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Position Paper of The Hong Kong Association of The Pharmaceutical Industry on the Regulation of medical beauty treatments/procedures

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, welcomes the opportunity to submit its views on the Regulation of medical beauty treatments/procedures.

Basically, HKAPI agrees that there should be a clear distinction between medical treatments and beauty treatments based on scientific evidence, and it is necessary to ensure the treatments are carried out by appropriately qualified practitioners in regulated premises, with reference to the regulatory framework in Singapore. As the review of the regulatory framework is induced by the DR incident, we reckon that the quality of the substance is the main cause of death and infection, it is important to include the products used for medical beauty treatment in the scope of the regulation.

Currently, injectable products for cosmetic treatments can be broadly classified into three types. The first type is classified as pharmaceuticals, for example, Botulinum Toxin. Pharmaceuticals have to go through multiple phases of clinical trials to prove its safety, quality and efficacy before obtaining registration approval from the Department of Health of Hong Kong. During the manufacturing process, there are also strict controls over the manufacturing process, environment of the manufacturing plant, packaging, labeling and quality control before product release. After the product is released in the market, there is also ongoing monitoring of product through post-market surveillance.

Another type of products, includes dermal fillers such as hyaluronic acid, falls into the category of medical devices. In Hong Kong, the registration of medical devices is still on a voluntary basis without statutory regulation. Therefore, substandard products exist in the market.

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Still another type is totally unregulated products such as placenta extracts. For these kinds of products, the public was misled and believe that the products are either pharmaceutical product or medical device products.

In view of the above problems, HKAPI suggests the following:

1. All injectable products used for invasive treatments should be classified as either pharmaceuticals or medical device and should be regulated accordingly.

2. To expedite the statutory regulation on medical device so that the quality, safety performance and use of medical devices can be monitored. In addition, high risk products should have comprehensive sales records in order to track and trace the products and monitor any users' adverse reaction.

3. Doctors and aestheticians should follow their Code of Professional Conduct and should explain clearly the treatment procedures, products involved and the risks of such treatment and obtain the informed consent from patients before carrying out the procedures. Also, the Government should increase public awareness on beauty products, treatment procedures and the associated risks.