Pharmacy and Poisons (Amendment) Bill 2014

Asia Regulatory Professional Association (ARPA) is an organization of Healthcare Regulatory Affairs professionals in Asia.

ARPA supports the amendment of the Pharmacy and Poisons (Amendment) Bill 2014 ("the Bill"). It is encouraging to learn that the Hong Kong Government continues to make progress to respond to the Review Committee on the Regulation of Pharmaceutical Products in Hong Kong's recommendation and commits to amend the existing Pharmacy and Poisons Ordinance and its subsidiary legislation to make Hong Kong's regulatory environment more in line with international practices.

ARPA supports the move to further strengthen the quality of pharmaceutical products by requesting licensed manufacturers to employ at least one authorized person be accountable for ensuring pharmaceutical products are manufactured in accordance to GMP standard. This is a good and responsible move as it mandates licensed manufacturers to offer critical manufacturing position to experienced pharmacists or other qualified personnel. Patient safety is of paramount importance and the amendment can further safeguard the quality of pharmaceutical products.

ARPA also supports the recommendation to require all wholesalers to keep transaction records of all pharmaceutical products, including Part II poisons and non-poisons in the same manner as for Part I poisons. From a good distribution practice point of view, it is essential for the wholesalers to have traceability of their products. Wholesalers of pharmaceutical products should understand that they are not distributing casual commercial commodities because pharmaceutical products are meant to have properties for treating or preventing disease in human beings. Pharmaceutical industry should be highly regulated because any product incidents may lead to potential detriments of public safety. Hence wholesalers must maintain a reliable system to trace the distribution of all pharmaceutical products, irrespective of their forensic classifications.

ARPA welcomes the changes on replacing the text "Poisons 毒藥" by " Prescription Drug 處方藥物" or " Drug under Supervised Sales 監督售賣藥物" for clearer and easier understanding for public. The current "Poisons 毒藥" labelling requirement is certainly outdated and may create unnecessary confusion or concerns from a lay person's point of view. Revamping the labelling of pharmaceutical products clearly brings alignment with other developed markets and makes the distribution control on different types of drugs more transparent and visible to the public.

The amendment also targets to expedite the registration process of pharmaceutical products by repealing the Poisons List Regulations and merging its contents to the Pharmacy and Poisons Regulations and that further amendments to the relevant Schedules to the Pharmacy and Poisons Regulation be made by means of negative vetting by the Legislative Council. These changes will make the registration of New Chemical or Biological Entities in Hong Kong be processed and completed in a more predictable timeframe. Again, this is good news to patients because they can have access to innovative medicines and vaccines in a more timely manner.

Last but not least, Hong Kong is a market famous for high quality clinical research work because of our excellent healthcare infrastructure and experienced investigators. However, the existing regulations require clinical trial applicant to submit drug sample at the time of application and will only issue a clinical trial certificate with a maximum of two years validity to successful applicants. These requirements add minimal value to the practices of clinical research in the territory but create a lot of administrative burden to the research community. It is good to note that the government listens to the stakeholders to remove the sample submission requirement and to extend the maximum validity period of clinical trial certificate from two years to five years. With theses advancements and initiatives, Hong Kong can move towards a more favorable direction and has a higher competitive winning edge in conducting clinical research.

To conclude, ARPA supports the bill to amend the existing ordinance and regulations to bring improvements to our current regime.