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Position Paper on the Regulation of Advanced Therapy Products
Consultation Document

The Hong Kong Association of the Pharmaceutical Industry (HKAPI) welcomes the opportunity to submit its views on the Regulation of Advanced Therapy Products Consultation Document. We submit this opinion paper on behalf of our 39 member companies engaging in the research and development of novel pharmaceuticals, and providing 70% of prescription medicines in Hong Kong.

While we in general agree with the rationale and framework as proposed in the consultation document, which is developed largely based on the established framework of the EU, there are areas of concerns and comments that we would like to highlight as follows.

Comments on Licensing System for Production Facilities

Due to the high-risk and complex nature of advanced therapy products (ATPs), we agree that production sites should fully comply with GMP and other standards as set by the regulatory authority.

Nevertheless, unlike MNCs' well-equipped production sites overseas, the facilities or laboratories in local universities and hospitals engaged in medical treatment or clinical trial might need extra support from the government, in terms of resources and expert opinions, in order to measure up to the required standards under the new regulatory regime. Ongoing patient's treatment and clinical studies may be put on hold or even severely jeopardized if local facilities fail to obtain the essential production licence due to a lack of support.

Comments on Record Keeping

Following the international trend on record keeping period for ATPs, we agree with the proposed record-keeping period of at least 30 years after the expiry date of the product. Yet, to enable manufacturers and/or product registration holders to comply with the record keeping requirement, more clarity on the specific requirements is needed. Among the types of items that need to be kept, we are particularly concerned with the following:

- "Storage"- Does it apply only to "finished product" or also raw and intermediate

materials? What record pertains to storage needs to be kept?

- "Transport" – What record pertains to transport needs to be kept?

- "Medical practitioner who is responsible for the use of the product" – Under current practice, transaction record at WDL holders only documents the hospital or clinic instead of the individual medical practitioner who uses the product. We recommend that the hospital, institution or private practice where the ATP is used establish and maintain a system for patient and product traceability. This recommendation should be built into the relevant stakeholder's regulations (e.g. Code of Professional Conduct by the Medical Council of Hong Kong).

Also, it is important to clarify in the regulation whether originals or electronic copies of records need to be kept. To avoid incurring tremendous storage cost and space spent on archiving originals, we recommend keeping only electronic copies.

Comments on Statutory Amendment

Besides the proposed amendments in the consultation document, we propose that section 36A of the Pharmacy and Poisons Regulations (Cap 138A) be revised for the reasons below:

- In response to the future technological advancement in medical treatments, the regulatory authority should be empowered to adopt any necessary changes regarding the technical requirements for the application for ATP, labelling and package insert. The regulatory authority should ensure that relevant information on envisaged measures are made available to interested parties without delay.

- Due to fast evolving scientific development of ATPs, we foresee some of the registered particulars (e.g. package insert) may be updated frequently.

- ATPs are highly individualized, disposable products. To recall and replace ATPs is not only impracticable, but would also jeopardize the anonymity of the patient and/or donor. Recall not related to patient safety is not encouraged as it not only causes confusion to the treating physicians, but also rises drug cost tremendously.

Other Comments

For any regulations that apply to physicians, there needs to be relevant mechanisms in place to ensure their compliance; the manufacturers/product registration holders have neither the authority nor duty to ensure the same.

To avoid further delaying the review timelines of the existing new chemical entity (NCE) and new drug applications (NDA), the regulatory authority needs to allocate extra resources and manpower dedicated to reviewing registration applications and pharmacovigilance monitoring for ATPs.

Lastly, it should be ensured that the regulatory authority possesses adequate relevant expertise and appropriate procedure to train and certify medical practitioners who will be using ATPs.

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