

**CTD Implementation Workshop, Dar es Salaam, United Republic of
Tanzania, 9-11 November 2010**

Summary report

In the framework on the African Medicines Registration Harmonization Initiative (AMRHI), the WHO Medicines Regulatory Support Programme has organized a training workshop on the implementation of CTD format, from 9 to 11 November 2010 in Dar es Salaam, United Republic of Tanzania, for the East African Community (EAC) Partner States and other Anglophone countries of Sub-Saharan Africa.

21 participants representing 11 Member States of four Regional Economic Communities in Africa (EAC, SADC, WAHO and IGAD) attended this workshop, namely Botswana, Burundi, Ethiopia, Ghana, Malawi, Mozambique, Nigeria, Tanzania (Mainland and Zanzibar), Zambia and Zimbabwe.

Three consultants from Medicines Regulatory Authorities of European countries provided the technical support and participated to this training session together with representatives of the EAC secretariat and WHO (Country Offices and the Headquarters). Participants from countries were exclusively experts from the National Medicines Regulatory Authorities (NMRAs), in charge of the medicines registration activities.

The objectives of the workshop were to increase the technical capacity of the NMRAs on the presentation of the requested data in a standardized and internationally recognized format of application for marketing authorization, and in particular:

- To improve the understanding of the Common Technical Document (CTD) format for the presentation of application for marketing authorization;
- To improve the understanding of the requirements/data/guidelines needed to fulfil this format in order to demonstrate the quality, the safety and the efficacy of pharmaceutical products with a specific focus on interchangeable products;
- To identify how this format, together with the relevant guidelines can be implemented at national and regional level, to support the harmonization of the regulatory requirements.

In addition to this workshop, two presentations were made: on the WHO Prequalification of Medicines Programme and on the regulatory actions to stop the marketing of the oral artemisinin monotherapies in the treatment of uncomplicated malaria

As conclusions of the discussions, participants agreed that thanks to existing regulatory basis, the CTD format should be easily implementable in most of the participating countries, except Burundi. Nevertheless, the participants acknowledged the fact that the implementation of the technical and scientific guidelines needed to populate this format (e.g. stability guidelines, impurities guidelines, etc.) will take much more time. Participants agreed to complete the situation analysis initiated during this exercise and to forward it to the WHO for consolidation and dissemination. Participants recommended to countries to develop their own strategic plan for implementation of these guidelines, following a regional approach.

Other harmonization issues have been discussed, such as the need to agree at national as well as at regional level on a recognized set of Pharmacopeia, to harmonize the product information requirements and to consolidate a list of comparator products for bioequivalence studies.