

## **Requirements for registration of generic insulin preparations**

1. The source of the insulin starting material (the active ingredient) must be a licensed manufacturer of the insulin starting material, pre-qualified by the Standing Committee for the Registration of Medicinal Products (SCRMP). The registered manufacturer of the insulin preparations should purchase the insulin starting material (ISM) directly from pre-qualified manufacturer.

2. For the pre-qualification of the manufacturer of the ISM his production site and facilities should comply in very respect with relevant WHO Guidelines of Good Manufacturing Practices (GMPs), Good Storage Practice (GSP) and Good Trade and Distribution Practice for starting materials (GTDP).

3. The registered manufacturer of the insulin preparation submitted for registration, or his local agent, is responsible for providing the SCRMP with adequate information about the competence of the licensed manufacturing source of his insulin; and in particular the following:-

(a) Site Master File of source of insulin and its Quality Manual.

(b) The prescribed form for registration of foreign manufacturers of medicinal products duly filled and signed.

(c) Certificate for Pharmaceutical Starting Materials (CPSM) issued by the competent national authority; WHO format: (reference WHO pharmaceutical starting materials certification scheme (SMACS)).

(d) A valid certificate of Good Manufacturing Practice; WHO format.

(e) The pharmacopoeia specification of the insulin produced (Ph Eur, BP or USP).

(f) A copy of Batch Certificate of Analysis issued by competent national authority in countries where that authority test every batch of insulin,

otherwise issued by the manufacturer and endorsed by the competent national authority.

(g) Types and amounts of insulin starting materials produced annually by the licensed manufacturer, the amounts used locally in the country of origin and the amounts exported with list of importing countries.

4. The SCRMP should inquire from WHO about the competence and reliability of the manufacturer of insulin starting materials, its compliance with all relevant WHO guidelines and the quality of its products.

5. Any generic insulin preparation registered and imported for the first time should be subject to quality monitoring throughout its shelf life, by sending samples for analysis abroad and observing its efficacy and adverse reactions.

6. Each batch of the registered generic insulin preparation should be accompanied by detailed batch certificates of both the insulin starting material used in its formulation and that of insulin preparation. Copies of these certificates should be deposited by the importer with the Federal Department for Control Medicines, Cosmetics & Medical Devices, Directorate General of Pharmacy, FMOH.

7. The registered source of insulin starting materials should not be changed unless the new source is pre-qualified as above.

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