

**CTD Implementation Workshop, Douala, Cameroon, 28-30 June 2010****Summary report**

In the framework of the African Medicines Registration Harmonization Initiative (AMRHI), the WHO Medicines Regulatory Support Programme has organized a training workshop on the implementation of Common Technical Document, from 28 to 30 June 2010, in Douala, Cameroon, for the experts from Economic Community of Central African States (ECCAS).

17 participants representing 5 ECCAS States attended this workshop, namely Angola, Cameroon, Central African Republic, Congo and Democratic Republic of Congo.

Three consultants from Medicines Regulatory Authorities of European countries provided the technical support and participated to this training session together with representatives of the secretariat of the Organization for the Coordination of the Fight Against Endemic Diseases in Central Africa (OCEAC) and the 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, safety and 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 activities of 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 Angola where a new regulation should be put in place soon. The situation analysis performed during this exercise has shown that, except for product information requirements, no detailed guidance has been provided, published or endorsed by the NMRAs in order to fill the marketing authorization application for pharmaceutical products.

The participants acknowledged the fact that the implementation of the relevant technical and scientific guidelines needed to populate this format (e.g. stability guidelines, impurities guidelines, etc.) will take much more time. They recommended a step by step approach to be followed in order to provide for the necessary training of the staff coming from the NMRAs as well as from the local manufacturers. Participants concluded on a recommendation to countries to implement the CTD format in all ECCAS States with the support of WHO, following a regional approach.

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