ZAZIBONA Collaborative Medicines Registration

Alternative/Expedited process to register medicines via the ZaZiBoNa collaborative process

Annex I: Documents to be Submitted with an Application for the ZAZIBONA Collaborative Process

NB: You should read the current Alternative/Expedited process to register medicines via the ZAZIBONA collaborative process. The document gives information on which products are invited for assessment in this collaborative process.

1. Covering letter, in English, expressing
   1.1. interest in participating in the ZAZIBONA process and information, whether the product is already registered in any ZAZIBONA participating country,
   1.2. confirmation/attestation that the information submitted in the product dossiers is "true and correct",
   1.3. confirmation/attestation that the same[1] dossier and data have been submitted to all participating countries,
   1.4. consent with sharing of the product related information during registration and in the post-registration period among ZAZIBONA participating authorities and with WHO staff and external experts, who support the process and are bound by confidentiality undertaking; and
   1.5. commitment to apply for the same variations and post-registration changes in all ZAZIBONA participating countries where the product is registered.
2. Product dossier, in English, organized in CTD format for submitting product data and information. For the purpose of generic medicine registration, data demonstrating quality of raw materials (Active Pharmaceutical Ingredients and Excipients) and FPP are necessary, as well as demonstration of bioequivalence with an acceptable comparator. Details are specified in the relevant guidelines that reflect the harmonized SADC position. Paper and electronic copies of the dossier should be submitted as per national requirements.
3. A product sample (for example a package of 100 tablets), for evaluation of product appearance, container material and labelling, and also to enable, under exceptional circumstances, chemical and pharmaceutical analysis. Where sample labelling does not comply with national requirements or the proposed final labelling, mock-up labels demonstrating design of final labelling should be submitted.
4. A site master file, for each manufacturing site of the medicine, in the requisite format.

How to organize the documentation

The documentation should be submitted in English in the format described below. Please follow specific country requirements for number of copies required.

For the product dossier the structure and format of the Common Technical Document (CTD), agreed within the framework of the International Conference on Harmonisation (ICH, see web site: http://www.ich.org) or the SADC CTD Format should be followed.

The submission of the documentation should be both electronic and paper copy (as per specific country requirements) otherwise only electronic should be submitted.

The submission should therefore include

1. A cover letter expressing interest (See template), and

[1] Specific national administrative documents, labelling and product information texts as submitted in the module 1 of the dossier do not represent a difference between dossiers of the same technical content.

2. An appropriately filled out QOS-PD[2] (Quality Overall Summary - Product Dossier) in Word format, and
3. An appropriately filled out QIS[3] (Quality Information Summary) in Word format, and
4. An appropriately filled out BTIF (Bioequivalence Trial Information Form) or BW-BCS[4] Biowaiver Application Form: Biopharmaceutics Classification System) (where applicable) - in Word format or BW-BCS Add Strength [5] (Biowaiver Application Form: Additional Strength) (where applicable) - in Word format, and
5. The dossier according to CTD format *in word or text selectable PDF* (see documentation requirements section); and
6. A copy of the current Site Master File for all the proposed FPP manufacturing sites.

Currently the only accepted word formats of the summaries and forms are as per WHO PQ. Please follow links below to access the current version.

Electronic submission

A well labelled CD or DVD containing the electronic documentation should be organized according to the CTD structure (Modules 1, Module 2, Module 3, Module 4 and Module 5) and this should be reflected in the corresponding file names. All CDs/DVDs should be numbered and the first folder should contain a Table of Content, reflecting the location of files as cross-referenced to the CTD format

The summaries of quality and bioequivalence files (QOS-PD, QIS and BTIF/BW-BCS) should be submitted in Word-format to facilitate the evaluation process.

Scanning of documents for electronic submission should lead to a file, which is readable and of reasonable size to allow scrolling (i.e. less than 5–10 MB).

Paper copies

Paper copies should be well organized according to the CTD structure, bound and paginated, and should include a Table of Contents. No loose sheets should be provided for any information submitted.

Site master file (SMF) requirements

An SMF[6] must be submitted - as an electronic copy (CD/DVD) only - for each proposed FPP manufacturing site. An SMF is a document prepared by the manufacturer containing information with respect to the production and/or control of pharmaceutical manufacturing operations carried out at the named site and to any closely integrated operations at adjacent and/or nearby buildings. If only part of a pharmaceutical operation is carried out at the site, the SMF need describe only those operations, e.g. analysis, packaging.

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[2] http://apps.who.int/prequal/info_general/documents/generic_guide/QOS-PD_Nov2014.doc
[3] http://apps.who.int/prequal/info_general/documents/generic_guide/QIS_Dec_2013.doc
[4] http://apps.who.int/prequal/info_applicants/Guidelines/GuideGenericSubmitDocFPPs_01_2010_Annex7.doc
[5] http://apps.who.int/prequal/info_applicants/BE/BW-AddStrengthsApplicationForm_May2012.doc
[6] http://apps.who.int/prequal/info_general/documents/TRS961/TRS961_Annex14.pdf