “Everybody who carries out the production/ business of prohibited goods, *fake drugs*, fake foods and other fake goods of foods which do not meet the safety and hygiene standards; who carries out the production/ business/ distribution of goods and services which *cause serious damage to the environment, to the life, health of the people* or which are against the fine custom; who *disseminates untrue information, advertisement*; who deceives in measuring, or who has other acts that breach the law of the protection of the interests of the consumer, shall, depending on the seriousness and the extent of the breach, be subject to discipline, administrative fine or prosecution of criminal liabilities and be responsible for paying compensation to the consumer in case of causing damage to consumer, in accordance with the law.” Accordingly, with regard to the pharmaceutical distribution sector, those prohibited practices which may harm the consumers include the manufacturing of fake drugs, endangering the life and health of the people and disseminating of untrue information and advertisements. Some examples would be provided

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<sup>146</sup> The 1999 Ordinance, Article 7.

in the annexes of the report.

Besides, Decree No. 55/2008/ND-CP also provides for obligations on enterprises and individuals to “publicly list the prices of all goods and services at their sites of business”, similar to the obligations of public listing of medicine prices.<sup>147</sup> The authority to check and handle violations in the pharmaceutical sector is assigned to the Ministry of Health.<sup>148</sup>

In summary, until recently, Vietnam has been developing quite a comprehensive legal and regulatory framework to regulate the pharmaceutical sector, competition therein and elsewhere, as well as special problems pertaining to the distribution of medicines in the country, the pricing of medicines or parallel imports. However, since the country has only been transformed into a market economy very recently and the liberalisation process has just been started, competition and economic regulation remain new topics. Gaps and deficiencies are, therefore, unavoidable. The fast development of the pharmaceutical industry, thanks to the high level of innovation therein, as well as the sophistication of competitive practices and business practices, requires us to keep a constant watch to be able to complete this legal and regulatory framework. The next section of the report will provide an overview of the real competitive practices in the market for pharmaceutical distribution in Vietnam; examine anti-competitive practices and unfair competition practices therein; and on that basis provide some recommendations to help complete the legal and regulatory framework.

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<sup>147</sup> Decree No. 55/2008/ND-CP – Article 6.

<sup>148</sup> Decree No. 55/2008/ND-CP – Article 26(2a).



## **Chapter III**

### **COMPETITION IN THE PHARMACEUTICAL DISTRIBUTION MARKET IN VIETNAM**

#### **1. The Characteristics and Status of Competition in the Pharmaceutical Distribution Market in Vietnam**

In the world, the pharmaceutical distribution systems are often separated from manufacturing. However, in Vietnam, this division is often blurred, since most of the manufacturers often have their own distribution networks as well.

From the number of pharmaceutical wholesalers and retailers provided in Part I/1.1 on the market structure prevailing in the industry, one can infer that the level of market participation in Vietnam is quite high. Besides, from the market share figures, calculated on the basis of turnover, also from Part I, the pharmaceutical market in Vietnam registers quite a low level of concentration. Therefore, basically, we can say that the market is quite competitive.

In order to recognise breaches of the Competition Law (specifically anti-competitive practices and unfair competition practices), we decide first to examine the competitive behaviours of all players in the market or the various characteristics of the competitive process therein.

##### ***1.1. Vertical Agreements***

According to competition policy theory, vertical agreements involve businesses operating at successive stages of the production process. In principle, vertical agreements can be undertaken at any stage along the whole process of manufacturing and distributing goods and products.

In the pharmaceutical distribution system in Vietnam, vertical agreements can be between manufacturers and distributors or between importers and distributors, in which one enterprise, say A, can be the in both types of agreements.

##### ***a) Manufacturer-2-Distributor Agreements***

According to the statistics provided by the DAV, there are currently 171 pharmaceutical manufacturers in Vietnam (including manufacturers of oriental medicines), out of which 77 satisfy the GMP standards, meeting around 52.86 percent of the total demand for medicines in the whole country.<sup>149</sup>

To reach the consumers, domestically-produced medicines would have to go through the following channels: direct distribution by manufacturers, distribution via private enterprises to pharmacies and small medical stores, etc. Out of this, the most important distribution

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<sup>149</sup> Report on Pharmaceutical Industry Development: Solutions to balance supply-demand and stabilize the pharmaceutical markets in Vietnam at the Pharmaceutical Conference 2008 organised by the DAV.

channel remains via hospitals and pharmacies. According to the statistics provided by IMS, in 2005, 61 percent of all the medicines used in hospitals and 71 percent of the medicines sold in pharmacies are domestically produced. Therefore, one can say that the major players in this type of vertical agreement/relationship are Vietnamese enterprises, without any foreign players participating therein (with the exception of manufacturing joint-ventures).

Regarding the size, Vietnamese pharmaceutical manufacturers are mostly former SOEs of quite large scale, such as Hau Giang Pharma Co., Vinapharm, Domesco, Trapharco, etc. However, their number is small (only 71 in total), while distributors are mostly small and medium-sized enterprises,<sup>150</sup> accounting for only a small share of the market, but the number is large (800 companies in total).

As mentioned above, vertical agreements in the pharmaceutical industry are often in the distribution sector and Vietnamese pharmaceutical distributors are mostly SMEs. As per the Competition Law 2004, exemption would be given to those economic concentration cases where, after merging, the new entities are still of small and medium size. Therefore, with this size, Vietnamese pharmaceutical distributors would not become dominant or monopoly after undertaking any forms of combination. Meanwhile, vertical agreements are only potentially harmful from the perspective of the Competition Law, if one of the undertakings holds a dominant position in the market. This means there would be no risk involving vertical agreements between small manufacturers and distributors. Attention should be paid to the larger enterprises dominating these distribution channels instead.

#### ***b) Importers-2-Distributors Agreements***

According to the statistics given by the DAV in its report at the 2008 Pharmaceutical Industry Conference, domestically-produced medicines now can provide for around 52.86 percent of the total demand, while imported medicines account for 47.14 percent. The DAV also reported that, despite meeting 52.86 percent of the total demand, domestically-produced medicines only account for 27 therapeutic categories, which are also mainly normal formulations.<sup>151</sup> Therefore, imported medicines account for a large proportion of all distribution channels in Vietnam.

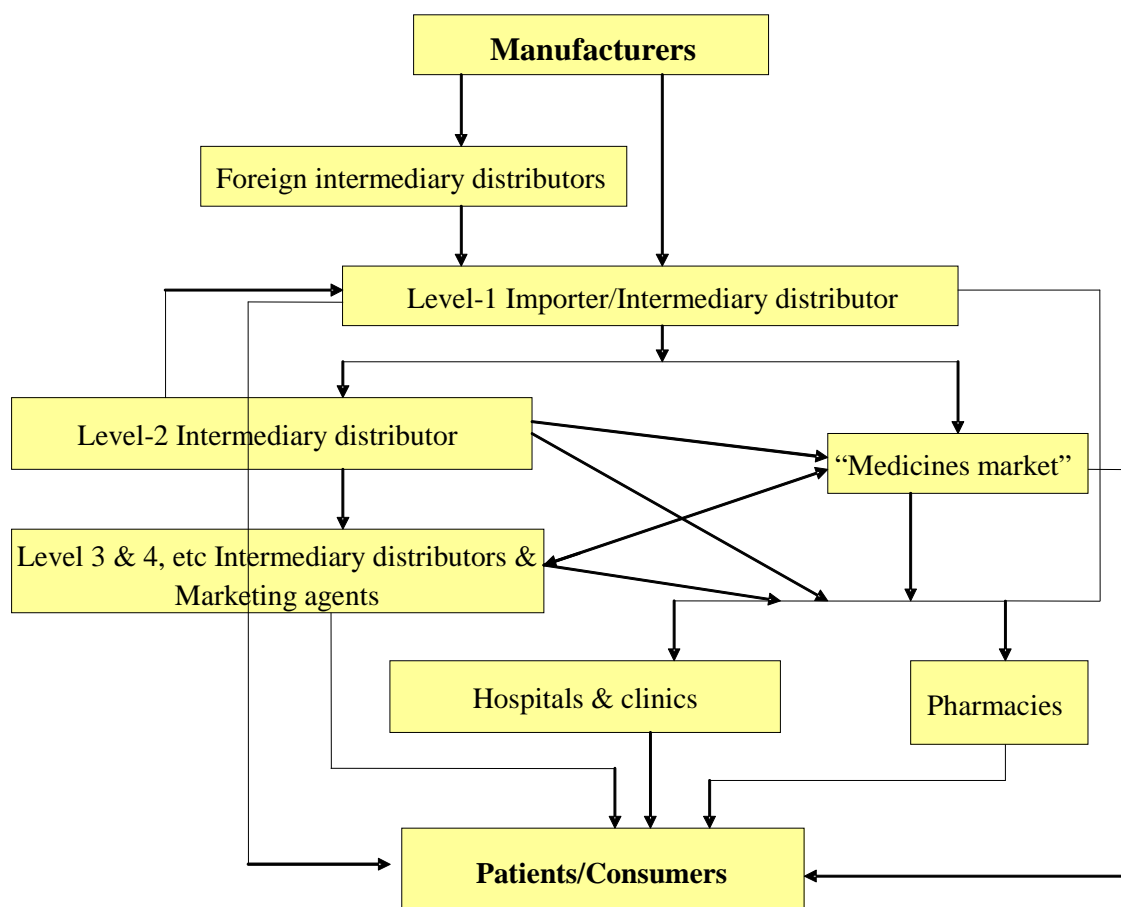
There are many types of players participating in the distribution channels for imported medicines, including foreign companies, representative offices, importing companies, distributing companies, enterprises providing storage facilities and other supporting services, private enterprises and pharmacies, etc. The distribution channels for imported medicines, therefore, are normally very complex and, hence, difficult to keep a check on, so far. (See Figure 4 below)

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<sup>150</sup> SMEs are those enterprises with legal capital below 10 billion VND and the number of staff members below 300.

<sup>151</sup> Normal formulations for treating common sicknesses and diseases in Vietnam: anti-infection, antibiotics, anti-fever and pain-killers, anti-steroid infections, vitamins and others.

Figure 4 – Distribution Channels for Imported Medicines in Vietnam

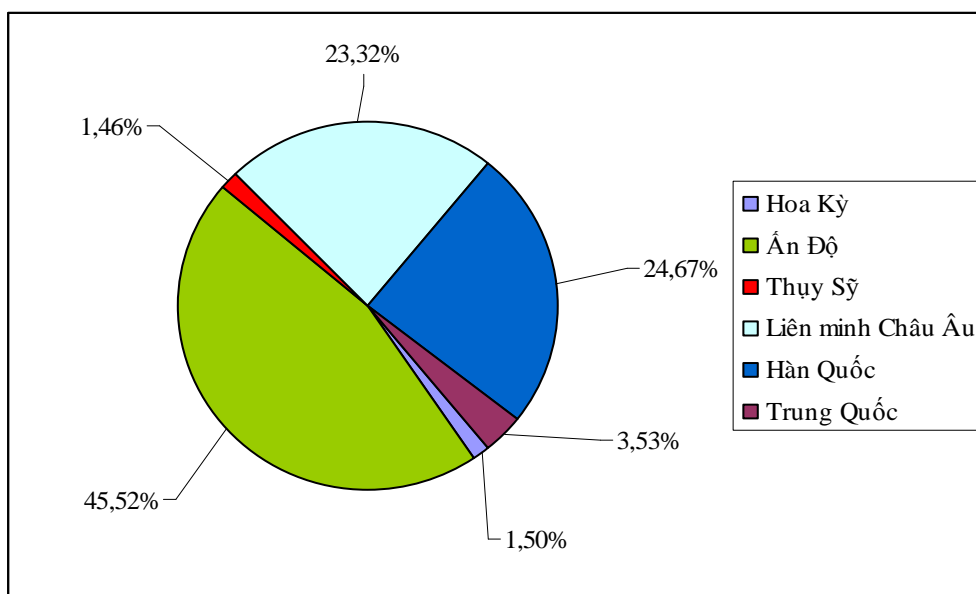


There are currently 72 enterprises with import licences for pharmaceutical products in the whole of Vietnam, of which 10 are large enterprises, accounting for around 76.5 percent of the total import value in the industry. However, holding the largest market shares are three companies, namely, Phytopharma, HCMC Pharma Co., and Vimedimex 2, accounting for 29.2 percent, 10.1 percent and 8.4 percent of the market, respectively.<sup>152</sup>

Regarding product composition, medicines imported into Vietnam are mainly from India, the European Union, the Republic of Korea, US, China and Switzerland, etc. Amongst all, medicines coming India, the European Union and the Republic of Korea account for 93.51 percent.

<sup>152</sup> Vietnam Pharmaceutical Industry Analysis – Vietcombank Securities 2008.

Figure 5 – Pharmaceutical Import Composition



Source: DAV – 2008 Pharmaceutical Industry Conference.

As per Vietnam law, FIEs and branches of foreign enterprises are not permitted to distribute medicines directly in Vietnam. Vietnam’s accession commitments to the WTO allow FIEs and branches of foreign enterprises to directly import medicines into Vietnam (from January 1, 2009), but not for direct distribution, only for re-sale to Vietnam enterprises with distribution licences.

As also mentioned in the Part on Market Structure, the forms taken by most FIEs participating in the Vietnam pharmaceutical distribution sector are representative offices or enterprises specialised in marketing and distributing medicines for one or more manufacturers. However, the level of involvement and influence exerted by these enterprises in the pharmaceutical distribution sector in Vietnam is very high. Specifically, even though they are only permitted to be the marketing agents for one or more manufacturers to Vietnamese enterprises with import licences and to enter into logistics<sup>153</sup> arrangements with these importers, they possess huge levels of market power, especially in negotiating the terms for importing medicines into Vietnam, thanks to their financial capacity, the relations and experiences of working with multinational pharmaceutical corporations in the world. They participate in all the stages of the distribution sector, directly and indirectly, by acting as intermediaries between Vietnamese importers and foreign manufacturers, registering products, marketing, transportation into Vietnam, storage, delivery and payment collection, etc. Therefore, if these enterprises participate in vertical agreements, there are bound to be harms to the competitive process. (More detailed discussion on this follows in subsequent parts).

<sup>153</sup> Logistic services include transportation, custom clearance, storage and warehouse, delivery, etc.

## **1.2. Horizontal Agreements**

Horizontal agreements are between competitors within the same trade, which might mean agreements between manufacturers with each other, between wholesalers, or between retailers of the same products/services. According to the Competition Law, only those in a horizontal relationship are true competitors.

In the pharmaceutical distribution sector in Vietnam, despite the clear provision of the Law on Medicines defining wholesalers and retailers, the relations between wholesalers with each other or between retailers with each other are very complex. Most of the pharmaceutical distributors in Vietnam can be both wholesalers and retailers at the same time.

Until 2007, the number of enterprises participating in the pharmaceutical distribution sector was very large (according to the statistics provided by the DAV):

- Limited liability companies, joint-stock companies and private companies: 897;
- Retailing medical stores: 29,541;
- Private pharmacies: 7,490;
- Retailing agents: 7,417;
- Medical stores within communal-level clinics: 7,948;
- Medical stores belonging to SOEs: 464; and
- Medical stores belong to equitized SOEs: 6,222.

According to the above statistics, theoretically, horizontal agreements can happen anywhere between limited liability companies, retailing medical stores or private pharmacies, etc. However, field surveys showed that there is almost no such agreement between competitors of the same forms that could potentially harm the competitive process; and most players often act quite independently of each other. On the other hand, the large number of and the small market shares (by turnover) held by such players mean that the combined market share of all parties to any such agreement would not be beyond 30 percent.

FIEs, as already mentioned several times, cannot participate directly in the pharmaceutical distribution sector in Vietnam. They can only provide logistics services such as marketing, storage, delivery, preservation, etc. Therefore, agreements between FIEs in the provision of such services would rarely happen in practice (as testified by representative offices of foreign pharmaceutical companies in Vietnam). This is understandable since, according to competitive practices in the world pharmaceutical market, horizontal agreements often happen between companies which have their own manufacturing and distribution systems.

## **2. Some Prevalent Anti-competitive Practices in the Pharmaceutical Distribution Sector in Vietnam**

This part will describe some practices which are potentially in breach of the Competition Law, as observed by the researchers during the field research process.

### **2.1. *Anti-competitive Practices***

#### **2.1.1. Agreements Restricting Competition**

Amongst the practices which might violate the Competition Law, practices that involve enterprises within the same relevant markets agreeing with each other so as to restrict competition in the markets are considered as serious breaches, which might distort or prevent the competitive process significantly. Agreements restricting competition might be *vertical* (i.e., between manufacturers or importers with wholesaler, or retailers) or *horizontal* (i.e., between importers with each other, wholesalers with each other or retailers with each other).

In the pharmaceutical distribution sector in Vietnam, one can easily recognise the agreements between intermediary companies and Vietnamese importers, representative offices, limited liability companies and domestic pharmaceutical companies, etc. They are potentially breaching the Competition Law by:

- *Fixing prices*: Even before the actual importation of medicines into Vietnam, distributors, intermediaries and representative offices of foreign companies have already agreed to “fix” prices. Foreign companies also set the wholesale and retail prices, sometimes reaching the level of 200-300 percent, as compared to the original prices (according to the 2007 Official Report on Medicine Prices). When being interviewed, all foreign enterprises say that medicine prices have been registered before importation into Vietnam and the wholesale and retail prices are set by Vietnamese importers and distributors on their own. However, when being interviewed, Vietnamese importers and distributors revealed that the prices are “set” by foreign companies. A noted evidence to this point is that the names of the distributors, the importers and the intermediary companies are all mentioned on the price quotation of Vietnamese enterprises.

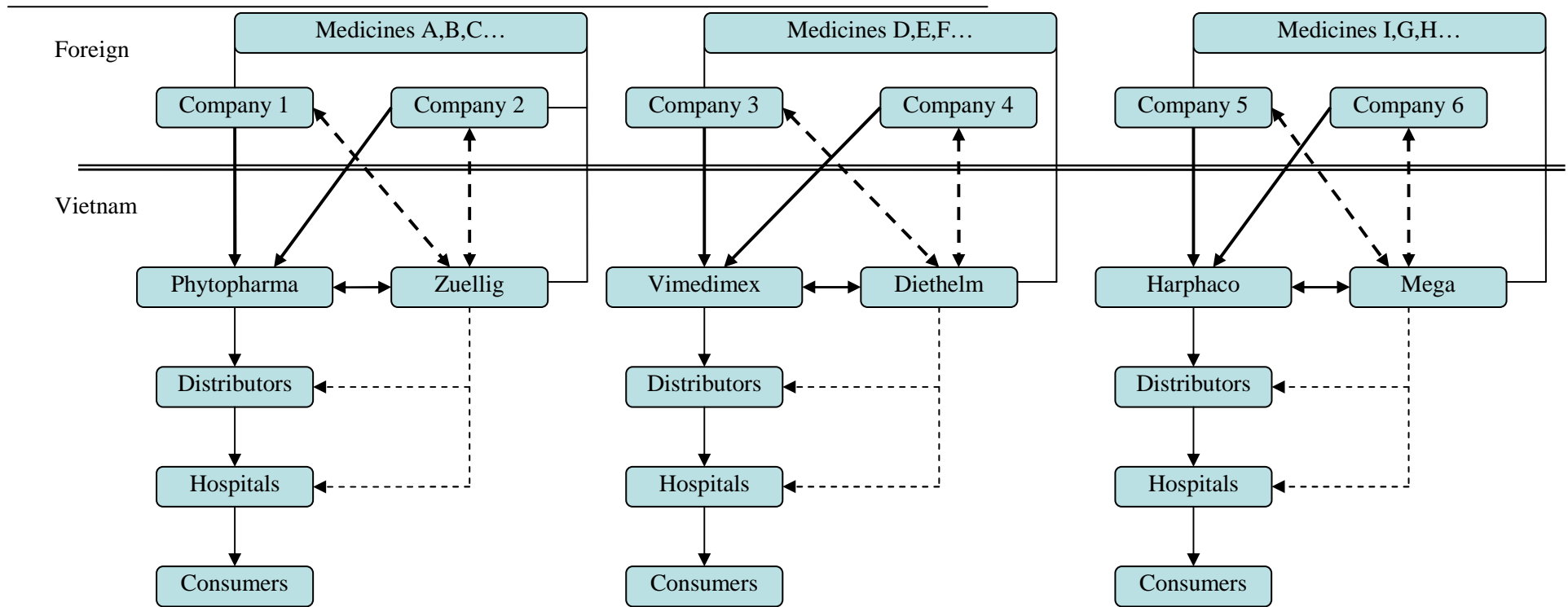
These “price-fixing” practices by enterprises are often due to the “pressures” exerted by the companies with market power (as will be discussed more below). However, Vietnamese importers and distributors also agree to such high prices without any objection. This might indicate their willingness and concerted action to “set” the prices. According to Article 14 of Decree No. 116/2005/ND-CP, “agreements that fix prices of products and services directly or indirectly mean concerted actions to set the prices”. Accordingly, these practices can be considered as one type of anti-competitive agreements. However, since these are vertical agreements between enterprises at different stages of the distribution system, the agreements need to be investigated and handled in conjunction with other factors (such as defining the

relevant markets in specific cases), in accordance with the Competition Law.

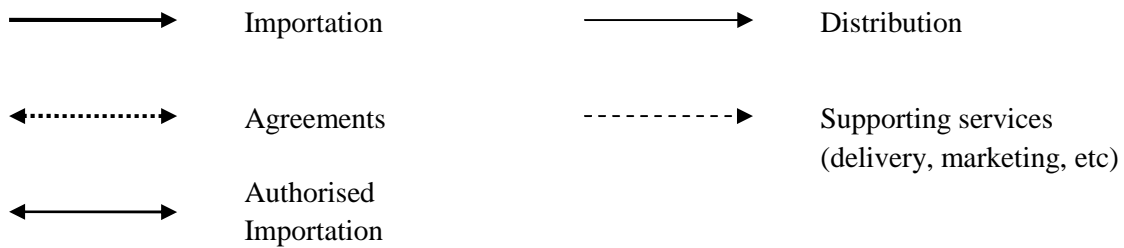
- *Dividing the markets:* See the figure below (Figure 6) for some typical systems for distributing medicines in Vietnam:

**Figure 6 – A Typical Pharmaceutical Distribution System**

*Using Competition Law to Regulate Anti-competitive Practices in the Pharmaceutical Distribution System in Vietnam*



Notes





It is quite clear that the market has been divided into several distribution networks, almost completely independent of each other from the intermediary companies specialised in marketing, of importers, distributors and the end consumers. In these networks, the role of the enterprises without direct import licenses in Vietnam, such as Zuellig Pharma, Diethelm, and Mega, etc., are to support the importers and the distributors at all stages of the distribution chain, such as finding supplies, registering products, transportation into Vietnam, storage and preservation to delivery and payment collection at wholesalers and retailers and even labelling. Meanwhile, the companies with import licences are only undertaking authorised imports for commissions. Besides, the medicines distributed via the three networks mentioned above are branded and special medicines are produced by large pharmaceutical manufacturers in the world. Therefore, it is easy to see that wholesale and retail prices of medicines in the Vietnam markets are also “set” by foreign enterprises (as mentioned above).

However, the division of the market amongst different distribution networks is entirely separate strategies of respective enterprises – avoiding competing with each other in the same market and not ‘agreeing’ with each other to divide the markets. This is what is termed as ‘tacit collusion’ in economic terms and it is not prohibited by law. The fact that these companies are distributing different categories or brands of products actually means that they are having marketing arrangements with parent foreign companies: Zuellig is acting on behalf of parent companies in Singapore, Diethelm is acting on behalf of parent companies in Europe and America, while Mega is acting on behalf of parent companies based in India and Thailand, etc. When asked whether they would like to import and distribute the products marketed by Zuellig or not, Vietnamese companies said that they do, but since they have already received products from Diethelm or Mega, Zuellig would not choose them as business partners any longer.

- *Supply-restricting or supply-controlling*: It has been a practice on the pharmaceutical distribution market that company A without import licences has to authorise its imports through company B. After a batch of products have been imported, company A would “collude” with company C to “exhaust” the batch, i.e., company C would buy 50 percent or 80 percent (depending on each case) of the batch, while the rest would be stored at company B as per the law. The remainder of the batch, after being “exhausted”, would be put on the market by a distributor for company A at normal prices. After the products have been almost sold out on the market, company A would inform company C, so that the latter would start selling the same products on the market with much higher prices. Since the products have almost been sold out, the wholesalers would have to buy from company C with the higher prices (while the wholesale prices, as reflected on the bills, would remain as before).

This practice of controlling supply is similar as the practice of restricting supply of

goods for “speculation”. This is a real practice on the market, however, the interviewers refused to disclose the identity of the enterprises which have engaged in such practices.

Besides, it is stipulated by the Competition Law that the practices are prohibited only if the parties to such agreements have a combined market share of beyond 50 percent of the relevant markets (for two enterprises). Therefore, it is a must to define the relevant markets before we can come to the conclusion whether this is a breach of the Law or not.

### *2.1.2. Abuses of Dominant Positions and Abuses of Monopoly*

The Competition Law stipulates that “enterprises shall be considered to hold the dominant position on the market if they have market shares of 30 percent or more in the relevant market or are capable of restricting competition considerably”. And, “an enterprise shall be considered to hold the monopoly position if there is no enterprise competing on the goods or services dealt in by such enterprise on the relevant market.” This means that enterprises having dominant positions or monopoly positions are those who possess market power.

#### Monopolistic Behaviours in Pharmaceutical Distribution

The report on “The Impacts of IPRs Mechanisms on Medicine Prices in Vietnam”, produced by the Vietnam Academy of Social Science (VASS), under an assignment of the Ministry of Health, and supported by the WHO in October 2006 identified five main reasons for the increases in medicine prices in Vietnam. One of these reasons is the monopolistic behaviours by pharmaceutical distributors.<sup>154</sup>

#### *A Monopolistic Behaviour Used to Happen in the Vietnam Pharmaceutical Distribution Sector: Monopoly over Drug Registration Number (‘Visa’ Number)*

As mentioned above, in order to be put into circulation, medicines have to be registered (issued a ‘visa’ number) at the DAV. If the registration number is given to the manufacturer(s), then all importers can import and distribute the product in subject. However, in Vietnam, this registration number can be given to a specific distributor as well, resulting in the fact that this distributor would have legal monopoly over the product in subject. Therefore, if a distributor holds the visa number of a specific product, the distributor becomes the monopoly enterprise selling that product. From the competition angle, when defining the relevant market, that distributor would be considered as holding a monopoly position.

The cause of this problem is Circular No. 06/2001/TT-BYT issued by the Ministry of Health on April 23, 2001, guiding the importation and exportation of medicines and cosmetics which directly affect human health in 2001-2005, which stipulates that, “Manufacturers can only supply medicines into Vietnam if those medicines have been registered in Vietnam”. This

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<sup>154</sup> The remaining four factors are: mechanisms for administering businesses, consumers’ patterns, lack of information and under-developed technology.

regulation has enabled certain enterprises holding registration numbers of medicines to become the sole suppliers of these medicines on the market. Therefore, other enterprises, even if having access to the manufacturers for the same products, cannot import and put these products in the market.

***This practice is no longer happening in the market. In the year 2004, Circular No. 06/2001/TT-BYT has been annulled.***

*At present, as prescribed by the Law on Medicines, both distributors and manufacturers can now register drugs, including foreign enterprises, after having been permitted by the Ministry of Health for operations in the pharmaceutical industry in Vietnam.*

In the pharmaceutical industry, there are three types of monopolies: over patented medicines, active elements and formulations. Therefore, theoretically, only manufacturers can have monopoly power. However, according to the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (Article 8 & 40), “*member States can take appropriate actions to prevent the owner and holder of IPRs to abuse the IPRs unreasonably to restrict trade or international technology transfer.*”<sup>155</sup>

In business, distributing monopolised products is a great advantage which is not prohibited by law. The Commercial law states that “Sole distributorship is the practice wherein a single enterprise or agent is given the right to sell, buy or supply certain goods and services within a specific geographical area.” However, the abuses of dominant positions and abuses of monopoly are prohibited by the Competition Law. Therefore, the monopolistic behaviours in pharmaceutical distribution in Vietnam, as analysed by the report on “The Impacts of IPRs Mechanisms on Medicine Prices in Vietnam”, need to be examined in order to be handled, if they are really in breach of the Law.

When scanning for such practices of abusing dominant positions or monopoly power as:

- Selling goods, providing services at prices lower than the aggregate costs in order to eliminate competitors;
- Imposing irrational buying or selling prices of goods or services or fixing minimum re-selling prices causing damage to customers;
- Restricting production, distribution of goods, services, limiting markets, preventing technical and technological development, causing damage to customers;
- Imposing dissimilar commercial conditions in similar transactions in order to create inequality in competition;

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<sup>155</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and patents in the pharmaceutical industry – World Trade Organisation (WTO) – Report – 9/2006.

- Imposing conditions on other enterprises to conclude goods or services purchase or sale contracts or forcing other enterprises to accept obligations which have no direct connection with the subject of such contracts;
- Preventing new competitors from entering the market;

Or such practice as

- Imposing unfavourable conditions on customers;
- Abusing the monopoly position to unilaterally modify or cancel the contracts already signed without plausible reasons.

We found that the following practices are undertaken by some foreign enterprises (such as Zuellig, Diethelm, Mega, etc) in pharmaceutical distribution: fixing the wholesale prices and retailing prices at excessive level harming the consumers; imposing conditions of delivery only upon full payment (extracting rents from customers), etc. However, in order to determine whether these enterprises are holding dominant positions or monopoly power or not, we need to follow the provisions of the Law.

#### About Zuellig Pharma

Zuellig Pharma (ZPV) is known as a monopoly distributor in Vietnam. Despite the law not allowing foreign enterprises to distribute medicines in Vietnam, ZPV has somehow managed to be “licensed” for distributing medicines in industrial zones in the country. In 2001, Zuellig Pharma Co. was established (as a branch of the regional company, which is headquartered in Singapore) with its headquarters based in Hanoi and a branch in HCMC.

From the day of establishment until its activities in respects of authorised importation and distribution of final imported products were suspended by the DAV, through its Official Letter No. 2570/CLD-HN dated March 4, 2004, effective from September 5, 2004, ZPV has been the sole provider of medicines having 180 active elements (out of 4,400 medicines having 900 active elements which have been registered in Vietnam). Most of these are patented products. Ninety-seven medicines are one single formulation (which is patented); and 18 medicines have 5 formulations (also patented); but they are all solely supplied by ZPV. (*Source: Inspectorate – Ministry of Health*).

When the licences of such companies are suspended, the consumers in Vietnam would be suffering the absence of patented formulations in the market.

#### *2.1.3. Economic Concentration*

From the perspective of the market size, the level of economic concentration is reflected in the level of entry and exit from the markets. From the perspective of the Competition Law, economic concentration means: (i) mergers of enterprises; (ii) acquisition of enterprises; (iii)

consolidation of enterprises; (iv) joint-ventures; and (v) other acts of economic concentration prescribed by Law.

Until now, there has been no case of economic concentration in Vietnam, which reach the market threshold for notification or prohibition by the Competition Law in the whole pharmaceutical industry, as well as in the pharmaceutical distribution sector in particular.

However, in the future, there might be trends of M&As in the pharmaceutical industry, due to the following reasons:

- (i) More competitive pressures are going to emerge. According to the statistics of the DAV, Ministry of Health, there are in total 180 manufacturers, 370 foreign enterprises supplying medicines, 800 enterprises trading in medicines and 41500 retailers. From January 1, 2009, when foreign companies are allowed to directly import medicines, competition between domestic companies and foreign companies is bound to be fiercer. If domestic companies do not improve their infrastructure and expand their markets, there is a clear possibility that they are going to lose their share of the markets to imported medicines. This is because, according to Vietnam's WTO accession commitments, after five years, the average tariff level would be reduced from five percent to 2.5 percent. Many domestic enterprises might have to merge or consolidate in order to be able to survive in this new context.
- (ii) As per the Law, from July 1, 2008, manufacturers not meeting the GMP standards, as recommended by the WHO, and importers and distributors not meeting the GSP standards would have to stop their manufacturing and importing activities. Until March 2008, only 78 out of a total 180 enterprises have met the GMP standards. According to the above schedule, many manufacturers would have to stop production and turn into sub-contractors for the other enterprises who have met the standards or merge and consolidate with other enterprises. However, this factor would not affect the market structure to a great extent, since the enterprises who have met the GMP standards account for around 95 percent of supply.
- (iii) In order to penetrate the Vietnam markets, instead of green-field investment (building factories, building the distribution networks, etc.), foreign pharmaceutical enterprises can buy the controlling stock of Vietnamese enterprises instead, including both listed companies and unlisted companies.

Therefore, in the next three years, many M&As might happen between domestic enterprises with each other or between foreign companies and domestic companies.<sup>156</sup>

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<sup>156</sup> Source: Report on Economic Concentration Activities in Vietnam – VCAD 2008.

## **2.2. *Unfair Competition Practices***

According to the Competition Law, unfair competition practices mean competition acts performed by enterprises in the process of doing business, which run counter to common standards of business ethics and cause damage or can cause damage to the state's interests and legitimate rights and interests of other enterprises or consumers.

Field research results showed that there are very few unfair competition practices happening in the pharmaceutical distribution sector in Vietnam (within the scope of this report), since acts such as infringements upon business secrets, spreading untrue rumours about other enterprises, disrupting other business, etc., are difficult to detect. Unfair competition practices in the pharmaceutical industries are mostly related to IPRs, such as misleading practices related to fake labels, fake designs or violations related to advertising and sales promotion (For more information, see Annex 5).

## **3. State Administration over Competition in the Pharmaceutical Distribution Sector**

### **3.1. *Relevant State Agencies***

#### **3.1.1. Competition Authorities**

In Vietnam, there are two competition authorities: (i) the Competition Administration Department (Ministry of Industry and Trade); and (ii) the Vietnam Competition Council.

#### **a) *Competition Administration Department***

Established under Decree No. 06/2006/ND-CP, the Competition Administration Department's (a subordinate agency under the Ministry of Industry and Trade) main tasks comprise of:

- Investigating competition cases relating to behaviours restricting competition;
- Investigating and settling competition cases relating to unfair competition behaviours and other behaviours in violation of the Competition Law;
- Controlling significant economic concentrations;
- Examining requests for exemption and submitting a proposal to the Minister of Trade or the Prime Minister for decision; and
- Creating and managing a database on dominant and monopoly undertakings, competition rules within associations and exemption procedures.

#### **b) *Vietnam Competition Council***

The VCC is an independent commission, established under Decree No. 05/2006/ND-CP, whose members are appointed by the Prime Minister upon recommendation of the Minister

of Industry and Trade. The VCC is composed of a Chairman, who is always the Vice-Minister of Industry and Trade, and at least eleven members from relevant line ministries and regulatory agencies. The members of VCC are experienced politicians who are not necessarily specialised in competition law.

The main tasks of VCC are to consider and decide cases relating to agreements in restraint of competition; consider and decide cases relating to practices constituting abuses of dominant position or of a monopoly position; and consider and decide cases of economic concentration.

### *3.1.2. Sectoral Regulator*

The regulator for the pharmaceutical sector is the Drug Administration of Vietnam (DAV), which is under the Ministry of Health. Its main function is to help the Minister of Health to undertake state administration and law enforcement and manage specialised activities in the pharmaceutical sector.

The functions and the responsibilities of the DAV are prescribed by Decision No. 2964/2004/QĐ-BYT issued by the Minister of Health on August 27, 2004.

### *3.2. State Administration over Competition Activities in the Sector*

The administration of competition in the market is the responsibility of both competition authorities and sector regulators. The competition authorities are responsible for ensuring a competitive environment for the whole economy, as well as the pharmaceutical industry, in particular, i.e., enforcing the Competition Law. In order to carry out this task, the competition authorities have to co-operate with the sectoral regulators on the basis of the division of the responsibilities, as per the functions of each agencies. This means that the competition authorities would control and forewarn about anti-competitive practices in order to ensure a competitive environment in each sector, investigate and handle anti-competitive practices in the market, etc. Meanwhile, the sectoral regulators (in this case the DAV) would be responsible for controlling the technical aspects of the pharmaceutical industry, ensure non-discrimination towards market entry, co-operate with and provide information to the competition authorities in specific cases, etc.

The Inter-ministerial Circular between the Ministry of Health, the Ministry of Finance and the Ministry of Industry and Trade No. 11/2007/TTLT-BYT-BTC-BCT issued on August 31, 2007, guiding the state administration of medicine prices is the legal normative document which prescribes in detail the mechanism for co-operation between the sectoral regulator (the DAV), the competition authorities (the VCAD) and the price regulator (Ministry of Finance). Section IV, Article 5.2(1) of the Circular assigns the task of “monitoring and controlling competitive practices, anti-monopoly practices and breaches of competition law” to the Ministry of Industry and Trade. And, the Ministry of Industry and Trade has, in turn, assigned this task to the VCAD.

In fact, the co-operation between competition authorities and sectoral regulators has been undertaken based on inter-sectoral memoranda of understanding, or establishment of working groups in specific cases. However, the state administration over competition in the market has not achieved the desired results for the following reasons:

- (i) The awareness of the private sector on competition issues is still limited. Therefore, the Competition Law has not really been integrated into the daily practice of enterprises. They are still not aware that they should be protecting themselves and co-operating with the state agencies (For more information, see Annex 4).
- (ii) There is a lack of information/data on the market structure, leading to difficulties in co-operation between state agencies, especially for the competition authorities in controlling the competitive behaviours of enterprises.
- (iii) The pharmaceutical industry is a highly technical and specialised area. Therefore, the determination of certain factors, as required by the Competition Law, in this industry is more difficult, for example, defining relevant product markets, defining economic concentration indexes, calculating market shares, etc.

\* \* \* \* \*

From the beginning till here, we have examined and analysed the market structure, the legal and regulatory framework, as well as the competition practices in the pharmaceutical distribution sector in Vietnam. In the following section, we would be looking at the international experiences with respect to regulating the pharmaceutical sector, as well as some famous competition cases therein, and the approaches taken by competition authorities around the world, in order to draw the lessons for Vietnam.





## Chapter IV

### INTERNATIONAL EXPERIENCES

The global pharmaceutical industry is presently valued at approximately US\$400bn. Growth rates differ across nations, with developing countries like South Korea, Taiwan, India, etc., notching high growth in the range of 12-15 percent pa. Countries can be classified into five categories, according to the stage of development of their pharmaceutical sector.<sup>157</sup> These categories are outlined in the following Table:

**Table 11 - The Structure of the Global Pharmaceutical Industry<sup>158</sup>**

Level	Stage of Development	Number of Countries		
		<i>Industrial</i>	<i>Developing</i>	<i>Total</i>
5.	Sophisticated pharmaceutical industry with a significant research base	10	Nil	10
4.	Innovative capabilities	12	6 (Argentina, Brazil, China, India, Korea and Mexico)	18
3.	Those producing both therapeutic ingredients and finished products	6	7	13
2.	Those producing finished products only	2	87	89
1.	No pharmaceutical industry	1	59	60
	Total	31	159	190

The pharmaceutical industry of Vietnam is often ranked into the 2.5→3 category, which means we can produce some generic medicines and have export capability. However, our technology is still not very sophisticated, producing only simple formulations, with less innovative composition.

The sophisticated, research-based part of the global pharmaceutical industry is highly concentrated in a handful of countries, notably the USA, the UK, Germany and Switzerland, and is composed of just a few companies. Currently, there are fewer than 40 firms, under patent protection, competing in highly lucrative drug markets. According to the

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<sup>157</sup> According to the classification of the World Trade Organisation (WTO) and the United Nations' Conference on Trade and Development (UNCTAD), there are in total 4 grades of developments for the global pharmaceutical industry, which is similar to this classification.

<sup>158</sup> Source: R. Ballance, J. Progan & H. Forstener, UNIDO, *The World's Pharmaceutical Industries: An International Perspective on Innovation, Competition & Policy* (1992), in K. Balusubramaniam, *Access to Medicines: Patents, Prices and Public Policy – Consumer Perspectives* (2001) (paper presented at Oxfam International Seminar on Intellectual Property and Development: What Future for the WTO TRIPS Agreement?, Brussels, March 20, 2001).

pharmaceutical industry, long-term patent protection is essential because otherwise drug companies cannot afford to develop new medicines. These companies derive most of their profits from a small number of drugs. In fact, 75 percent of drug company profits come from 10 percent of drugs. These figures point to the high level of concentration in the global pharmaceutical industry, even though respective domestic markets might be divided and segmented. M&As activities by multinational corporations (MNCs) (no matter where they are based or where the transaction actually takes place) would have strong impacts on the competitive scenario in each country.

Pressure on drug prices has made global pharmaceutical TNCs resort to mergers and alliances, in a bid to reduce R&D duplication and costs, combine product portfolios and increase the reach. The total number of alliances increased from 120 in the mid-1980s, to nearly 400 in the mid-1990s. These alliances often allow pharmaceutical companies to draw upon each other's research expertise and bring products to market more rapidly and more effectively. The mega-mergers in the global pharmaceuticals industry, in the last few years, have been Glaxo-Wellcome-SmithKline Beecham; Hoechst-Marion-Merrell Dow-Roussel; Pfizer-Warner Lambert; Ciba-Sandoz (to form Novartis); and Hoechst Marion Roussel-Rhone Poulenc (to form Aventis).

<b>Mega-merger – Glaxo Wellcome and SmithKline Beecham</b>
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<p>Two large pharmaceutical giants, Glaxo Wellcome and SmithKline &amp; Beecham merged to become GlaxoSmithKline (or GSK). This merger created a leading global pharmaceutical company with sales of £18.1bn in the year 2000. Headquartered in the United Kingdom, GSK supplies products to 140 markets in the world. Obviously, the merger created competition concerns in several countries, yet it went unchallenged in most of them. India did not have a merger review provision in its extant competition law, the MRTPA, so the merger was not investigated. In Sri Lanka, the competition authority did not even take up the case of merger between Glaxo Wellcome and SmithKline Beecham, saying that that it did not have jurisdiction, even though both the companies had commercial presence in the country!</p>
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<p>In an earlier instance, during the merger of Glaxo Laboratories Pakistan Limited and Wellcome Pakistan Limited, the Monopoly Control Authority (MCA) of Pakistan took initiative to investigate. But, MCA failed to take any action and the case was abandoned halfway. The reason provided by the MCA for this abandonment was that calculating market shares of individual products with the identification of their substitutes, as required in the case, was complicated and the MCA did not have qualified and trained staff for this exercise.</p>
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<p>The handling of the merger case by South Africa is quite illustrative. Upon investigation and evaluation of the merger, the Competition Commission reached the conclusion that the transaction should be prohibited on competition and public interest grounds. In particular, the Commission was concerned that the merger would result in the merging parties having high market shares in two therapeutic categories. The Commission stipulated that there would be unacceptable level of concentration in respect of Bactroban, Zelitrex and Famir and there</p>
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were no appropriate substitutes to counter any price gouging or ease of entry to offset the concern. Upon prohibition of the merger by the Commission, the merging parties volunteered to license out some of their products identified by the Commission to be the cause of competition concern. The merging parties and the Commission reached an agreement and the merger was allowed conditionally. Interestingly, the conclusion of the Commission in making its recommendations to the Competition Tribunal was substantially the same as the conclusions of the EC, in so far as the overlap of products was concerned. This may partly be due to the fact that the Commission sought and received extensive co-operation from both the US and the EC. However, it may be noted that the Commission completed its investigation before the case was decided by the EC.

M&As of this size have increased the level of concentration in the global pharmaceutical industry significantly. Even where these MNCs do not have factories, they are still key distributors or importers.

## **1. The Regulatory Experiences of some Countries in the World in the Pharmaceutical Sector**

### ***1.1. China***

China is a country quite similar to Vietnam, in terms of the pharmaceutical industry, even though its level of development might be a bit higher than that of Vietnam. After the economic reform, China started to develop its comprehensive pharmaceutical policies on control assurance, production and distribution regulation, advertising control, promotion of R&D on new medicines, pricing control and management of pharmaceuticals produced in China and imported from overseas. Over this period, new regulations and decrees regarding the medicine production and distribution were also developed to help introduce more market mechanisms into the state-owned pharmaceutical manufacturers in order to promote and expand the industry. In September 1984, “The Drug Administration Law of the People’s Republic of China” was issued and acted effectively from 1 July 1985. However, it has now been found that the Law and other regulations and decrees on pharmaceutical policies had many shortcomings or could not adequately tackle emerging issues and problems related to pharmaceutical production and registration, distribution and utilisation. Specifically:

#### ***Pricing***

Under the market-oriented economy, Chinese pharmaceutical manufacturers have their autonomy to decide what products they would produce and how much they should produce, as long as they have got their products registered with the State Food and Drug Administration in China (SFDA), which was given mandate to be responsible for reviewing and approving the applications of new medicine registration on the ground of medicine safety and efficacy, while the National Development and Reform Commission (NDRC) is mandated to approve and regulate the prices of new products that are suggested by the manufacturers

based on so-called self-reported production costs. Actually, all authorities for medicine pricing management do not have sufficient human and technical resources to assess how rational the production costs provided by the manufacturers are. The prices of medicines, to a great extent, are set at the level at which manufacturers wish to achieve.

The cost of health care in China has increased significantly since the economic reform. In order to help the vast majority of Chinese people remove financial barriers in seeking health care, the NDRC has, since 1997, issued guidelines on medicine pricing 20 times. Each time the prices for a number of selected medicines were cut down significantly. However, such good intention has not actually resulted in expected outcomes fully, although the service users did benefit from the price reduction of some medicines. Once they found that there was less profit in producing particular products, the manufacturers would immediately stop producing them. Therefore, it is not surprising to find out from a study that, among 1,500 essential medicines defined by the SFDA, one-third of them could not be seen in the pharmaceutical market in Beijing. Of those not available in Beijing, some 30 percent of the products are no longer produced by any Chinese pharmaceutical manufacturers.

### ***Distribution***

Prior to the reform, three levels of medicine wholesalers (province, prefecture and county) had been established to supply pharmaceuticals to hospitals at their levels on a regular basis. The advantages of this distribution network were to have effective control and monitoring over the quality of medicines and prices. However, the disadvantage of the system was the lack of competition and had too many bureaucratic procedures, which might be associated with poor management and storage practices.

After the reform, both the medicine distributors and manufacturers are allowed to sell medicines directly to hospitals and pharmacies. In other words, each of the 4,600 pharmaceutical manufacturers in China can also act as distributors, apart from the 12,000 wholesalers. Most distributors are small or middle-sized. However, it appears to have too many distributors in the distribution system of pharmaceuticals in China. They are competing with each other in the same marketplace, which is not well regulated by the state, resulting in unfair competition practices being used by enterprises to increase their market shares. Recently, reports of corruption related to the pharmaceutical sector have been frequently seen in the Chinese newspapers, TV, radio, etc. Though the law and the regulations ban all these illegal practices in the promotion of medicine sale and use, the capacity of the government for monitoring the distribution system has not adequately developed. In other words, the enforcement of such laws and regulations has not been effective. Furthermore, the punishment and discipline system has also not been appropriately developed to police these actors in the medicine distribution and service delivery system from using illegal means, further aggravating the situation.

Recently, China has adopted a competition law on August 30, 2007 – which is called the Anti-monopoly Law of the PRC, in addition to the Law Against Unfair Competition Practices

adopted in 1999. The Anti-Monopoly Law has been in effect only from August 1, 2008, but the newly-established competition authority of the country has been quite active. These laws, together with the set of sectoral regulations mentioned above, prohibit cartels, abuse of dominant positions and monopoly and protect consumers. However, their effectiveness is still to be seen.

## **1.2. South Africa**

Until 1993, the South African pharmaceutical supply chain followed the traditional and still predominant international model: from manufacturers → wholesalers → retailers (including dispensing doctors) → consumers. Multinational pharmaceutical companies feature prominently in the production stage of the supply chain. Distribution of pharmaceutical products is by independent wholesalers who buy stock for their own account from manufacturers and resell to retailers. Wholesalers cover their costs and make a profit, based on the difference between the price at which they buy from the manufacturers and the price at which they resell to the retail trade. The price differential takes the form of a discount (historically 17.5 percent) granted by manufacturers to wholesalers off the list price. Wholesalers pass on a significant portion of this discount, as is demonstrated by reported margins, to retailers, as they compete for market share.

There have been some significant changes in the regulatory system of South Africa in the pharmaceutical sector, resulting in reactions (structural) from the enterprises here. To begin with, the amended *Medicines and Related Substances Control Act*, No. 101 of 1965, proposes mandatory generic substitution. A pharmacist will be required to inform “all members of the public who visit his or her pharmacy with a prescription for dispensing of the benefits of the substitution for a branded medicine of an interchangeable multi-source medicine” (s22F). Another significant challenge for producers is implicit in the proposed single exit pricing provided for in s22G, 3(a). This means that a single price will be prescribed for manufacturers when they sell to anyone other than the state. The differential system of discounts operated by some manufacturers and wholesalers will no longer be permissible. The elasticity of the demand curve (which is traditionally inelastic in this sector, dictated by doctors’ prescriptions) was higher than it used to be, as a result of the changes. Manufacturers, therefore, try to (rationally) consider their market positions very carefully as follows.

### ***International Health Care Distributors***

In 1992, four companies, Boehringer Ingelheim, Roche, Bayer and Ciba-Geigy committed to the formation of a common distribution venture ([www.ihd.com/milestone.htm](http://www.ihd.com/milestone.htm)). Representatives of the four companies submitted a proposal (that became International Health Care Distributors [IHD]) to their principals in Europe and received formal approval in July 1993 from the European head offices. Since then, a number of pharmaceutical manufacturers have joined IHD (including 7 companies in total, namely, Abbott Laboratories, Aventis, Bristol-Myers Squibb, Eli Lilly, MSD, Novartis, Schering and Wyeth) and it is now jointly

owned by eleven multinational manufacturers for whom it distributes pharmaceutical products to the retail trade.

The entry of IHD (which may be described as a joint, exclusive distribution venture) into the market for the wholesale distribution of pharmaceutical products changed the configuration of the pharmaceutical supply chain by effectively segmenting the market. Traditional wholesalers are displaced with respect to the products of those manufacturers that distribute their products through IHD. Wholesalers, either full-line or short-line may still buy the products of these manufacturers through their exclusive distribution agency, but they buy on exactly the same terms as the retailers to whom they resell. The discount structure that used to apply to wholesalers (a 17.5-percent discount) no longer exists. This, the wholesalers have argued (in submissions to the Competition Tribunal in support of applications for Interim Relief), makes their role of suppliers to the retail trade, commercially unviable.

#### ***Kinesis Logistics and Pharmaceutical Health Distributors (PHD)***

In 1998, a second joint exclusive distribution agency was established when five pharmaceutical manufacturers formed an investment company, Synergistic Alliance Investments (SAI). SAI acquired Druggists Distributors (DD), a traditional full-line wholesaler to exclusively distribute the products of the principals and two other manufacturers. Druggists Distributors currently trades under the name Kinesis Logistics.

As of 25 November 2000, AstraZeneca (AZ) has used Pharmaceutical Health Distributors (PHD), another distribution firm, as its sole distribution agent, on a fee-for-service basis. In terms of the distribution agreement, the warehousing and distribution functions, as well as the generation of orders, credit control and debt management are provided by PHD until the end of 2002. AZ maintains ownership of stock until sold to a third party.

#### ***Impacts on Competition***

The complaints and applications for interim relief that have been brought by the traditional wholesalers to the competition authorities have attempted to show that the joint exclusive distribution arrangements constitute restrictive practices, either of a horizontal or vertical nature, or that they involve abuse of a dominant position. These prohibited practices are covered by Chapter 2 of the Competition Act, No. 89 of 1998 (as amended).

In support of their positions, the pharmaceutical manufacturers have advanced a range of pro-competitive arguments, citing efficiency gains, technology gains and the promotion of the public interest as factors motivating the formation of the joint exclusive distribution enterprises and countering claims of anti-competitive effects resulting from these arrangements.

The Competition Tribunal of South Africa has come to the following decisions, in view of these cases:

Case No. 98/IR/Dec00 - *Natal Wholesale Chemists (Pty) Ltd vs. Astra, Merck, & PHD* – Natal complained that Astra and Merck had engaged in exclusive dealing arrangements with PHD, which prevented Natal from distributing the products of Astra and Merck, restricting competition in the market, in contravention of Article 5(1) of the Competition Act. The complainant also accused the defendants of applying discriminatory price-related conditions and terms, in contravention of Article 9 of the Act, which prohibits dominant undertakings from applying discriminatory terms. The Competition Tribunal, after carefully reviewing all the details, as well as the arguments of the complainants, concluded that there were not enough grounds for deciding that the vertical agreements between the defendants had constituted an anti-competitive practice and thus annulled the complainants' request for interim relief.

Case No. 68/IR/Jun00 – *Pharmaceutical Wholesalers vs. GlaxoSmith Wellcom* – The Competition Tribunal concluded that exclusivity does not necessarily contravene the Competition Act, but that the joint nature of the agreement (joint ownership in the case of IHD) implied horizontal collusion such that interim relief could be granted to the applicants.

The various different decisions of the Competition Tribunal of South Africa point to the complexity in assessing the impacts on competition of distribution agreements. Competition authorities would have to differentiate between:

- Strategic behaviours and anti-competitive behaviours by enterprises;
- The exclusivity of agreements and its impacts on competition in the market;
- The difference between manufacturers-distributors relationship and joint ownership; and
- Impacts on the nature and scope of intra-brand competition and inter-brand competition, etc.

### **1.3. *The European Union***

In Europe, enforcement priorities in the pharmaceutical sector have traditionally focused on (intra-brand) competition between producers of patented prescription drugs and parallel traders. More recently, however, the European Commission has started to focus increasingly on practices believed to be aimed at delaying the entry of generics or innovative products – which essentially means abuse of dominant positions to disrupt the innovative process (traditionally been the case of the US's policy). This policy trend is clearly reflected in this competition authority's latest action – springing a sector-wide enquiry into these issues.

Primarily due to differences in national pricing regimes and health care spending, there exist substantial price differences – as high as 70 percent in some instances – in medicines between member states. This has created a significant parallel trade activity. Wholesalers purchase products in low-priced countries in order to sell in high-priced countries at or near the reimbursement price of the medicine in the country of importation, that effectively arbitrages



to take advantage of the price differentials. Pharmaceutical manufacturers have sought to restrict these parallel imports through unilateral means and also by agreement or concerted practice with their distributors. Such action is potentially in breach of EC competition law, either as a restrictive agreement (Article 81 of the EC Treaty) in the case of concerted measures or as an abuse of a dominant position (Article 82 of the EC Treaty) in the case of unilateral measures. These issues are clearly reflected in two exemplary cases – known as the *Greek GSK* case and the *GSK Dual pricing* case in Spain. Both cases are currently pending before the European Court of Justice (ECJ).

In the *GSK Dual pricing* case, GSK has submitted to the European Commission for approval their dual-pricing policy (in accordance with Regulation 17 – Article 81(3) of the EC Treaty) with two main objectives: (i) to maintain the incentive for innovation in member states where prices remain high; and (ii) to ensure the access to medicines by consumers in member states where the prices are low. The EC has refused the submission, saying that these benefits are not clear. However, the European Court of First Instance stated that the EC had not considered these benefits appropriately.

In the *Greek GSK* case (also known as the *SYFAIT* case), GSK had decided to restrict its supply to meet orders in Greece after seeing that the products it sold in Greece had been traded all over Northern Europe. The Greek Competition Commission had referred the case to the ECJ with regard to abuse of dominant positions (refusal to deal).

In June 2005, the Commission imposed a 60-million euro fine on AstraZeneca for misusing national patent systems and national procedures for marketing pharmaceuticals to block or delay market entry for generic competitors to its ulcer drug Losec.

Lately, on January 15, 2008, the European Commission (EC) disclosed that it had launched a "sector inquiry" into the pharmaceutical industry, including unannounced inspections, known as "dawn raids." The EC has the legal authority to conduct a general "sector inquiry" into an industry when it suspects, based on price trends or other factors, that there may be a distortion of competition in an industry even in the absence of actual evidence of wrongdoing.

The EC stated that it had launched the sector inquiry because it was concerned that fewer new drugs were being brought to market and that the entry of generic drugs appeared to be delayed. The EC noted that while 40 new drugs were introduced per year by drug companies between 1995 and 1999, the average fell to 28 between 2000 and 2004. The EC stated that it is considering several potential competitive issues: agreements between pharmaceutical companies, such as patent litigation settlements and the creation of barriers to entry through the misuse of patent rights, vexatious litigation and abuse of the regulatory process or other means.

EC, using its power to launch the sector-wide enquiry on the basis of its own concerns, does a good practice/lesson aiming at a healthy pharmaceutical industry. However, it should be noted that the EC is a powerful competition authority and the EU is a huge market. These are the two factors which can exert pressure on pharmaceutical MNCs, which make them

cautious when engaging in strategic behaviours, in order not to trigger actions by the EC.

Turning to the member states, the United Kingdom's Office of Fair Trading (OFT) has recently issued the results of its market study into the use by branded drug companies of the 'direct-to-pharmacy' sales model. Under this model, the company contracts directly with pharmacies, merely using the logistical support of one or more wholesalers. It gives it more control over prices and also avoids the risk of counterfeits through parallel trade. The OFT is concerned that the model may result in lower discounts for pharmacies and lower service levels in the distribution of medicines. It recommends that the government address the concern over lower discounts in the UK price regulatory system (PRS) and also set down minimum service standards.

In France, the Competition Council has imposed certain conditions to make the supply quota system in force between a number of branded drug companies and their wholesalers more flexible and transparent, ensuring that the system can adapt to potential growth on the market, without distorting competition between wholesalers. The Council did not object to the supply quota system as such, but rather had concerns over its practical implementation.

#### **1.4. The United States**

In the United States, the Federal Trade Commission (FTC) has shown a similar interest in the pharmaceutical industry. The FTC has routinely challenged mergers or other allegedly anti-competitive conduct in the pharmaceutical industry for a long time, but in recent years, its focus on the industry has risen to a new level. The most controversial aspect involves the FTC's challenges to patent branded/generic litigation settlements involving so-called "reverse payments." The FTC has settled a number of cases with branded and generic pharmaceutical companies involving reverse payments and it has studied the competitive implications of such settlements.

In 2001, the FTC brought a complaint against Schering-Plough Corp. challenging settlement agreements that it had entered into with two generic companies it had accused of violating its patents for its potassium chloride supplements. The FTC concluded that the settlement agreements — which the FTC found involved payments from Schering-Plough in return for delayed generic entry — violated the antitrust laws. On appeal, however, the 11<sup>th</sup> US Circuit Court of Appeals overturned the decision, finding no evidence that the agreements had impaired competition beyond the scope of Schering-Plough's patents.

In February 2007, the FTC brought a suit to challenge brand drug manufacturer Cephalon's settlements with four generic firms (all of whom would have shared the 180-day exclusivity period). Each settlement involved a side-agreement, including intellectual property licence payments from the brand as well as supply agreements and product development agreements under which the brand paid the generic. The FTC argues that these are agreements not to compete.

### **1.5. Canada**

Created in 1987, under the Patent Act, as an independent quasi-judicial tribunal, the Patented Medicine Prices Review Board (PMRRB) limits the prices set by manufacturers for all patented medicines, new and existing, sold in Canada, under prescription or over the counter, to ensure they are not excessive.

As an independent quasi-judicial body, the PMPRB carries out its mandate independently of other organisations, such as Health Canada, which approves drugs for safety and efficacy and public drug plans, which approve the listing of drugs on their respective formulas for reimbursement purposes.

The PMPRB has a dual role:

- *Regulatory*: To protect consumers and contribute to Canadian health care, by ensuring that prices charged by manufacturers for patented medicines are not excessive; and
- *Reporting*: To contribute to informed decisions and policy making, by reporting on pharmaceutical trends and on the R&D spending by pharmaceutical patentees.

Canadian regulators have ordered the local subsidiary of US-based ICN Pharmaceuticals to cut the price of its Virazole, anti-infection, drug by almost 90 percent and pay a C\$1.2mn (US\$876,000) penalty for excessive pricing. It found ICN had sold Virazole at “an excessive price” since January 1994 and ordered the company to reduce the price of a 12-hour dose from C\$1540 to about C\$200.

The ruling is the first since the establishment of the Patented Medicine Prices Review Board in 1987, under reforms to extend patent protection on brand-name pharmaceuticals. However, the Board has reached 100 “voluntary” settlements, which it claims have saved consumers about C\$110mn.

### **1.6. Thailand**

Similar to other countries in Asia, the pharmaceutical industry in Thailand is mostly formulating active ingredients and manufacturing generic products. The number of local manufacturing companies is limited, thus Thailand relies on imports. In 2005, domestically-produced medicines accounted for 65 percent of the total demand and 35 percent are provided by imported medicines. In Thailand, the drug manufacturers are categorised into three groups:

- Multinational corporations which manufacture active ingredients and pharmaceutical formulation;
- Thai-owned companies, which primarily focus on producing pharmaceutical formulation and, to a smaller extent, manufacturing active ingredients ; and

- The Government Pharmaceutical Organisation (GPO), which primarily prepares pharmaceutical formulations for public medical establishment.

The GPO enjoys the benefits of the government's former regulation of the pharmaceutical market and nearly holds a monopoly over the supply to the public sector. According to the annulled regulation, public hospitals are legally obliged to purchase 80 percent of their drugs from the GPO and only 20 percent from private organisations, the impact of the annulment is however not certain. Thanks to these advantages, so far, the GPO has always ranked amongst the top-ten pharmaceutical corporations in Thailand, together with other MNCs such as Pfizer, Sanofi-Aventis, GlaxoSmithKline, AstraZeneca, Novartis, Roche, etc. It is considered as the backbone of the domestic pharmaceutical industry of the country, helping to stabilise the supply of medicines to all Thai people (to avoid being dependent too much on foreign and imported products) and ensure the access of the poor to essential medicines.

The Thai pharmaceutical regulatory system is based on the Drug Act B.E. 2510 (1967), together with its four amendments, ministerial regulations and ministerial notifications. The fundamental basis of Thai drug regulation is that all activities in relation to the trading of pharmaceutical products must be licensed/approved by the competent authorities. Drug regulation is centred at the Thai Food and Drug Administration (FDA) under the Ministry of Public Health (MoPH).

Generally, the procedure for seeking marketing approval for drugs will depend on whether the applicant is the drug originator or a generic producer. Drug originators face the most onerous task, as each element of drug safety, efficacy and effectiveness must be demonstrated to the satisfaction of the Drug Control Division of the FDA. Such practice is partially due to the government's health care policy, which seeks to improve access to medicines and make affordable drugs available to all patients who need them.

Other than this pro-generics policy, the MoPH has also made various efforts towards making affordable drugs available for all. The most recent, and perhaps most controversial, attempt was the MoPH's decisions to issue compulsory licences to six key drugs that are still under patent in Thailand. The drugs include Merck's antiretroviral Efavirenz (Stocrin), Abbott Laboratories' antiretroviral Lopinavir/Ritonavir (Kaletra), Sanofi-Aventis' heart disease drug Clopidogrel (Plavix), the breast cancer drug *Letrozole* produced by Novartis, the breast and lung cancer drug *Docetaxel* made by Sanofi-Aventis and the lung cancer drug *Erlotinib* produced by Roche. In all these cases, the MoPH has insisted upon implementing the compulsory licences to import generic products into Thailand, through the state-owned GPO. These decisions are based on the Thai Patent Act and are highly controversial.

Thailand also has a Trade Competition Act since 1999 (which replaces the Price Control and Anti-Monopoly Act 1979), but the implementation has remained ineffective. Regulations in the pharmaceutical industry have been following a sectoral approach.

### **1.7. The Philippines**

The Philippines has been considered as one country in Asia where medicine prices are at their highest. The drug prices are probably the highest in the world in relation to per capita income. For example, a 500 mg. tablet of Ponstan, a painkiller manufactured by Pfizer, costs US\$0.45 in Philippines, while the very same item costs only US\$0.06 in India, a nearly 800 percent differential.

A major reason for the high cost of pharmaceuticals in the Philippines is the existence of a “cartelised system” of marketing and distribution therein. There exists a Philippine drug industry “cartel” which controls the supply and sets the prices. Such pricing has little or no relation to the actual cost of production and retailing and is determined solely by what the cartel believes the market can take. More than 60 percent of the retail trade in pharmaceuticals in the Philippines is controlled by one privately-owned company, Mercury Drug. Mercury Drug, with over 600 outlets all over the country, has annual sales of approximately US\$1bn. By its sheer size and economic clout, Mercury is in a position to dictate the pricing and distribution policies of the drug makers. They have to dance to Mercury’s tune or risk being left out of the party altogether. Moreover, approximately 80 percent of the toll manufacturing for foreign drug companies is done by Interphil Laboratories. About 80 percent of wholesale distribution of medicines is handled by Zuellig Pharma/Metro Drug, a sister corporation of Interphil. With so few dominant industry players, it is no wonder that a cartel evolved which now effectively controls the market.

The Philippines does not have a competition law yet (though there have been some demands for the same to be adopted recently, in order to punish these cartels). The government has been trying to ease the medicine prices and solve the problem of monopolistic arrangements by many different policies and measures, though with limited success.

The Philippines has a National Drug Policy (NDP) since 1986-1987. In 1988, the Philippines enacted a law on generics in consonance with the NDP. Helping usher in an era of social-reform measures, Republic Act No. 6675 sought to promote, require and ensure the labelling, prescribing and dispensing of medicines, using their generic names. Besides, clinics in rural areas are required to maintain all drugs mentioned in the Essential Drug List (EDL). A programme called “Boticang Bayan” is also undertaken, which is essentially a grass-roots distribution and retailing network, intended to bring cheaper generic drugs to the people who need it most.

However, such programs are hampered by bureaucratic and budgetary limitations. Whether this will loosen the cartel’s stranglehold on the Philippine pharmaceutical market remains to be seen. Generics still account for below 10 percent of the whole Pilipino pharmaceutical market and the prices are still incredibly high.

## **2. Specific Issues Related to the Implementation of Competition Law Policy in the Pharmaceutical Distribution Sector**

Pharmaceutical manufacturing and distribution is a very distinctive industry. Therefore, competition law policy only constitutes one part of the legal and regulatory framework regulating the sector, in addition to regulations on pricing, quality, standards, distribution (the way that wholesalers and retailers are allowed to do their business) and drug registrations, etc. The lead role of competition law policy, as well as that of the competition authorities, is to ensure that market players do not engage in anti-competitive practices (for example, price-fixing agreements, abuse of monopoly, abuse of IPRs to block the innovative process, etc.), erect barriers to entry or extract rents from unfair competition practices (for example resale price maintenance, excessive pricing, misleading advertisements, etc). In some cases, competition authorities can also undertake policy advocacy with other sectoral regulators or relevant state agencies (for example on marketing practices, distribution practices and the organisation of the distribution systems, pricing, advertising or the maximum margin of profits for distributors, bidding for supply contract to hospitals, etc.) so that there is no regulation which may potentially restrict competition in the market or prevent competition, in order to ensure the legitimate benefits of the consumers, as in the case of the United Kingdom and France, mentioned above.

On October 29, 2007, Canada's Competition Bureau released a report which claims that consumers in Canada are still paying high prices for generic drugs, despite vigorous competition between drug manufacturers. According to this report, pharmacists drive competition by exchanging shelf space for discounts on drugs, yet have little incentive to pass those savings onto individuals and insurance plans.

The study also showed that rebates or payments accounted for close to 40 percent of the price the pharmacy is invoiced. In provinces that forbid manufacturers to pay pharmacists to stock their drugs, drug companies often pay for pharmacies' professional services, such as patient counselling.

However, consumers and insurance plans that serve consumers rarely see the benefit of those deep discounts, the bureau found. Instead, the prices often reflected the highest charges for generic drug prices allowed under Ontario's drug plan.

Although drug plans often contain policies to reduce the cost of generic drugs, "they provide little incentive for manufacturers to compete by offering competitive prices to end payers", the bureau said in its report.

To help boost competition and consumer savings, the bureau has recommended that public and private insurance plans, rather than pharmacies, help spur competition amongst manufacturers. The bureau has also suggested that insurance providers allow drug companies to bid on what drugs would be covered under certain plans and provide other incentives for manufacturers to compete.

There are some major issues related to the implementation of competition law in the pharmaceutical distribution system on which we can draw on the lessons of other countries in the world, as follows:

**2.1. Defining the Relevant Market in order to Calculate Market Share and the Level of Economic Concentration**

For defining the relevant product markets in relation to medicines, most countries use standardised systems such as the Anatomical Therapeutic Classification “ATC” system<sup>159</sup> – recognised by the WHO – in addition to consulting with medical/pharmaceutical experts or considering other factors such as mode of delivery (medicines only for use in hospitals, prescribed medicines or over-the-counter medicines), the usage (for injection or normal usage), etc., so as to add or exclude some (ir)relevant products.

According to the ATC system, finished pharmaceutical products can be categorised as follows:

**Table 12 – Major Drug Groups**

<b>Major Drug Groups</b>	
<b>Gastrointestinal tract/metabolism (A)</b>	<i>stomach acid</i> ( <a href="#">Antacids</a> , <a href="#">H<sub>2</sub> antagonists</a> , <a href="#">Proton pump inhibitors</a> ) • <a href="#">Antiemetics</a> • <a href="#">Laxatives</a> • <a href="#">Antidiarrhoeals/Antipropulsives</a> • <a href="#">Anti-obesity drugs</a> • <a href="#">Anti-diabetics</a> • <a href="#">Vitamins</a> • <a href="#">Dietary minerals</a>
<b>Blood and blood forming organs (B)</b>	<a href="#">Antithrombotics</a> ( <a href="#">Anticoagulants</a> , <a href="#">Antiplatelets</a> , <a href="#">Thrombolytics</a> ) • <a href="#">Antihemorrhagics</a>

<sup>159</sup> In the Anatomical Therapeutic Chemical (ATC) classification system, the drugs are divided into different groups according to the organ or system on which they act and their chemical, pharmacological and therapeutic properties. Drugs are classified into groups at five different levels. The drugs are divided into fourteen main groups (1st level), with one pharmacological/therapeutic subgroup (2nd level). The 3rd and 4th levels are chemical/pharmacological/therapeutic subgroups and the 5th level is the chemical substance. The 2nd, 3rd and 4th levels are often used to identify pharmacological subgroups when that is considered more appropriate than therapeutic or chemical subgroups. The complete classification of metformin illustrates the structure of the code:

- A            Alimentary tract and metabolism  
(1st level, anatomical main group)
- A10        Drugs used in diabetes  
(2nd level, therapeutic subgroup)
- A10B      Blood glucose lowering drugs, excluding insulins  
(3rd level, pharmacological subgroup)
- A10BA     Biguanides  
(4th level, chemical subgroup)
- A10BA02  Metformin  
(5th level, chemical substance)

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<u>Cardiovascular system (C)</u>	<u>cardiac therapy/antianginals</u> ( <u>Cardiac glycosides</u> , <u>Antiarrhythmics</u> , <u>Cardiac stimulant</u> ) • <u>Antihypertensives</u> • <u>Diuretics</u> • <u>Vasodilators</u> • <u>Beta blockers</u> • <u>renin-angiotensin system</u> ( <u>ACE inhibitors</u> , <u>Angiotensin II receptor antagonists</u> , <u>Renin inhibitors</u> ) • <u>Antihyperlipidemics</u>
<u>Skin (D)</u>	<u>Emollients</u> • <u>Cicatrizant</u> • <u>Antipruritics</u> • <u>Antipsoriatic</u> • <u>Medicated dressings</u>
<u>Reproductive system (G)</u>	<u>Hormonal contraception</u> • <u>Fertility agents</u> • <u>SERMs</u> • <u>Sex hormones</u>
<u>Endocrine system (H)</u>	<u>Corticosteroids</u> • <u>Sex hormones</u> • <u>Thyroid hormones</u> • <u>Antithyroid agent</u>
<u>Infections and infestations (J, P)</u>	<u>Antibiotics</u> • <u>Antivirals</u> • <u>Vaccines</u> • <u>Antifungals</u> • <u>Antiparasitic</u> ( <u>Antiprotozoals</u> , <u>Anthelmintics</u> )
<u>Malignant and immune disease (L)</u>	<u>Anticancer agents</u> • <u>Immunomodulators</u> ( <u>Immunostimulators</u> , <u>Immunosuppressants</u> )
<u>Muscles, bones, and joints (M)</u>	<u>Anabolic steroids</u> • <u>Anti-inflammatories (NSAID)</u> • <u>Antirheumatics</u> • <u>Corticosteroids</u> • <u>Muscle relaxants</u> • <u>Bisphosphonate</u>
<u>Brain and nervous system (N)</u>	<u>Anesthetics (General, Local)</u> • <u>Analgesics</u> • <u>Anticonvulsants</u> • <u>Mood stabilizers</u> • <u>Psycholeptic (Anxiolytics, Antipsychotics, Hypnotics/Sedatives)</u> • <u>Psychoanaleptic (Antidepressants, Stimulants/Psychostimulants)</u>
<u>Respiratory system (R)</u>	<u>Decongestants</u> • <u>Bronchodilators</u> • <u>Cough medicine</u> • <u>H<sub>1</sub> antagonists</u>
<u>Other ATC (V)</u>	<u>Antidotes</u> • <u>Contrast media</u> • <u>Radiopharmaceuticals</u> • <u>Dressing</u>

The European Commission often uses the ATC-3 (the third level) for market definition purpose, especially in merger cases. Many countries in the Organisation for Economic Co-operation and Development (OECD) also take the same approach, while some countries even use the fourth level, as in the case of Italy. Some other countries may use other ways of expression, but the essence remains the same. For example, Korea uses “commonly accepted therapeutic categories” as the basis; while the US would determine:

“(1) whether drugs treat the same disease, condition, or indication; (2) whether drugs treat a disease by interacting with the body in the same manner (i.e., whether they



*have the same "mechanism of action"); (3) whether drugs have the same specific chemical compounds; (4) whether drugs have the same dosage form such as injectable, liquid, capsule, tablet, or topical; (5) whether drugs have the same frequency of dosage, such as once-a-day or extended release; (6) whether drugs have the same strength of dosage, distinguishing, for example, 30mg and 60mg tablets; (7) whether drugs are branded or generic; (8) whether drugs require a prescription or are sold over-the-counter; and (9) whether drugs are currently marketed or are in development."*

Many studies on the competitive structure of the pharmaceutical markets in the world showed high concentration levels within these different therapeutic groups. In some cases, there are only one or two firms accounting for the turnover of many markets (groups).<sup>160</sup> However, it should be noted that data on market shares, calculated at one point of time in accordance with this method, might not be relevant for long time, since the market shares may change when substitutes are marketed or when patents expire.

## **2.2. *Dealing with Anti-competitive Agreements in the Pharmaceutical Industry***

Anti-competitive agreements can be vertical (often between manufacturers and distributors – wholesalers or retailers), for example in exclusive dealing arrangements or resale price maintenance practices or horizontal (between manufacturers with each other or between distributors with each other), for example in price fixing, dividing the customers or bid rigging. After we have been able to define the relevant markets, it is an easy job to calculate the market shares of enterprises involved, the level of contestability/concentration of the markets or estimate the potential impacts (restrictive) on competition of these agreements. While horizontal restrictive agreements can be prohibited, notwithstanding the combined market share (or market power) of all parties to the agreements, the competition authorities need to calculate the exact market share, the level of market power, as well as the potential impacts on competition of vertical agreements in order to handle them.

1. On July 13, 2006, Turkey's Competition Board fined three companies – Roche, Eczacibasi and Beser – for running a prescription drug cartel in 2003. Roche, which has over 68,000 employees worldwide, makes prescription drugs used to treat cancer, obesity, AIDS, acne and influenza. Eczacibasi manufactures over 400 medicines, including Setron, which is used to treat nausea and vomiting induced by chemotherapy. Roche makes a competing remedy called Kytril. According to the competition board, both companies used a single local warehouse – Beser Pharmacy Retailers – to stock and distribute Kytril and Setron. This allowed them to fix prices and divide up the market when fulfilling public procurement contracts agreed with the Social Insurance Association and other state hospitals.

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<sup>160</sup> For this task, it is necessary to collect information on the turnovers of each enterprise for each type/brand of medicines. The competition authorities may make use of their authority to require enterprises to provide such data and information.

2. In 2007, Italy's Antitrust Authority has fined four pharmaceutical wholesalers, Alliance Healthcare, Comifar, SAFAR and Itriafarma – for refusing to supply over-the-counter drugs to non-pharmacy outlets in the regions of Abruzzo, Puglia and Basilicata. The authority claims the arrangement led to a general lack of supply of OTC drugs for two months, creating negative effects on the benefits to consumers. These companies were fined an amount of €24,840 for anti-competitively coordinating commercial policies.
3. In 2008, Germany's Federal Cartel Office has fined nine pharmacy associations and several individual pharmacies a total of €465,000 for urging their members and other pharmacies not to compete on the retail price of some drugs. According to the office, the associations spent much of 2003 touring parts of Germany giving presentations on why they should charge uniform prices for simple OTC medications such as aspirin and cold medicine.
4. Also in 2008, the UK's Office of Fair Trading was investigating a price-fixing cartel comprising of several generic medicines producers (Kent Pharmaceuticals, Goldshield, Ranbaxy, Generics and Norton Healthcare), which were accused of raising their prices as much as 800 percent, causing damages worth £150mn from 1996 till 2000. There are several medicines involved, including blood-thinner Warfarin and certain penicillin-based antibiotics. Some of the companies have already paid out £34mn to settle allegations without admitting liability.

### **2.3. *Dealing with Abuses of Dominant Position and Monopoly***

Abuses of dominant positions can be related to excessive pricing, such as in the case of Canada, as mentioned above, or to IPRs, as in the case of the US or the EU. For these practices, determining that an enterprise is holding the dominant position is crucial in order to conclude whether the alleged enterprise is guilty or not. Therefore, market definition becomes very critical to the outcome of each case.

1. In 2003, the South African Competition Commission found that GlaxoSmithKline South Africa and Boehringer Ingelheim have contravened the Competition Act 1998, by abusing their dominant positions in the anti-retroviral (ARV) drug market. Each of the firms had refused to license their patents in return for a reasonable royalty. In particular, the Commission found that the firms denied a competitor access to an essential facility, set excessive prices and engaged in an exclusionary act. Finally, the companies had decided for out-of-court settlement, after the case was referred to the Competition Tribunal. It should be noted that in this case, the Commission determined that each type of ARV is one relevant product market, as in the approach "one-product-one-market" mentioned in the part on Market Structure of the report. This is a useful experience for the competition authorities of developing countries, in general,

as well as Vietnam, in particular.

2. In 2007, some US pharmaceutical retailers have accused drug maker Abbott Laboratories of leveraging its monopoly position over an HIV drug patent called Norvir, to inflate the cost of the drug by almost 400 percent over the last four years to offset losses due to increased competition for other HIV-related drug it makes. Although Norvir can be used alone, it is typically a component drug used to boost the effectiveness of other HIV inhibitors, including Kaletra, another Abbott brand. Several rival producers use Norvir, which is the only drug of its kind, to supplement their drugs. When competitors to Kaletra began gaining market share, Abbott charged them more for Norvir to offset its losses and regain market position. This case was supposed to be brought out for hearing in 2008.

#### **2.4. Reviewing Economic Concentration (Mergers and Acquisitions)**

Mergers and acquisitions can also be vertical, as in the case of Kinesis Logistics in South Africa or horizontal, as in the multi-jurisdictional merger between Glaxo Wellcom and SmithKline Beecham. In these M&A cases, which might potentially lead to the formation of a dominant business, or restrict competition (due to combination of IPRs, expansion of the distribution networks or increase of market power in different market segments, etc); competition authorities in the world often set certain conditions for approval to ensure that the merging parties are not becoming too powerful and can control the market.

In 2007, the US Federal Trade Commission has conditionally cleared a merger between the country's third and fourth-largest pharmaceutical companies, Rite Aid and Brooks & Eckerd. Rite Aid had expected to close US\$3.5bn acquisition of Brooks and Eckerd pharmacies in March 2007, but the commission raised concerns that the deals would be anti-competitive in 23 local markets, allowing Rite Aid to "unilaterally exercise market power" in certain areas and demanded that Rite Aid sell at least one pharmacy in each of the markets to commission-approved buyers. This condition is supposed to ensure that consumers continue to have a choice in where they shop for prescription drugs.

The deal would give Rite Aid control of over 1,800 Brooks & Eckerd stores and six distribution centres on the US east coast. Rite Aid would control over 5,000 stores in 31 states after the takeover and expect annual revenue of around US\$27bn. Seventy percent of the acquired stores are in states where Rite Aid already operates.

Quebec-based pharmacy Jean Coutu – Brooks' and Eckerd's parent company – would keep 327 Canadian shops and would gain a 32-percent stake in Rite Aid. Rite Aid said it would close up to 200 stores to avoid overlap.

Overall, enterprises can always abuse their own distribution networks or patent rights or right to business to increase prices, set prices, exclude competitors from the market or maintain their dominant positions. The experiences of other countries in the world mentioned above have revealed the significance of competition law to protect the consumer and ensure circulation.

In summary, international experiences showed that competition authorities play a great role in putting forward recommendations or policies which could help remedy the various distortions in market structure, level of economic concentration or be the facilitator so that innovations can come to the markets and consumers. However, they can only do that if they have constant access to information over the happenings in this very distinctive market.

Besides, anti-competitive practices (including both restrictive business practices and unfair competition practices) can be quite prevalent in this industry, especially abuses of dominant positions (to increase prices unreasonably and block market entries by new competitors) and restrictive vertical and horizontal agreements. These practices can be shelled as strategic business behaviours or efficiency-enhancing agreements or simply under the shadows of the “legal monopoly” conferred by IPRs. The crucial tasks in handling these cases include accurate market definition, the possibility of using legal authority to order the companies under its scrutiny to provide information or access to the content of their agreements and contracts. Besides fines and cease-and-desist orders, competition authorities should also look at innovation-enhancing measures (to promote competition in the future) and market-opening measures (to allow alternative sources of supply, new manufacturers and importers to participate in the market, to allow parallel imports, etc.) so that competition gets breathing space.

## **Chapter V**

### **ASSESSMENT AND RECOMMENDATIONS**

#### **1. Assessing the Competitive Environment in the Pharmaceutical Industry**

In this report, the competitive environment in the pharmaceutical industry, in general, and the pharmaceutical distribution system, in particular, are examined from three main aspects: (i) the legal and regulatory framework, which include competition policy and law and other relevant laws and regulations; (ii) the degree of competition in the market, which is reflected through the prevailing market structure and the competitive behaviours of enterprises in the relevant markets; and (iii) the existence of barriers to entry, which include economic barriers, barriers erected because of the strategic behaviours of enterprises in the market and regulatory barriers. On the basis of the analysis in the preceding parts, some of the general assessments can be drawn as follows:

##### ***1.1. The Competitive Environment in the Whole Pharmaceutical Industry***

- **The legal and regulatory framework**, in particular with the adoption of the competition law, for regulating the pharmaceutical distribution system is quite comprehensive. The considerable consistency between the Competition Law and the overall legal framework for economic activities show that the competitive environment in the whole pharmaceutical industry is quite good. Specifically, all the legal normative documents have set the regulatory framework stipulating prohibited anticompetitive practices, pharmaceutical price administration, drug information provision, advertisement and promotional sales, as well as fines and remedies to be imposed on violations.
- **The market structure** has been changed considerably, with the number of market participants on the rise. There are in total around 800 enterprises doing business in the industry, including both manufacturers and distributors, out of which 439 are FIEs with 40,000 retailing agents (as compared to around 500 enterprises in total in 2001). On the other hand, statistics on market entry and exit show that this is quite a competitive market (with all market players having sufficient information about the market and enterprises being able to enter into and exit from the market with ease). It can be said that the pharmaceutical industry, in general, has quite a competitive structure, resulting in fierce competition between market players, sometimes unfair competition practices and anti-competitive practices.

Field survey results show that enterprises compete in order to take control of the market. Specifically, competition therein is characterised by behaviours such as fake trademarks, misleading indications, taking undue control of other enterprises' markets or under-pricing during bidding. Besides, in addition to competition by way of quality, choice and more competitive prices, as well as sales services, there have been signals of anti-competitive practices which are potentially in violation of the

Competition Law as well. The existence of anti-competitive practices in the market also reflects, to some extent, the degree of fierce competition therein. On the other hand, the pharmaceutical market's most distinctive feature is the existence of barriers to entry, since pharmaceutical is a very special product - the consumers only purchase the products when they are really in need (for treatment) and the demand is decided by doctors' prescriptions. Therefore, the size of the relevant product market (for each type of drug) would not increase in accordance with the demand, as in the case of other products. This characteristic of the market leads to the consequence that, when an enterprise is excluded from the market for a certain product, it is not easy for it to enter into another market for a similar substitute, resulting in fiercer competition amongst market participants.

Domestic pharmaceutical manufacturers have to compete within a small market, since they are all only capable of producing medicines which treat ordinary sicknesses (statistics show that domestically-produced medicines can only treat ordinary sicknesses, meeting around 50 percent of the total demand). This small market will become even smaller, once the tariff is reduced as per Vietnam's WTO accession commitments. Therefore, the pressure of competition would be even higher when the market 'pie' gets smaller, while the number of market participants is on the rise.

- There exist a **significant number of barriers to market entry**, especially technical barriers, since pharmaceutical manufacturing and trading is a conditional business (enterprises have to meet certain qualifying requirements in terms of manufacturing facilities, technology and human resources in order to be able to participate in the market) and hence the cost of entering the market is quite high. Besides, the costs involved for R&D for inventing a new medicine or formula are also very high. What's more, there is another type of barrier: the use of relationship with doctors and pharmacists so as to influence the consumers' buying decision. Finally, medicine is a product of low substitutability, *i.e.*, the use of medicine is decided by doctors' prescriptions or the guidance of pharmacists for OTC drugs. The survey results with pharmacies show that, in most cases, consumers/customers do not have a choice since they have to follow the prescriptions of the doctors.

In summary, it can be said that the competitive environment in the pharmaceutical industry, in general, is quite good, since it possesses quite a competitive structure, with a great number of market participants (the three-firm ratio – CR3 – for this market is only 22.5 percent, *i.e.*, the level of concentration is low and no enterprise has substantial market power). Therefore, the degree of competition is quite high, leading to the emergence of a great variety of competitive behaviours, which include anti-competitive practices. Barriers to market entry are mainly technical ones, which increase the costs of participating in the market, but do not deter entry significantly.

## **1.2. *The Competitive Environment in the Pharmaceutical Distribution Sector***

- **The regulatory framework:** The legal and regulatory framework regulating the pharmaceutical distribution sector is quite comprehensive. Amongst all, the Competition Law becomes the standard code for regulating anti-competitive practices and unfair trade practices, aimed at healthy competition and protection of consumer interests. Other relevant laws and regulations regulating economic activities in the pharmaceutical distribution system (such as wholesaling, retailing and franchising) are also quite consistent with the Competition Law and with each other in ensuring and promoting fair and healthy competition. The simplification of administrative procedures involved in registering businesses and investment projects also contributed significantly in this regard. However, the regulatory framework also sets quite stringent requirements for market participation or rules regarding the state's role in overseeing the pricing autonomy of enterprises or requirements regarding medicine quality, information and advertising, which may limit market entry and business expansion. Therefore, even though it may erect certain technical barriers to market entry, the overall regulatory framework helps to equip enterprises with legal instruments (regarding competition law and policy and other relevant policies) to protect their legitimate rights and interests during the course of doing business. Regulations regarding anti-competitive practices and unfair trade practices are quite consistent across all laws and policies, including the prohibition of restrictive business practices in the pharmaceutical distribution system.

### **Specifically**

***At present, it is difficult to define exactly the market for pharmaceutical distribution since there has been no specific and consistent regulation on “the pharmaceutical distribution system”.***

As defined in the part on market structure, the distribution system is a process of circulating the final finished products manufactured by both domestic and foreign producers, which means this process can start from outside the national territory set by physical borderlines. Accordingly, regulating the distribution system amounts to regulating the behaviours of foreign enterprises which are based outside the territory of a country, but do participate in distributing the final finished products they supply to the customers in that economy.

As of now, the “distribution” concept is provided for in the Commercial Law and the Law on Medicines. The Commercial Law provides that distribution services comprise of four types of businesses: wholesaling, retailing, franchising and marketing agents. The Law on Medicines, on the other hand, provides only specific regulations regarding wholesalers and retailers. Therefore, there is still no specific and consistent definition of the distribution system in the overall legal and regulatory framework for

the pharmaceutical industry. Looking at both the laws mentioned above, the pharmaceutical distribution system, therefore, might contain only medicine wholesaling and retailing. Without a clear definition, the task of defining the market structure in the pharmaceutical distribution system would become extremely difficult, resulting in controversies regarding relevant market definition and establishment of restrictive business practices. This is one legal element which needs to be specified consistently across all the laws and regulations regarding the pharmaceutical distribution system in Vietnam.

- **Market size and structure:** The pharmaceutical distribution market in Vietnam is quite complex since there is an overlapping of functions between enterprises (manufacturing cumulative with distributing). In 2007, the total number of pharmaceutical enterprises is 800, out of which 90 are direct importers or exporters, with around 39,016 retailing shops. This shows that the degree of market participation is high and so is the level of contestability, resulting in fierce competition between existing market players. In the distribution system, as per the field survey results, fierce competition is mainly between importers and wholesalers, due to the limited market scope for each type/brand of medicines. In order to enter a market and gain control over it effectively, enterprises often have to try to exclude their competitors. It should also be noted that there are some abuses of dominant positions in some small market segments, for example, imposing financial conditions on customers. *This means the competitive environment is restricted by behavioural factor.*

Besides, January 1, 2009 onwards, the market structure in the distribution sector would be significantly affected by Vietnam's WTO accession commitment regarding the right to trade in pharmaceutical products.<sup>161</sup> The numbers of pharmaceutical importers would increase, with more participation of 100-percent foreign-owned enterprises. Therefore, the degree of competition within the distribution sector would increase and the control over different market segments would change, affecting the competitive environment in the distribution sector.

- **Regarding barriers to entry,** most prominent in this sector are the inelasticity of demand, IPRs and stringent regulations on conditions for business. The sector is also characterised for its high level of vertical integration, which means most distributors also have their own factories or have relations with pharmaceutical manufacturing sub-contractors, resulting in difficulty for enterprises which only desire to enter the distribution sector. Besides, wholesalers are also trying to form their own retailing

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<sup>161</sup> Vietnam's accession commitment to the WTO regarding the trading right in the pharmaceutical sector: Vietnam would allow foreign individuals and enterprises to directly import medicines into Vietnam from January 1, 2009. This right to import includes the right to resell the imported products to individuals and enterprises which are licensed to distribute such products in Vietnam. This commitment does not mean that Vietnam automatically grants the right to distribute goods in Vietnam for these importers. This commitment only means that 100-percent foreign-owned enterprises will be able to participate in the starting stage of the whole distribution chain, though they are still not allowed to participate in the chain (only the right to access).



systems, creating pressure on retailers during their negotiation process with wholesalers who used to be more dependent on retailers to market their products.

According to the statistics provided by the GSO, the number of distributors has increased significantly since 2001 till 2005, from 492 distributors to almost three times the number in 2005 to 1444 enterprises. This shows that this is an attractive market for investors, despite the existence of barriers to entry and high participation costs, since it is quite competitive.

### **1.3. *Competitive Behaviours in the Markets***

According to current regulations, only 100-percent foreign-owned enterprises can participate in the pharmaceutical distribution system. The field survey results show that these 100-percent foreign-owned enterprises (Diethelm Vietnam, Mega Lifesciences Vietnam Co. Ltd., and Zuellig Pharma Vietnam Co. Ltd.) are holding dominant positions in several market segments. This is especially clear if one look at the bargaining power they have over retailers. Even though there is no explicit agreement amongst these enterprises, each of them only supplies some certain medicines of certain therapeutic groups. And, these medicines and therapeutic groups are not the same amongst these enterprises, amounting to some form of tacit collusion. This can be seen through the price quotations and product lists offered by Mega, Zuellig and Diethelm. Accordingly, each of these enterprises has significant market power over certain products. For example, Mega only supplies medicines for diabetic patients or life products for women. The consequences are that:

- Foreign enterprises have better bargaining power over Vietnamese wholesalers and retailers, so there is a high risk that they may abuse their market power to impose unreasonable conditions during negotiation with Vietnamese enterprises, affecting medicine prices in the market, affecting consumers.
- Foreign enterprises have better relations with foreign manufacturers, while distributors do not have such access, so foreign manufacturers refuse to deal directly with Vietnamese distributors, especially in some patented products where they dominate the market.

It is quite common that some Vietnamese distributors lose control over some market segments due to lack of bargaining power vis-à-vis authorised distributors for foreign manufacturers. However, this is not stipulated by the Competition Law, so the losing enterprises could not make use of this legal instrument for self-protection, even in case they are aware of the possibility of doing so. Therefore, they were forced to exit those market segments and try to enter others. This is another issue that needs to be addressed.

If we follow the approach “one-product-one-market”, as mentioned in the part on market structure, market entry and exit with regards to each specific products are often changing, leading to frequent changes in the prevailing market structure and high competitive pressure. (For example, Vietnamese enterprise A is in the market for product A1, but is forced to leave

this market after the entrance of a foreign enterprise. Enterprise A would then enter the market for product B, leading to changes in the market structure in both markets A1 and B). Therefore, the status and degree of competition in the market for pharmaceutical distribution is quite distinctive, as compared to other markets. It needs the specialised regulation of the sectoral regulator (the DAV), in close collaboration with the competition authorities.

It should also be noted that most foreign pharmaceutical companies do not see themselves as being subject to the purview of the Competition Law, since their commercial presence in Vietnam is only restricted to the form of representative office (i.e., not having business function – according to the Commercial Law), whereas Competition Law only regulates individuals and organisations doing business in Vietnam. Therefore, it remains a question whether the collusion between the representative offices, the limited liability companies and domestic pharmaceutical enterprises setting the market prices at two or three times the original prices is subject to the purview of the Competition Law of Vietnam or not. This question needs to be clarified and addressed.

### **Other Factors Affecting the Competitive Environment in the Distribution Sector**

The pharmaceutical distribution system comprises of the two main following sectors:

- *Manufacturing – distributing*: It is with branches and marketing agents with a system of shops, pharmacies. Most enterprises have set up their own distribution channels as a chain of retail shops. This type accounts for around 50 percent of the pharmaceutical market, corresponding to the capacity to meet market demand of Vietnamese pharmaceutical producers. This distribution sector is quite clear in structure and operates in line with the current laws and regulations. Since this market mainly comprises of generic products or products of the same therapeutic categories manufactured by various domestic producers, the market prices for all are quite stable. Therefore, competition within the distribution sector for “domestic medicines” is quite normal and healthy. It can be said that the competitive environment for distribution of domestic pharmaceuticals is quite good and not distorted by strategic behaviours of market participants.
- *Importing – distributing* (wholesaling and retailing), and authorised imports: Most enterprises in this sector do not produce medicines themselves, but only deal in importing and exporting and, after imports, participate in the distribution system via wholesaling and retailing at pharmacies. In fact, even though they are only intermediaries between importers (100-percent Vietnamese-owned enterprises) and foreign pharmaceutical manufacturers, these enterprises are those which decide the prices on the market. These enterprises are foreign-owned distributors which deal only in patented medicines and not domestically-produced medicines.

This practice of setting the prices is not a marketing strategy of firms in the market, but it is a practice induced by the monopoly gained from sole distributorships of various patented products. Each foreign-owned distributor often has sole

distributorships over some certain patented products. They are selected by manufacturers on the basis of criteria such as: (i) credibility and market position of the distributors, and (ii) meeting the conditions for quantity of imports. After they have been granted sole distributorships over certain patented products, these foreign-owned distributors can set the market prices and impose whatever commercial conditions they want on other domestic distributors. *Therefore, it can be said that there are some signs of collusive practices in distribution orchestrated by the representative offices of foreign distributors in Vietnam, but this type of ‘invisible’ abuse of dominance seems to be out of the scope of regulation by the Competition Law.*

Looking closely at these collusive practices orchestrated by the representative offices of foreign distributors in Vietnam, one can say that there are signs of competition-restricting agreements. From international experiences, competitive behaviours between distributors mainly comprise of competition-restricting agreements, such as exclusive dealing, price-fixing cartels and abuse of dominant positions to set excessive prices. In the world, these agreements between distributors are quite common. And the abuse of dominant positions is often caused by pharmaceutical distributors with patent rights. Monopolistic behaviours in distribution often happen in countries like India, China or Vietnam, where sole distributorships are quite a common practice. For the countries at the same level of development (with regard to the pharmaceutical industry, as classified by UNIDO), such as Vietnam, the market for imported medicines is quite often controlled by foreign distributors and, therefore, is quite dependent on their behaviours. Domestic importers usually do not have sufficient credibility and bargaining power to negotiate the terms with manufacturers and, therefore, cannot compete effectively.

Another distinctive feature of the pharmaceutical distribution system in Vietnam, as compared to that of other developed countries, is that, in developed economies, there are often only a few big distributors (wholesalers). For example, in the US, there are only three such companies, in France 7-12, resulting in a high level of concentration, whereas in Vietnam, there are thousands of entities in the whole system. This means the market is quite open and attractive, but also complex, multi-structured, hard to regulate and resulting in high prices. These types of markets are quite competitive in structure, with prices fluctuating quite often in accordance with the market mechanism. Whereas, in those market segments where there is only one distributor, price is often excessively and unreasonably high.

**In general, the competitive environment in the market for distributing imported pharmaceutical products has the following characteristics:**

- The market structure (calculated on the basis of data on the import value) is quite competitive, while the level of concentration is low. The enterprise (Phytopharma II) with the highest import value only accounts for around 29.2 percent of the total market. Most of the others account for less than 10 percent of the total import value.

However, since this is mostly the value of authorised imports by foreign enterprises, the statistics do not reflect correctly the market positions of Vietnamese enterprises. There is a high possibility that companies such as Zuellig Pharma (importing via Phytopharma II) are holding dominant positions and are capable of restricting competition in the market significantly, even though their market shares (by turnover and import value) are not high.

- There exists quite a comprehensive regulatory framework for the sector. However, implementation has not been effective, due to lack of clear and specific provisions to define the distribution system, so as to ensure that enterprises are not making use of such loopholes (some are not allowed to participate in the distribution system, but are actually doing so).

As already analysed above, in order to regulate the pharmaceutical distribution system in an effective manner, there is a need to put in place laws and rules which regulate the activities of enterprises without commercial presence in Vietnam. Even though the activities of those enterprises without commercial presence in Vietnam has been stipulated in Decree No. 90/2007/ND-CP issued by the Government on May 31, 2007, this regulation is not applicable to the competitive behaviours of such enterprises. Therefore, this is another issue which needs to be addressed when the Competition Law is amended.

- The existence of those technical barriers to entry which lead to high participation costs, does not negatively affect the competitive environment, since the number of enterprises active in the market is quite large and increasing significantly during recent times. The number of market participants at present show that the degree of competition is quite high, unavoidably leading to the emergence of several strategic behaviours in order to exclude competitors. However, in most cases, enterprises could not be excluded from the whole distribution system altogether.

It can be said that the high degree of competition in the market is caused by the fierce competition amongst market participants and between the existing market players with new entrants, the bargaining power of customers and bargaining power vis-à-vis manufacturers supplying to that market. (This is clearly reflected in the case of Vietnam, where the market would be opened for 100-percent foreign-owned companies from January 1, 2009, which means foreign enterprises would be allowed to import directly from foreign suppliers and resell to Vietnamese distributors). The fact that these 100-percent foreign-owned pharmaceutical distributors have bargaining power over domestic enterprises and good relations with foreign suppliers means that competition between these distributors and these enterprises is unavoidable. This is a behaviour-induced barrier to entry after January 1, 2009. And, if the consequence of this competition is price increase, it would adversely affect consumers.

It should also be noted that there is a possibility of vertical collusive agreements between pharmaceutical suppliers (with or without commercial presence in Vietnam) and distributors so as to monopolise certain markets. Meanwhile, the legal instruments for regulating and preventing such practices are still absent. Therefore, in the long run, it is a must to incorporate regulations on vertical agreements into the Competition Law and other relevant laws and policies. In the short term, it is necessary to enhance the supervisory role of relevant state agencies (DAV and VCAD) to ensure a check over and timely measures to deal with such practices, which might restrict competition in the pharmaceutical distribution sector.

In summary, the competitive environment in the pharmaceutical distribution sector is quite good and attractive to investors. The degree of competition in the market is quite high and there are inherent potentials for competition-restricting factors. There are also monopolistic practices in supplying patented medicines manufactured by MNCs in this market. These remaining problems lead to some distortions in the overall competitive environment, which need to be addressed and remedied in the future. On the basis of these assessments, several groups of recommendations would be mentioned in the next part of this report.

## **2. Recommendations**

### ***2.1. General Recommendations with regard to Competition Policy in the Pharmaceutical Industry and the Pharmaceutical Distribution Sector in particular***

In order to protect the consumer interests and increase social welfare, policy makers in the pharmaceutical industry of Vietnam need to put in place an appropriate development strategy for the industry, including the distribution sector, which is consistent with international commitments and which ensures the right to competition by enterprises under the regulation of the state (via sectoral regulator). Even though the pharmaceutical market operates on the basis of market mechanisms (demand vs. supply), there is an urgent need for the regulatory role by the state, since this is also a highly distinctive market with direct and significant impacts on the health and life of human beings. Competition policy, therefore, needs to be integrated into the industrial and sectoral policies for the pharmaceutical industry in both short and long terms. These two types of policies have to go hand in hand and be treated equally, so that they do not result in protectionism against foreign investors or in opening the market without safeguards for infant industries.

In order to achieve the balance and consistency during the policy-making process in the pharmaceutical industry, including the distribution sector, there is a need to ensure that the implementation of the Competition Law in this industry is not adversely affected by specific sectoral regulations.

In order to realise this goal, the policy-making process of sectoral regulatory policies by the DAV needs to have the participation of the VCAD. ***And, the government should consider giving the VCAD the function of reviewing sectoral regulatory framework and policy, as an integral part of its competition policy advocacy function.***

## **2.2. Recommendations on Specific Legal Provisions**

In order to enhance the effectiveness of state regulations, in general, and the effectiveness of competition law enforcement, in particular, vis-à-vis the pharmaceutical distribution system, there is a need to complete the regulatory framework regarding the following specific legal provisions:

- ***Specific provisions to define exactly the pharmaceutical distribution system should be adopted:*** Currently, even though already dealt with in some laws, there remains no clear and consistent definition of the pharmaceutical distribution system. On the other hand, in order to enhance the supervisory role of the state in this field, this is a need of the hour. As mentioned in the part on market structure, the general concept of distribution comprises of all wholesaling, retailing, franchising and licensing activities. Meanwhile, the Law on Medicines states that pharmaceutical businesses include: manufacturers, exporters, importers, wholesalers, retailers, those enterprises which provide logistics services and those which undertake clinical tests and quality control. Therefore, we can understand that distribution means wholesaling and retailing. However, in practice, some understand distribution only as the retailing system. Thus, we need clear and specific provisions which can help to categorise various business activities, such as distribution services, and help determine the starting point of access to the distribution system.

Real business practices also show that some foreign logistics providers can easily get access to the distribution system by ways of exclusive logistics agreements, which cover the sale of inventories, even though they are not officially allowed to do so. Therefore, it is extremely essential that we adopt comprehensive and clear regulations on pharmaceutical distribution, especially in view of the January 1, 2009, milestone.

- ***Provisions regulating vertical agreements should be incorporated into the Competition Law:*** Business practices in pharmaceutical distribution system show that there are often vertical agreements therein, be it between manufacturers and distributors or between importers and distributors. And, most notable amongst all is the agreement between foreign manufacturers/suppliers and foreign distributors operating in Vietnam. Even though they are not allowed to import, these distributors often import under the cover of Vietnamese enterprises and impose certain conditions on these Vietnamese enterprises. Field survey results show that foreign distributors often establish long-term co-operation with Vietnamese enterprises regarding these authorised import orders. What's more, the imports by these Vietnamese enterprises are quite different from each other, which means each Vietnamese enterprise is only solely authorised to import specific products. The agreements between foreign distributors operating in Vietnam and foreign manufacturers/suppliers result in significant market power for the former, enabling them to set the prices for specific products with distributors. These practices are rampant because of two problems:

- The Competition Law of Vietnam does not provide for extra-territorial jurisdiction for the competition authorities.

- Besides, the Competition Law also does not have a clear distinction between horizontal and vertical agreements. Therefore, it is not possible to regulate vertical agreements using this Law, even though vertical agreements are most prevalent in the pharmaceutical distribution system in both developed and developing countries (as shown in the part on International experiences).

Therefore, in the long run, the Competition Law needs to be amended in order to be able to regulate the activities of enterprises, which are based beyond the territory of Vietnam, but have significant impacts on competition in Vietnam and regulate vertical agreements. In particular, in the pharmaceutical industry, which comprises of manufacturing-distributing and importing-distributing segments, it is essential to regulate vertical agreements, since their impacts on the overall competitive environment are not minimal. For example, in the case of vertical agreements, if a specific enterprise has market power over some types of medicines (patented and manufactured outside Vietnam), it can abuse this power to create pressure on its distributors and erect barriers to entry by potential competitors. If their conditions are not accepted, they might withdraw the medicines altogether from the market, while no other enterprise can import these medicines.

### ***2.3. Recommendations on Enhanced Supervisory and Regulatory Role by Relevant State Agencies over Competitive Practices in the Pharmaceutical Distribution Sector:***

The experiences of some countries at similar levels of development as Vietnam (such as China, Thailand and the Philippines) show that competitive behaviours in certain sectors are regulated by sectoral regulators, rather than the competition authorities, due to two main reasons: (i) there are no comprehensive and cross-cutting competition laws in place yet, and (ii) the competition law has been adopted, but enforcement is still limited, due to the absence of certain specific provisions or the lack of experiences of competition authorities to deal with distinctive behaviours in certain sectors, such as the pharmaceutical industry. This is also the case in Vietnam at the moment. In the long run, it is necessary to complete the legal and regulatory framework, as recommended above. In the short term, we need to enhance the mechanisms to be used by state agencies for supervising and regulating competitive behaviours in the pharmaceutical market, including distribution. The focus areas are:

- ***Competition monitoring and supervision in the pharmaceutical distribution sector should be promoted, in order to detect and adopt pre-emptive measures against anti-competitive practices such as abuses of dominant positions/monopoly to fix resale prices and impose unreasonable commercial conditions on customers:*** The Vietnam VCAD is responsible for regulating competitive behaviours in all markets in Vietnam. The Drug Administration of Vietnam (DAV – Ministry of Health) is responsible for regulating the behaviours of all pharmaceutical enterprises in the market. Besides, the Inter-ministerial Circular between the Ministry of Health, the Ministry of Finance and the Ministry of Industry and Trade No. 11/2007/TTLT-BYT-BTC-BCT dated August 31, 2007, which guides the implementation of state administration over prices of medicines used for humans, states that: The Ministry of Industry and Trade is

responsible for inspecting and regulating all competitive behaviours, monopolistic behaviours and other violations of the Competition Law. Therefore, with the functions clearly described in these laws and regulations, the important thing is to promote this supervisory and regulatory role of these relevant state agencies, as well as promote collaboration amongst them in both stages of *ex ante* and *ex post* regulation. *Ex ante* regulation has to be undertaken in a transparent manner and there should be separation between registration and granting of import licences. This would facilitate clear determination of whom allowed to participate in the distribution system (foreign enterprises are allowed to import, but not allowed to participate in the distribution system). Regulation has to be enhanced during the business registration process, as well as the course of doing business, specifically:

- Regarding market entry: There should be a database to monitor the competitive practices in the market.
  - Regarding the course of business: Monitoring to detect signs and potential risks of anti-competitive practices, such as horizontal and vertical agreements restricting competition or abuse of dominant positions or monopoly by enterprises with significant market power (equivalent to the capacity to raise prices above the level which prevails during normal competitive conditions and maintain the prices at such levels for a sufficiently long period, independent of the reactions of other market players). During the course of regulation, if detecting signs and risks of such violations, the state agencies need to timely inform enterprises so that they can take voluntary remedial actions.
- ***There is a need to promote the monitoring and supervision of vertical agreements, specifically:***

As mentioned above, vertical agreements can only restrict competition if the upstream firm has market power. In the current distribution system in Vietnam (with foreign enterprises supplying only imported medicines and imported medicines cater for around 50 percent of total domestic demand), there is no single enterprise in possession of dominant positions in the market (as per turnover). However, in practice, in some small market segments, some foreign enterprises are possessing significant market power (reflected through the capacity to set the market prices). In order to eliminate and prevent this practice, in the context that Competition Law does not regulate vertical agreements yet, there is a need to promote the monitoring and supervision of vertical agreements through the supervision of the undertakings such as:

- *Agreements between foreign enterprises with domestic enterprises, which have their own distribution network or such cases where foreign enterprises purchase assets of the domestic enterprises in order to gain control of the*



*distribution network of the latter:* Accordingly, in some specific markets, where these foreign enterprises have monopoly over imports, such purchase would adversely affect the competitive environment therein, deter new entries and affect existing players. For these cases, the DAV needs to collaborate closely with the VCAD during the review process and may need to apply certain conditions in specific cases to ensure competition.

- *Agreements between foreign enterprises with domestic enterprises regarding sole distributorship of some certain products in the market:* In these cases, even though these enterprises do not participate directly in the distribution system, they can still affect competition therein, through requirements of resale price maintenance. On the other hand, potential risks against competition are normally not made explicit in the content of the contracts, but are agreed implicitly, making them hard to be detected. Detection is only possible with the close co-operation amongst all relevant state agencies and between state agencies and the private sector (through provision of information and determination of violations).
- ***There is a need to strengthen the monitoring and supervision of economic concentration activities (M&As) in order to prevent foreign enterprises from taking control of domestic enterprises in order to gain access to the distribution system: There is also a need to pre-empt those factors which lead to “legal” abuse of dominant position in order to exclude other enterprises from the market since the manufacturers (foreign) do not sell to distributors.***

The field survey results show that, even without import licences, foreign enterprises have taken control of the market and forced some domestic distributors to exit from some certain markets, since they are unable to get access to foreign suppliers. In the future, when foreign enterprises are allowed to import directly, this risk would be even higher and unavoidable. Therefore, it is necessary to enhance the supervision of transactions on the Stock Exchange. The DAV is the focal point for receiving all the information regarding such transactions on the Stock Exchange. Therefore, the DAV needs to collaborate with the VCAD to update information and be able to prevent such potentially competition-restricting transactions.

#### ***2.4. Recommendations on Supporting Measures in order to Strengthen the Competitive Nature of the Pharmaceutical Distribution Sector - Increase the Transparency of Information, Create an Conducive Environment for Fair Competition, in accordance with the Competition Law, and not Erecting any Barrier to Entry***

- It is necessary to ***build up a database*** on existing market players, so as to identify those holding dominant positions/monopoly in the relevant markets or having the potential to become dominant/monopoly. This database needs to be transparent and

made public annually so that state agencies and enterprises, alike, are aware of the situation, the market structure and potential risks against competition in the market.

- ***VCAD should undertake studies and research so as to recommend pre-emptive measures against breaches of the Competition Law to be incorporated into other relevant laws and policies***, such as recommendations for planning and developing the pharmaceutical industry of Vietnam, recommendations for restructuring and organising the distribution system, joint co-operation programme between the Ministry of Health and the Ministry of Industry and Trade. This would help enhance the effectiveness of the supervision and regulation by the state over the sector on the basis of: strictly prohibiting anti-competitive practices, abuses of market power and providing fines and remedies with deterrent effects.

### ***2.5. Recommendations for the Business Community***

- ***Increasing the awareness of enterprises currently doing business in the pharmaceutical industry and those in the pharmaceutical distribution sector, in particular***: In the first place, the field survey results show that most pharmaceutical enterprises are not interested in getting to know more about the Competition Law. Besides, some foreign enterprises think they are not within the purview of the Law, since they do not have commercial presence in Vietnam (only representative offices). Therefore, they might:
  - Violate the Competition Law unintentionally;
  - Not know how to use the law to protect their legitimate rights and interests; and
  - Not be able to assess the impacts and consequences that distorted competition might have on them.

The process of awareness-raising needs to be holistic, including activities such as campaigns and information dissemination sessions or publication of materials on the Competition Law for enterprises.

Secondly, enterprises need to be proactive in learning more about the Competition Law and other relevant laws and regulations, as well as updating information. Enterprises need to proactively consult with relevant state agencies when they think there are signs of anti-competitive practices which affect their business.

- ***Warning enterprises not to include such contractual clauses that may restrict competition, for example***:
  - fixing prices directly or indirectly;
  - dividing customers or supplies; or

- preventing other enterprises from entering the market.

## **ANNEXURES**

### **ANNEX 1**

#### **LIST OF LARGE DISTRIBUTORS IN VIETNAM**

##### **1. Domestic Companies**

- PhytoPharma – HCM City
- Coduphar – HCM City
- Sapharco – HCM City
- Vimedimex II – HCM City
- Vimedimex I – Hanoi
- Hapharco – Hanoi
- Dapharco - Danang

##### **2. 26 Representative Offices of Large Foreign Pharmaceutical Companies in Vietnam**

GlaxoSmithKline – UK	Sandoz – Switzerland
Astra Zeneca – UK	Peirre Faber – France
Pfizer – US	Le Servier – France
Bristol Mayer Squyp – US	Organon – Holland
Merck – US	Solway – Holland
Janssen Cilag – belonging to Johnson & Johnson (US)	Gedeon Richter - Hungary
Bayer – Germany	Egis – Hungary
Baxter – US	Medochemie – Kypros
Boehringe – Germany	Ebewe – Austria
Berlin Chemie – Germany	Biocheme – Austria
Schering AG – Germany	Alcon – Belgium
Roche – Switzerland	Ciech Polfa – Poland
Ipsen – France	Konimex – Indonesia

##### **3. Specialised Distributors/Marketing Agents for One or more Manufacturers**

Zuellig Pharma – Singapore	Vien Dong – Vietnam
Mega Product – Thailand	Dong A – Vietnam
Diethelm – Switzerland	Do Thanh – Vietnam
Tenamyd Canada – Canada	IC Vietnam – Vietnam
Tedis SA – France	

## **ANNEX 2**

### **THE METHODOLOGY FOR FIELD SURVEYS**

#### **1. Motivations for Undertaking Field Surveys**

The report of the DAV at the Pharmaceutical Conference 2008 states that one of the biggest problems remaining in the supply of medicines at present in Vietnam is the fierce competition, whereas demand is increasingly steadily. Therefore, in order to be able to assess, in the most realistic manner, the status of competition in the market, as well as to detect signs of anti-competitive practices therein, we decided to undertake the field surveys. Field surveys helped us collect specific, most updated and accurate information about the business activities and competition amongst enterprises. Through the undertaking of field surveys, already available information would be compared with the real practices, in addition to new revelations during interviews with enterprises. On that basis, we build a comprehensive picture of the pharmaceutical distribution system in Vietnam.

#### **2. Selection of Target Groups for Field Surveys**

With the number of 800 enterprises in total in the market, it requires huge financial and human resources to interview all of them. Therefore, the best choice possible is through conducting interviews, through sampling.<sup>162</sup>

Enterprises were selected on the basis of:

- Representative sampling

In accordance with the prevailing market structure, we selected enterprises on the basis of their types:

- State-owned enterprises: mainly amongst those previously owned by the state, now already equitized, including manufacturers with licences to directly import medicines into Vietnam;
- Private enterprises; and
- Foreign-invested enterprises (FIEs).

- Random sampling

- On the basis of the list of enterprises in the whole industry, we randomly selected some enterprises for interview. This random selection was mainly for retailing enterprises such as hospital pharmacies or private pharmacies.
- Besides, we also chose, at random, 100 patients, 50 doctors, 20 pharmacists and pharmaceutical salesmen in some hospitals, private clinics, pharmacies

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<sup>162</sup> Sampling means the selection of certain enterprises amongst all for interviews, then on the basis of the results collected, deduction can be made for the whole system. The advantage of this approach is that it requires less financial and human resource. It can be undertaken with less time, provides accurate results and quite in-depth information.

and retailing stores to take stock of consumption patterns and the “substitutability” of medicines.

### **3. Methodology for Field Surveys**

- Examining secondary sources of information: We studied the information and data already available from sources such as the General Statistics Office (GSO), the DAV, other research studies and the mass media.
- Mapping of information to be collected, including:
  - o Awareness of enterprises regarding the Competition Law;
  - o Enterprises’ perceptions regarding state administration in the pharmaceutical sector;
  - o Competitive practices of enterprises so as to detect signs of anti-competitive practices in the pharmaceutical distribution system; and
  - o Consumption patterns and the substitutability of products.
- Questionnaire design
- In-depth interviews with enterprises in two ways:
  - o Getting to understand the general information possessed by enterprises regarding the general pharmaceutical market, as well as the distribution sector, strategic behaviours of enterprises as well as competition between them on the market.
  - o Proposing some specific problems to understand the reactions of enterprises on issues related to competition in the pharmaceutical distribution system, as collected before.

### **4. Geographical Coverage**

We selected Hanoi and Ho Chi Minh City as the field survey sites, since these are the two biggest commercial and financial centres in the whole of Vietnam. These are also the two regions where consumption of medicines is the highest, accounting for 76 percent of the total national demand. Ho Chi Minh City is the biggest market, accounting for 55 percent of the total demand, while Hanoi accounts for 21 percent.<sup>163</sup>

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<sup>163</sup> Vietnam Pharmaceutical Industry Analysis – Vietcombank Securities 2008.

**ANNEX 3**

**QUESTIONNAIRE**

**Note**

Information collected is meant for a report on “Using Competition Law to Regulate Anti-competitive Practices in the Pharmaceutical Distribution System in Vietnam”.

The Vietnam Competition Administration Department (VCAD) would ensure the confidentiality and anonymity of the information provided by you, especially for those specified as confidential information.

**A. General Information**

Please provide us with the following information:

1. Name of the company:
2. Area of business:
3. Address:
4. Telephone:
5. Legal representative:
6. Year of establishment:
7. Number of workers:
8. Geographical coverage:
9. Annual turnover:

**B. Enterprises’ Awareness on the Competition Law**

1. Are you aware of the existence of the Competition Law?
  - a. No
  - b. Yes, but not in details
  - c. I have read through it once
  - d. I have gone through it many times
  - e. I have quite a good grip over competition issues
2. In your opinion, are you subject to the regulation by the Competition Law?
  - a. Yes
  - b. No
3. Do you think the provisions of the Law are appropriate?
  - a. Yes
  - b. No

Please explain why for both options.

4. In the event of unfair trade practices by your competitor(s), how would you react?
  - a. Filing a complaint
  - b. Retaliating with similar measures
  - c. No reactions
  - d. Others, please specify
5. Where would you go for filing a complaint?
  - a. The court of law
  - b. The Competition Administration Department

**C. State Administration in the Pharmaceutical Sector**

1. In order to distribute medicines in the market, what types of permits, certificates are required? Who is the issuing authority for these permits and certificates?
2. Do you think it is justifiable for the State to intervene (such as through price administration) into the operations of the pharmaceutical market?

**D. Economic Activities and Competition in the Sector**

1. Please describe the distribution chain for medicines to reach the consumers?
2. What are the pharmaceutical products you are distributing? How many are domestically-produced and how many are imported products?
3. Please specify whether visa numbers are given to specific type/brand of medicines or to manufacturers?
4. What benefits would sole possession of visa numbers bring?
5. In the case where sole distributorships for certain products are granted to distributors by manufacturers, who would decide the prices of such products, the manufacturers or the sole distributors?
6. What are the bases for calculating market prices?
7. Who is responsible for registration and listing of medicine prices in your company?
8. Who are your large business partners/customers?
9. Do you think the combination of large distributors in the market to increase their competitive advantages is legal? Is it beneficial for the distribution system or the consumers?
10. Please name five biggest companies in the pharmaceutical distribution sector in Vietnam?
11. Do you think it is justified to have a network of agreements between importers and distributors? Please explain these agreements/relationships.



12. Are you aware of any such agreements?
13. Have you encountered any unfair trade practices in your course of doing business?  
Please provide some more details.
14. Please 3 to 5 behaviours you consider as unfair and unjust in the market.
15. In your opinion, after Vietnam becomes a WTO member, would competition in the pharmaceutical market be fiercer?
  - a. Yes
  - b. NoPlease explain why in both cases
16. After Vietnam becomes a WTO member, there would be more foreign enterprises entering into the market (as direct importers), how could these enterprises get access to the Vietnam market in the most effective manner, in your opinion?
17. Did you ever try to defend your position in the market?
  - a. Yes
  - b. NoIf yes, please describe how
18. Are you ready to cooperate with other companies in the same trade to defend your position against the entrance of such foreign companies?
  - a. Yes
  - b. No
19. What would you do if a foreign enterprise offers to buy your stocks or enter into a joint-venture with your company?
20. What do you think are the influences that doctors, hospitals and pharmaceutical salesmen have over the distribution system and the overall competitive environment?

## **ANNEX 4**

### **SOME FIELD SURVEY RESULTS**

#### **1. Enterprises' Awareness on the Competition Law**

##### ***1.1. Assessment Criteria***

Competing is one of the essential business strategies in a market economy. In order to survive and grow, enterprises have to defend themselves against their competitors. Therefore, they form their own strategies. The state is responsible for ensuring a fair and healthy competitive environment for all market players by using competition law and policy as legal instruments, in accordance with the distinctive features of each industry and sector.

The Competition Law of Vietnam was passed by the National Assembly in the VII<sup>th</sup> working session of the XI<sup>th</sup> National Assembly and took effect from July 1, 2005, which is more than three years ago. The law has quite a comprehensive scope of regulation, including the pharmaceutical industry and its distribution sector.

The assessment criteria regarding the awareness of enterprises in the pharmaceutical distribution sector on the Competition Law include:

- Awareness of the existence of the Competition Law;
- Understanding of the content of the Law;
- Understanding of the role of the competition authority; and
- Understanding of the rights and obligations of enterprises in specific competition cases and understanding how to use the Competition Law as an instrument to protect their own legitimate rights and interests in the market.

##### ***1.2. Survey results***

Awareness of the overall business community about the Competition Law is not high. Field survey results show that 82 percent of the interviewees are aware of the existence of the Law, but they do not have deep understanding of the Law. Eighteen percent of the interviewees are not even aware of the existence of the Law, including one large enterprise (previously owned by the state).

Most of the interviewees are aware of the role played by the competition authorities.

The survey results regarding the understanding of the rights and obligations of enterprises in specific competition cases and understanding on how to use the Competition Law as an instrument to protect their own legitimate rights and interests in the market is quite surprising. Most enterprises do not know these issues. Two 100-percent foreign-owned enterprises even said they are not subject to the regulation of the Law.

Some enterprises pointed out that there are a lot of unfair trade practices in the market (they have encountered), but these practices have not been effectively handled by competition authorities. Even the enterprises do not know that they can file a complaint in such cases.

## **2. Enterprises' Perception regarding the State Administration in the Pharmaceutical Sector**

Most enterprises thought that the pharmaceutical industry is a very distinctive sector, which calls for stringent administration and supervision by the state. They also opined that the requirements set by professional licences or permits and standards such as GMP, GDP, GLP, GPP or GSP are appropriate. However, there remain some problems such as:

- The period of time required for consideration and issuance of permit is still long, which might affect the business opportunities;
- There is inappropriate administration of medicine prices, resulting in unfair pricing in the market, especially between prices of domestically-produced medicines and imported medicines (for example, the DAV did not allow enterprises to increase medicine prices during the period for inflation control, but did not provide any support either, whereas input prices had increased significantly, further aggravated by the increased value of US dollars, as compared to Vietnamese dong, etc.).
- Regulations requiring that the maximum spending for advertisement and sales promotion is 10 percent of the turnover are not appropriate for domestically-produced medicines. (In the case of imported medicines, these expenditures have already been included in prices, inflating the prices and also making it impossible for domestically-produced medicines to compete, etc.).

## **3. Substitutability of Products**

Patients do not have any choice over the medicines to be 'consumed', since they are dependent on the prescriptions of doctors. The question is who would be considered as "consumers" – the doctors or the patients – in defining the relevant markets as per the Competition Law?

The survey results are as follows:

<b>S. No.</b>	<b>Issues</b>	<b>Patients</b>	<b>Doctors</b>	<b>Pharmaceutical salesmen</b>
1	Demand for normal medicines (aspirins, pain relievers, vitamin, etc)	Purchase by themselves	No need for prescription	Sale according to orders
2	Demand for patented medicines	Purchase according to prescriptions by doctors	Prescribing according to treatment charts	Sale according to orders

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3	Substitutability between medicines in terms of therapeutic categories	Don't know	Might be similar	
4	Substitutability between medicines in terms of usage	Don't know	Might treat the same diseases, but their effects might vary, depending on dosage, time, etc.	
5	Substitutability between medicines in terms of pricing	For prescribed medicines, purchase is a must even in the case of price increase.  Switching between stores for the best options possible or re-consultation with doctors.	No comment	When there is no supply for order, might recommend other similar medicines of the same therapeutic categories.

This result shows that pharmaceuticals comprise of many different types, used to treat different diseases. Even when they contain similar active elements or ingredients and treat the same diseases, they may still have different medical effects and can be used only with different specific dosage, on different groups of patients. Therefore, they are not easily substitutable, especially in terms of prices (as mentioned in the Competition Law).

## **ANNEX 5**

### **SOME UNFAIR TRADE PRACTICES AND VIOLATIONS OF CONSUMER PROTECTION POLICY IN THE PHARMACEUTICAL INDUSTRY IN VIETNAM**

According to the Competition Law 2004 of Vietnam, unfair competition acts mean competition acts performed by enterprises in the process of doing business, which run counter to common standards of business ethics and cause damage or can cause damage to the state's interests, legitimate rights and interests of other enterprises or consumers.

Amongst the unfair competition acts prohibited by the Competition Law, practices such as misleading indications, advertising and sales promotion with the purpose of unfair competition are those most closely related to the benefits of the consumers.

Besides, according to the current consumer protection policy of Vietnam, in the pharmaceutical industry, we can detect such practices as: manufacturing and trading in fake medicines, misleading information, advertisements and sales promotion, deceptions and acts which are harmful to the health and life of consumers.

Finally, the fact that medicine prices in Vietnam are often inflated excessively, as compared to other countries in the region, may also affect the rights and interests of the consumers.

#### **1. Manufacturing and Trading in Fake Medicines**

Fake goods are quite rampant in Vietnam under many covers, such as: fake quality, fake labels or fake in both quality and labels. Especially, faking of famous brands has switched to labelling in similar fashions as those in famous brands. These practices are not only in violation of the law but are also deceptive in nature, harming the legitimate right and interests of consumers and adversely affecting the safety and health of consumers, especially in such an area as the pharmaceutical sector. Fake medicine is a serious issue in Vietnam which needs to be addressed urgently.

Some cases which have been resolved related to fake medicines vis-à-vis patented medicines in Vietnam are presented below:

- (i) UPHA-BIO medicine vs. ANTIBIO produced by Organon Co.;
- (ii) GASROTODIC medicine vs. Ipsen's GASTROPULGITE;
- (iii) Haipharco's 'Hoat Huyet Duong Nao' vs. Traparco's 'Hoat Huyet Duong Nao';
- (iv) NAPHANOR medicine vs. POSTINOR;
- (v) POSINIGHT medicine vs. POSTINOR; and
- (vi) POSTOROSE medicine vs. POSTINOR.

## **2. Misleading Information or Insufficient Information**

According to current laws and regulations, medicine prices (for wholesaling, retailing as well as importing) have to be registered with the relevant state agencies. Especially, retailing prices have to be clearly and fully listed at the site of the pharmacies. Besides, the retailing prices have to be pasted on the cover or package of the medicines so that the consumers can see and must not be higher than the listed prices. However, these regulations are hardly observed in practice, harming consumers. Violations detected include:

- (i) Not listing the prices or listing the prices of only some products;
- (ii) Only listing the generic names but not the names of prescribed medicines;
- (iii) Listing the prices of imported medicines but selling domestically-produced medicines at the same prices; and
- (iv) Having price lists but not updating or keeping the price lists as small in size as possible, etc.

These deceptive practices by retailing stores and pharmacies are in violation of their obligations to provide clear and sufficient information to consumers. Health inspectorates in big cities like Hanoi and Ho Chi Minh City have uncovered and handled several such cases in the last two years. However, in remote regions or rural areas, where the level of awareness of consumers remains limited, such practices must be more rampant and more serious.

Another violation related to information is about the expiry date of medicines or the withdrawal of choice between imported medicines, domestic medicines and generic medicines.

In Vietnam, it is quite a common practice to sell prescribed medicines over the counter or unlabelled medicines or expired medicines, both at wholesaling or retailing stores and in hospitals. These deceptions are based on withdrawal of important information from consumers and may harm them seriously.

Consumers might also be cheated when trying to buy frequently-advertised medicines on the mass media. Taking advantage of the limited awareness of consumers, manufacturers or wholesalers and retailers might sell them other products with similar names.

Besides, since large pharmaceutical companies often pay a lot of commissions to doctors, doctors may prescribe or tend to prescribe more expensive imported medicines. Coupled with limited awareness of the end consumers, imported medicines are often traded more popularly, despite high prices.

## **3. Illegal Advertisement or Sales Promotion Activities**

These above-mentioned mistakes of the consumers are very often caused by advertisements or sales promotion tactics or measures to gain more market shares and maximise the turnover by pharmaceutical companies. At present, in Vietnam, it is prohibited to advertise poisonous medicines, addictives, unregistered medicines and other medicines related to the mental system. Prescribed medicines are also not allowed to be advertised, but marketed directly to

consumers via doctors and health care staff. Pharmaceutical companies are allowed to market their products to doctors and health care staff by ways of conferences, seminars and through specialised salesmen. However, most OTC medicines can be advertised on the mass media quite freely. Some companies have gone overboard on such advertisement or chose to withdraw certain information adversely affecting the safety and interests of the consumers.

According to the WHO, in 2004, only 16 percent of all countries in the world can manage pharmaceutical advertising effectively, while 30 percent do not take any measures or do not do much.

In Vietnam, there is also another type of ‘sham’ advertisement – which might be seriously deceptive. These advertisements are published on the mass media as letters of thank from the patient to doctors, pharmacies or patented medicines. Sometimes, they are ‘shammed’ as doctors’ advice or awards or instructions by doctors, etc. These ‘sham’ advertisements need to be closely checked and dealt with.

## REFERENCES

Consumer Unity & Trust Society (2006), *Options for Using Competition Law/Policy Tools in Dealing with Anti-competitive Practices in the Pharmaceutical Industry and the Health Delivery System*, Report prepared for Office of the World Health Organisation to India and the Ministry of Health and Family Welfare, Government of India, available at <[http://whoindia.org/LinkFiles/Trade Agreement Final Report IND GPE 002-3rd.pdf](http://whoindia.org/LinkFiles/Trade_Agreement_Final_Report_IND_GPE_002-3rd.pdf)>

Nitya Nanda and Ritu Lodha (2002), *Making Essential Medicine Affordable to the Poor*, Wisconsin International Law Journal, Vol. 20, No. 3.

World Bank (2009), *Doing Business*, 2009.

Tang Van Nghia (2007), *Problems and Solutions for Effective Enforcement of the Competition Law*, Research study at ministerial level No. 2005-78-012, Hanoi.

Dang Vu Huan (2004), *Laws and Regulations on Anti-monopoly and Unfair Trade Practices in Vietnam*, National Political Publishing House, Hanoi.

Central Institute for Economic Management (2002), *Legal and Institutional Issues regarding Competition Policy and Regulation of Monopolies*, Transportation Publishing House, Hanoi.

Alice Pham (2005), *The Development of Competition Law in Vietnam in the Face of Economic Reforms and Global Integration*, Northwestern Journal of International Law and Business.

Le Danh Vinh (2003), *Building Competition Law in Vietnam to Meet the Need of Regulating Market Economy and in the Light of Trade Liberalisation and International Economic Integration* (2003), Presentation at the ASEAN Conference on Competition Law and Fair Trade Policy in the ASEAN Free Trade Area (AFTA), Bali, from 5 to 7 March 2003, [www.jftc.go.jp/eacpf/01/vietnam\\_p.pdf](http://www.jftc.go.jp/eacpf/01/vietnam_p.pdf) at 20/10/2008

Vietnam Chamber of Commerce & Industry (2006), *The Study on Capacity Building for Enforcement of Competition Law and Implementation of Competition Policy in Vietnam*, Pilot Market Research.

OECD (2000), *Competition in the Pharmaceutical Industry – Korea*, DAFFE/CLP/WP2/WD (2000)25.

European Association of Euro-Pharmaceutical Companies (2005), *Understanding Competition in the Distribution of Pharmaceutical Products in Europe - An Analysis of the Application of Article 82 EC to Supply-Restrictions in the Pharmaceutical Sector*, available at [www.eaepc.org](http://www.eaepc.org)

BMI (2008), *Vietnam Pharmaceuticals and Health Care Report Q1/2008*, Part of BMI's Industry Survey and Forecasts Series.

VCBS (2008), *Vietnam Pharmaceutical Industrial Analysis*, available at [www.vcbs.com.vn](http://www.vcbs.com.vn)



Trudi Hartzenberg (2002), *Select Competition Issues Arising from Changes in the Distribution of Pharmaceutical Products in South Africa*, Development Policy Research Unit, University of Cape Town

World Trade Organisation (2006), *Report of the Working Party on the Accession of Vietnam*, WT/ACC/VNM/48.

US DOJ & FTC (2004), *Improving Health Care: A Dose of Competition*, Joint Report.

Shenglan Tang, Jing Sun, Gang Qu and Wen Chen (2006), *Pharmaceutical Policy in China: Issues and Problems*, Internet.

Danish Trade Council (2006), *The Pharmaceutical Industry in Thailand*, Sector Overview.

Ellen F.M. Hoen (2009), *The Global Politics of Pharmaceutical Monopoly Power - Drug Patents, Access, Innovation and the Application of the WTO Doha Declaration on TRIPS and Public Health*, AMB.

Law No. 34/2005/QH11 on Medicines of Vietnam

Law No. 27/2004/QH11 on Competition of Vietnam

Law No. No. 50/2005/QH11 on Intellectual Property Rights of Vietnam.

And other laws and regulations