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INDIA PROPOSES NEW GUIDELINES FOR BIOSIMILARS/VACCINES

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INDIA PROPOSES NEW GUIDELINES FOR BIOSIMILARS/VACCINES

The Central Drugs Standard Control Organization (**"CDSCO"**) has released draft guidelines in an effort to streamline the regulatory process for granting marketing permission to similar vaccines and other biosimilars in India. The proposed revised Guidelines on Similar Biologics, 2016 ("**Draft Guidelines**") seek to supplement the earlier "Guidelines on Similar Biologics: Regulatory Requirements for Marketing Authorization in India" (**"2012 Guidelines"**).

A. Biologics and Biosimilars

Biologics are medicinal products composed or derived from living entities such as tissues and cells. They primarily include a wide range of products such as vaccines, blood and blood components, gene therapy, tissues and recombinant therapeutic proteins.

A biologic similar to another biologic is called a biosimilar. In common parlance, it can be understood as the generic version of a medicine, which can obtain registration upon proving to be as effective as the original/innovation medicine.

B. Draft Guidelines vs. 2012 Guidelines

The Draft Guidelines attempt to simplify the process for marketing approval in India for a biologic (say a vaccine) which is similar/comparable to another biologic/vaccine already approved for marketing in India, or elsewhere in the world, as specified. Biosimilars (as well as other generic versions of medicines) are

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usually attempted to be manufactured and marketed after expiry of the patent of the original drug or in case of healthcare emergencies.

Although the 2012 Guidelines were mostly aligned with global requirements, the Draft Guidelines seek to introduce ICH referencing and stipulate that a reference biologic (based on which the biosimilar seeks approval and entry into India) if not marketed/licensed in India, should be licensed in a country that has adopted the Technical Requirements for Pharmaceuticals for Human Use prescribed by the International Council for Harmonisation (**"ICH"**).

The ICH referencing in the Draft Guidelines may attract criticism. Reportedly, the CDSCO has itself in the past blocked import of ICH standards in Indian regulations. The CDSCO and various other groups have opposed ICH, arguing that ICH is a pharma industry driven body, prescribing such high standards which do not necessarily add value beyond a certain point but definitely add to the cost of manufacturing of medicines. India has a thriving generic drugs industry, and generic drugs are arguably required to provide healthcare to the vast Indian population at an affordable price. Reportedly, the ICH also does not find much approval even with organizations advocating for low/middle income countries.

The 2012 Guidelines did not prescribe ICH referencing and stipulated that a reference biologic could come from any country with a well-established regulatory framework. The ICH referencing prescribed in the Draft Guidelines may arguably impose an indirect barrier for approvals of biosimilars in India.

In addition to the above revision, the Draft Guidelines prescribe that Phase III trials for biosimilars shall have at least 100 evaluable patients and Phase IV trials shall have at least 200 patients. The Draft Guidelines also permit a smaller trial population size for trials of biosimilars for treating rare or severe diseases or where therapeutic options are limited. The 2012 Guidelines did not specify the minimum number of patients. It is generally expected that specifying a minimum number of patients will ensure maintenance of uniform safety data.

The Draft Guidelines are open for suggestions and feedback till April 30, 2016.

Feedback