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Comments on the Proposals to Enhance the Regulation of

Pharmaceutical Products in Hong Kong

1. The rationale that underpins the legislative proposals is sound, including the recommendation to require the presence of pharmacists during all business hours of pharmacies and the recommendation to require retailers and doctors to have written records for drug orders.

    1.1 The requirement of pharmacist to be on duty during business hours is international best practice. Only the pharmacist has the training and experience to evaluate the prescription and assess risk vs. benefit for the patient, the time and skill to motivate the patient to adhere to the therapeutic plan, and the expert knowledge to judge drug product quality.

    1.2 All transaction records must be verifiable. That said, verbal orders are not verifiable whereas written orders are. Moreover, whereas written orders lend themselves to trend analysis during an audit, verbal orders do not and therefore corrective action/preventive action is not possible.

2. The August 30, 2013 application to join PIC/S membership is a milestone in the history of regulation of pharmaceutical products in Hong Kong. This action is an unambiguous signal from the Drug Office to the pharmaceutical trade of its determination to uphold rigorous quality standards. By default, the panel's previous concern about the rigor and frequency of the current practice of inspection of local drug manufacturing facilities will be dealt with under PIC/S.

3. Several long-standing issues that bear on the efficiency of the Drug Office were recognized but a concrete plan and/or timetable was not forthcoming.

3.1 Digital connectivity: A digital connectivity super express is critical to the overall operational efficiency of the Drug Office. Aside from partnering with sister departments in monitoring the distribution of imported pharmaceutical products destined for re-export, the super express has an equally important role play in tracking and tracing registered pharmaceutical products and other components in the entire health care supply chain. This is important in times of product recall and is also important in forecasting impending drug product shortages, in deterring counterfeiting, and in tackling the silent epidemic of prescription drug abuse. Eventually. when robotics-driven automated continuous manufacturing becomes the norm in the globalized contract manufacturing facilities, digital connectivity would enable 24/7 remote inspection of drug manufacturing facilities wherever they are.

3.2 Manpower: This is a perplexing issue not unique to the Drug Office. In fact, it is being studied by the Steering Committee on Strategic Review on Healthcare Manpower Planning and Professional Development established on January 31, 2013. Proper staffing of the Drug Office by number and expertise is as important as digital connectivity in determining the efficiency of the Drug Office. Presently, the two pharmacy programs enroll a total of only 80 students each year, which is about 4 times fewer than the 300 projected according to WHO standard. Moreover, like the majority of pharmacy curricula overseas, neither program provides in-depth training for the skills in pharmaceutical manufacturing and regulation, postgraduate training is necessary. Since it will take six years to train a pharmacist with the competency in pharmaceutical manufacturer and regulation, prompt action to find solutions to this challenge is imperative.

3.3 Authorized Person ("AP"): The Review Committee had identified key issues concerning formal education and experiential learning expected of AP's. This should be a good starting point for delving into new issues brought about by the growing diversity of pharmaceutical products and new business models of drug development. On the premise that knowledge of the science and technology of products is part of the qualifications, would it be desirable to certify AP's by product complexity, risk, and the like?

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