

A three day technical training on the documentation and bioequivalence data required for submission to the WHO prequalification of medicines programme was held from 20 to 23 June 2011. The training aimed at providing technical assistance to a selection of potential manufacturers in preparing and reviewing their product dossiers' content before submission to the programme.

The training was attended by six manufacturers and regulators from Member States in the Region including: Jordan, Egypt, Islamic Republic of Iran, Pakistan, United Arab Emirates, Saudi Arabia, Oman, and Syrian Arab Republic. The content of the programme was categorized into the following four main sessions:

Presentation of the prequalification of medicines programme requirements with specific focus on dossier content, evaluation, methodology and criteria

Screening dossiers

Evaluation of bioequivalence and clinical data

Evaluation of the quality for active pharmaceutical ingredients and finished product.

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