HKAPI
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Position Paper on the Pharmacy and Poisons (Amendment) Bill 2014

Formed in 1968, the Hong Kong Association of the Pharmaceutical Industry (HKAPI), represents 40 international companies engaged in the research and development of pharmaceuticals including the world's top 20 (Appendix 1). Our member companies, including regional distributors, provide over 70% of the prescription medicines and distributing over 80% of imported pharmaceutical products in Hong Kong.

The principal consideration of the Association when examining the proposed amendments to the Pharmacy and Poisons Ordinance is, whether these proposed changes can practically enhance the existing supply chain system and further protecting patients safety in Hong Kong.

In addition, Pharmaceutical Industry is the second highly regulated industry in the world as Aviation is number one. There are international practices which were developed for decades, such as **Good Clinical Practice** for clinical trial, **Good Manufacturing Practice** for drug manufacturing, **Good Distribution Practice** for pharmaceutical and medical device distribution. Whether these changes are in line with international practices and whether the industry can comply with the regulations to achieve the objectives of the legislation are also considerations.

HKAPI supports the legislative amendments put forward by the Food and Health Bureau in response to the recommendations made by Review Committee on the Regulation of Pharmaceutical Products in Hong Kong.

Specifically, we have some comments on the following proposed amendments:

Clinical trial certificate

It is proposed that the maximum validity period of any clinical trial certificate to be extended from 2 to 5 years. It takes on average 10 to 12 years for a new drug to be developed, which include three phases of clinical trial. All approved clinical trials in Hong Kong are required to follow **Good Clinical Practice (GCP)** guidelines which define the standards on how clinical trials should be designed and conducted by the

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investigators. Investigators also need to submit a progress report every year on the clinical research to the health authority. The application for a renewal of the clinical trial certificate will interrupt the trial until a renewal is granted and the administrative approval procedure has to be repeated every two years. Extending the validity of the clinical trial certificate can reduce unnecessary administrative burden without reducing the safety monitoring of clinical trials, and more importantly, can increase Hong Kong's attractiveness and capacity for medical research and clinical trial.

Negative vetting for new drug registration

To improve the efficiency of the drug registration system while maintaining appropriate regulatory control, employing negative vetting procedure could be the first step for Hong Kong to catch up with international regulatory practice in drug registration.

It is proposed by World Health Organization (WHO) to evaluate drug registration by efficacy, safety and quality. The evaluation is a pure scientific evaluation based on clinical papers that in most countries, the drug registration decisions are made under the health authorities without any intervention of administrative authorities, not to mention it has to go through the legislative procedure. Currently in Europe, the US and some advanced Asian countries such as Korea, Japan, Taiwan and Singapore, decision of drug registration is designated to the Health Authorities.[1]

In Hong Kong, the applicants of drug registration need to provide two Certificates of Pharmaceutical Products (CPP) issued by ICH countries[2] when applying for drug registration. The application will then be evaluated by the Registration Committee, Poisons Committee and the Pharmacy and Poisons Board. The scientific evaluation

[1] None of the legislative bodies in Australia, Korea, Singapore, Taiwan, EU, and the States plays a role in the drug approving procedure. The classification and approval of NCE falls entirely under the responsibility of the Health Authority. It is no Legislative procedures during the drug evaluation process.

[2] The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of pharmaceutical product registration. ICH countries refer to countries with their health authorities using the ICH guidelines for pharmaceutical product registration.

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takes 8-12 months on average. If approved, the whole registration procedure will be completed with the legislative approval procedure in the Legislative Council (LegCo).

We agree with the negative vetting procedure for new drug registration approval as it also avoids delaying in registration caused by ad hoc agenda items at LegCo meetings and increases the efficiency of the new drug registration process as we found that some new drugs, including those for the treatment of cancer, had taken 3 to 9 months to be tabled in LegCo during 2011-2012, and with recent debates in important political agenda, the process can be further delayed.

Written Order

Drug incident in 2009 proved that things can go wrong if we rely too much on a single procedure and person. **Good Distribution Practice (GDP),** which has been developed for more than two decades, with guidelines under WHO and European Commission, is a quality warranty system that includes requirements for purchase, receiving, storage and export of drugs, by which order verification and delivery verification are important parts of it.

Written order is an important and integral part of the supply chain management of pharmaceutical products under GDP for order verification. The guidelines on GDP of medicinal products published by the European Commission states that **'Written documentation should prevent errors from spoken communication and permits the tracking of relevant operations during the distribution of medicinal products.'** In Hong Kong, the Hong Kong Medical Association recommended in their Good Dispensing Practice Manual that the ordering of drugs from suppliers should be made in writing, the written orders should be kept for verification and all practising doctors should comply with the Good Dispensing Practice Manual.

In general, a written order contains the name of the product, dosage, pack size and quantity. Although the information required for an order is not a lot, wrong orders happen from time to time, and without written order, there would not be any solid reference to verify the order during delivery.

For other products, wrong delivery can be returned. However, it is not the case for

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pharmaceutical products as there are stringent requirements on the storage of pharmaceuticals, including the control on temperature and humidity and the **First In First Out** procedure [3] has to be followed. For example, vials needed to be refrigerated between 2 to 8 ºC. In some cases, the returned pharmaceutical products cannot be re-distributed. Relying on verification at delivery without a written order is not a comprehensive supply chain management. Written order can certainly reduce the miscommunication and errors in drug ordering.

We understand that this requirement may require changing ordering practices. However, this is worth implementing in view of its enhancement to patient safety by order validation, and reduction of wastage caused by wrong orders, as drugs are valuable resources for patients. Members of our Association who distribute more than 80% of drugs in Hong Kong are dedicated to enhance our workflow to cope with this requirement.

Authorized Person (AP)

In accordance with the WHO guidelines and European Commission's requirements, the release of pharmaceutical products should be the responsibility of the AP as a part of **Good Manufacturing Practice.** To qualify as an AP, the person needs to have the knowledge of pharmacy, pharmacology, microbiology, etc and have relevant training and working experience in quality assurance and drug manufacturing process. (Please refer to Appendix 2 for the Personnel Requirements provided in the WHO guidelines on quality assurance of pharmaceuticals) In many countries, the eligibility of an AP needs to be certified by professional bodies. It is reasonable to require each licensed manufacturer to employ at least one AP.

Conclusion

The Association supports the proposed legislative amendments which aim to enhance regulatory monitoring that span across the whole supply chain including the regulations for manufacturers, wholesalers, retailer of pharmaceutical products and

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[3] First In First Out: An inventory control system where products are retrieved according to the date of entry into the warehouse, products stored first will be sent out first. When there is discrepancy between the manufacturing date and the storage entry date, products should be retrieved according to the manufacturing date.

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pharmacists. We believe that the amendments can bring these provisions in line with international regulatory practice which is necessary to safeguard public health.

The Association is disappointed with the delay in passing the above legislative proposals. Despite the fact that the drug incidents happened six years ago, the necessary legislative amendments still have not been made and there is still no timetable for the implementation of some of the recommended changes in regulations and policies.

We reckon that now is a good opportunity to amend the Pharmacy and Poisons Ordinance and Regulations in order to improve the overall standard of supply chain management for pharmaceutical products in Hong Kong and further enhance drug safety for patients in Hong Kong.

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Appendix 1

THE HONG KONG ASSOCIATION OF THE PHARMACEUTICAL INDUSTRY

FULL MEMBERS (40)

A. MENARINI HONG KONG LIMITED
ABBVIE LIMITED
ALCON HONG KONG LIMITED
ALLERGAN HONG KONG LIMITED
ASTELLAS PHARMA HONG KONG COMPANY LIMITED
ASTRAZENECA HONG KONG LIMITED
B. BRAUN MEDICAL (H.K.) LTD
BAUSCH & LOMB (HK) LTD
BAXTER HEALTHCARE LTD
BAYER HEALTHCARE LTD
BOEHRINGER INGELHEIM (HK) LTD
BRISTOL-MYERS SQUIBB PHARMA (HK) LIMITED
CELGENE LIMITED
CSL BEHRING ASIA PACIFIC LIMITED
DAIICHI SANKYO HONG KONG LIMITED
EISAI (HK) CO LTD
Ell LILLY ASIA INC
FERRING PHARMACEUTICALS LTD
FRESENIUS-KABI H.K. LIMITED
GALDERMA HONG KONG LIMITED
GILEAD SCIENCES HONG KONG LIMITED
GLAXOSMITHKLINE LTD
IPSEN PHARMA (HONG KONG)
JANSSEN, A DIVISION OF JOHNSON & JOHNSON (HK) LTD
KYOWA HAKKO KIRIN (HONG KONG) CO LTD
LUNDBECK EXPORT A/S
MEDINOVAAG
MERCK PHARMACEUTICAL (HK) LIMITED
MERCK SHARP & DOHME (ASIA) LTD
MUNDIPHARMA (HONG KONG) LIMITED
NOVARTIS PHARMACEUTICALS (HK) LTD
NOVO NORDISK HONG KONG LTD
OTSUKA PHARMACEUTICAL (H.K.) LTD
PFIZER CORPORATION HONG KONG LIMITED
RECKITT BENCKISER HONG KONG LTD
ROCHE HONG KONG LIMITED
SANOFI-AVENTIS HONG KONG LIMITED
SERVIER HONG KONG LTD
TAKEDA PHARMACEUTICALS (HONG KONG) LIMITED
UCB PHARMA (HONG KONG) LTD

AFFILIATE MEMBER (1)

AMGEN (ASIA) LIMITED

Quality assurance of pharmaceuticals

A compendium of guidelines
and related materials

Volume 2, 2nd updated edition

Good manufacturing practices
and inspection

World Health Organization

of each other. In large organizations, it may be necessary to delegate some of the functions; however, the responsibility cannot be delegated.

9.7 Key personnel responsible for supervising the manufacture and quality control of pharmaceutical products should possess the qualifications of a scientific education and practical experience required by national legislation. Their education should include the study of an appropriate combination of:

(a) chemistry (analytical or organic) or biochemistry;
(b) chemical engineering;
(c) microbiology;
(d) pharmaceutical sciences and technology;
(e) pharmacology and toxicology;
(f) physiology;
(g) other related sciences.

They should also have adequate practical experience in the manufacture and quality assurance of pharmaceutical products. In order to gain such experience, a preparatory period may be required, during which they should exercise their duties under professional guidance. The scientific education and practical experience of experts should be such as to enable them to exercise independent professional judgement, based on the application of scientific principles and understanding to the practical problems encountered in the manufacture and quality control of pharmaceutical products.

9.8 The heads of the production and quality control generally have some shared, or jointly exercised, responsibilities relating to quality. These may include, depending on national regulations:

(a) authorization of written procedures and other documents, including amendments;
(b) monitoring and control of the manufacturing environment;
(c) plant hygiene;
(d) process validation and calibration of analytical apparatus;
(e) training, including the application and principles of quality assurance;
(f) approval and monitoring of suppliers of materials;
(g) approval and monitoring of contract manufacturers;
(h) designation and monitoring of storage conditions for materials and products;
(i) performance and evaluation of in-process controls;
(j) retention of records;
(k) monitoring of compliance with GMP requirements;
(l) inspection, investigation and taking of samples in order to monitor factors that may affect product quality.

9.9 The head of the production generally has the following responsibilities: