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Contents

Drug - Healthcare	2
New Law To Bring Pharmaceutical Prices Down.....	2
Other documents in healthcare sector.....	3
Other Sectors.....	4
Finance	4
Price	4
Trading.....	4
Banking	4
Securities	4
Customs	5
Labour	5
Insurance.....	5
Information Technology.....	5
Industry	5
Inspection.....	5
Land.....	5
Miscellaneous	5
Contact Details.....	7

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Drug - Healthcare

New Law To Bring Pharmaceutical Prices Down

By Nguyen Thanh Xuan

The National Assembly passed the Pharmaceutical Law (Law) at its seventh session on 19 May, 2005. Published on 13 July, 2005 and effective as from 1 October 2005, this is the first ever enacted text governing all fields of pharmaceuticals in Vietnam. Prior to the Law, all activities in connection with pharmaceuticals were conducted in accordance with an array of decisions, circulars, official letters and even internal regulations issued by various authorities.

The Law governs the trade, registration, circulation, use and supply of pharmaceuticals. It also covers the information and advertising of pharmaceuticals; pharmaceutical clinical trials; management of addictive drugs, psychotropic medicines, pre-substances used for pharmaceuticals and radioactive pharmaceuticals and specification and testing of pharmaceuticals.

Local pharmaceutical production now meets only 40 per cent of the domestic demand and the remaining 60 per cent depends on imports. In the past, consumers have vehemently criticised astronomical drug price rises and called for more regulatory changes so drugs become affordable to patients. In an attempt to deal with this issue, the Law stipulates clearly in Article 3 of the State's policies on pharmaceuticals, the priority to turn the pharmaceutical industry into a key economical one is regarded as a long term policy. The State encourages local and foreign individuals and organisations to carry out research on biological technology and pharmaceuticals so as to manufacture new drugs and invest more in the sector.

Along with encouraging policies, prohibited activities are also listed in the Article 9 of the Law in order to ensure the core function of drug regulatory system, protecting consumers from products which are unsafe, ineffective and fraudulently marketed.

On the management of drug prices, Article 5.1 of the Law stipulates that the State manages the drug prices on the basis of respect of the right to fix manufacturers' drug prices and import-export companies and traders. However, the State will use appropriate measures to stabilise drug prices in the market. The State management of drug prices will be the responsibility of the Ministry of Health (MoH) in co-ordination with the Ministry of Finance, Ministry of Industry, Ministry of Trade, Ministry of Planning and Investment and other relevant agencies.

As for the manufacturers and import-export companies, under Article 5.2 of the Law, they have to fully comply with the following principles: (i) drug prices must be declared prior to circulation of drugs on the market and re-declared upon changes with the competent authority, ensuring that the drug prices in Vietnam are not higher than those in regional countries which have the same conditions of economy; (ii) the manufacturers and import-export companies will be responsible for the declaration of drug prices; and (iii) the wholesale and retail selling prices must be listed.

In fact, the above principles are not new to the manufacturers and import-export companies. They are implementing these guidelines pursuant to the Circular 07/2004/TT-BYT dated 31 May, 2004 governing the import and export of pharmaceuticals and cosmetics affecting people's health up to the end of the year 2005. However in spirit of the Articles 5.1 & 5.2, it is recognised that the manufacturers and import-export companies are entitled to fix the drug prices and they are only required to notify the changes on declaration of drug prices without waiting for written approval for changes from MoH or any relevant authorities. Article 5 should be implemented in accordance with this interpretation as the changes of drug prices may happen as long as the fluctuation of the import drug prices and the lengthy of the time-limit (six months) for registration of a pharmaceutical finished product.

As defined in Article 2 of the Law, pharmaceuticals include pharmaceutical finished products, pharmaceutical raw materials, vaccines and biological items and exclude nutrient foods. But it seems that Chapter III relating to the registration and circulation of pharmaceuticals is only applied to the pharmaceutical finished products. The vaccines and bio-medical products will be registered in compliance with current regulations. Under the Law, the Minister of Health will grant visas for registered pharmaceutical products within six months upon full receipt of a proper application. This procedure is regarded as an improvement as under the current Decision 3121/2001/QĐ-BYT, dated 18 July 2001, of the MoH, such duration is 12 months.

The Law is almost silent on most related issues of pharmaceutical intellectual property rights. With 73 articles and 11 chapters, the Law only provides an overall structure for conducting pharmaceutical activities in Vietnam. It still requires issuance of implementing guidelines to fill in a number of issues left unaddressed by the Law. We need to wait for a more detailed and comprehensive guidance on the registration, the import-export of pharmaceuticals in the coming time as promised by the director of Drug Administration of Vietnam in the Workshop on the export-import, supply and distribution of drugs held in Hanoi in June this year.

Other documents in healthcare sector

- Decision 20/2005/QĐ-BYT, dated July 26, 2005, of the Ministry of Health, regulating the function, tasks, rights and organizational structure of Department of Preventive Medicine of Vietnam.
- Interministerial Circular 20/2005/TTLT-BYT-BTC, dated July 27, 2005, of the Ministry of Health and the Ministry of Finance, guiding the implementation of bidding for supplying medicine to State owned healthcare establishment.
- On August 08, 2005, the Prime Minister issued Decision 196/2005/QĐ-TTg, on the establishment of Medical Insurance Department, which belongs to the Ministry of Health.

Other Sectors

Finance

- Circular 57/2005/TT-BTC, dated July 15, 2005, of the Ministry of Finance, guiding the management, using and the finalization of the expenditure supported by the State budget for the employment organization.
- Decision 2403/QD-BTC, dated July 21, 2005, of the Ministry of Finance, on announcement of the finalization of the State budget of 2003.
- Decision 52/2005/QD-BTC, dated July 25, 2005, of the Ministry of Finance, on abrogation of the fees on quota for exporting of garment and textile to the US market.
- On August 04, 2005, the Ministry of Finance issued Decision 54/2005/QD-BTC, promulgating the fee for granting work permit for foreign employee working in Vietnam.
- On August 04, 2005, the Ministry of Finance issued Decision 55/2005/QD-BTC, regulating the import duty for garment and textile from Australia.
- On July 26, 2005, the Ministry of Finance issued Circular 59/2005/TT-BTC, guiding the collection, payment, management and use of driving testing fee.

Price

- On August 03, 2005, the Prime Minister issued Decree 101/2005/ND-CP, on the appraisalment of the price.

Trading

- The Ministry of Trade issued Decision 2085/2005/QD-BTM, dated July 26, 2005, on the establishment of Export Supporting Centre, under the Trade Promotion Department.

Banking

- On August 01, 2005, the State Bank of Vietnam issued Decision 1130/2005/QD-NHNN, on amendment of and supplementation to a number of articles of the Regulations on regulatory reservation on credit institutions.

Securities

- The Prime Minister issued Decision 189/2005/QD-TTg, on July 27, 2005, on the establishment of Centre of Securities Deposit.

Customs

- The Ministry of Finance issued Decision 50/2005/QD-BTC, on July 19, 2005, regulating the process of the pilot implementation of electronic customs procedure.

Labour

- On August 09, 2005, the Ministry of Labor, War Invalids and Social Affairs issued Circular 21/2005/TT-BLDTBXH, on additional guiding Circular 11/2005/TT-BLDTBXH, on adjustment of pension and social insurance allowance.

Insurance

- Interministerial Circular 21/2005/TTLT-BYT-BTC, dated July 27, 2005, of the Ministry of Finance, the Ministry of Health, guiding the implementation of compulsory health insurance.

Information Technology

- Interministerial Circular 02/2005/TTLT-BCVT-VHTT-CA-KHDT, dated July 14, 2005, of the Ministry of Post and Telecommunication, the Ministry of Culture, the Ministry of Public Security and the Ministry of Planning and Investment, on the management of Internet agencies.

Industry

- The Ministry of Industry issued Circular 04/2005/TT-BCN, on August 02, 2005, guiding the mineral export for the period of 2005-2010.

Inspection

- On July 28, 2005, the Government issued Decree 99/2005/ND-CP, with detailed regulations and guiding the implementation of a number of articles of the Law on Inspection, especially on the organization and operation of People's Inspection Section.

Land

- The Ministry of Resources and Environment issued Circular 04/2005/TT-BTNMT, on July 18, 2005, guiding the management and using of land in the time of arrangement, innovation and development of State-run farms.

Miscellaneous

- Decision 181/2005/QD-TTg, dated July 19, 2005, of the Prime Minister, regulating the classification and ranking of public professional and service organizations.

- Decision 184/2005/QĐ-TTg, dated July 21, 2005, of the Prime Minister, on the approval of the Project on national archives insurance to the year of 2010.
- On August 19, 2005, the Prime Minister issued Decree 108/2005/NĐ-CP, on amendment of and supplementation to a number of articles of Government's Decree 51/CP, dated May 10, 1997, on registration and management of residence books.

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