Industry perspectives on implementation of Quality Overall Summary-Product Dossier (QOS-PD) and Quality Information Summary (QIS) for innovative medicinal products

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Continuous product supply of quality-assured, safe and effective medicines is in the best interest of patients, regulators and industry. During the COVID-19 pandemic, harmonization of regulatory requirements has proven to increase efficiency in the registration process[1]. While especially important for marketing applications and renewals, harmonized requirements should also apply to documentation for lifecycle management activities. Due to the growing complexity of product lifecycle management, all stakeholders need to work together to harmonize regulatory requirements. This will facilitate efficient regulatory review and approval to support timely implementation of changes and product improvements, leading to more resilient supply chains.

In many African countries, supplementary technical quality templates such as the Quality Overall Summary-Product Dossier (QOS-PD)[2] and a Quality Information Summary (QIS)[3] are being implemented as regional or national requirements with the submission of reliance and non-reliance marketing authorization applications. The information contained in these technical templates can be considered a duplication of quality information that is also presented in ICH Common Technical Document Modules 2.3 and 3 (both modules are prepared by manufacturers according to the guidance in ICH M4Q (R1)).

[1] For more information, access the IFPMA policy briefing on regulatory agilities and regulatory agilities, which summarizes experiences in the use of agilities to allow safe and effective COVID-19 medicines and vaccines to be rapidly developed, assessed, approved and accessed. IFPMA website, accessed December 2023.

[2] The QOS-PD is a summary of the quality information presented already in the CTD Module 2 & 3. The template has been adopted from WHO "Guidelines on Submission of Documentation for a Multisource (Generic) Finished Pharmaceutical Product: Quality Part. WHO Technical Report Series, No. 986, 2014, Annex 6.

[3] The QIS is a summary of the QOS-PD and represents the final, agreed upon key information from the product dossier review (inter alia identification of the manufacturer(s), API/FPP specifications, stability conclusions and relevant commitments). This has also been adopted from WHO "Guidelines on Submission of Documentation for a Multisource (Generic) Finished Pharmaceutical Product for the WHO Prequalification of Medicines Programme: Quality Part. WHO Technical Report Series, No. 970, 2012, Annex 4.

What is the impact of the QIS and QOS-PD requirement?

Additional QIS and QOS-PD documents for innovative product applications, renewals and variations duplicates information that is already available in ICH CTD Module 2.3 Quality Overall Summaries.

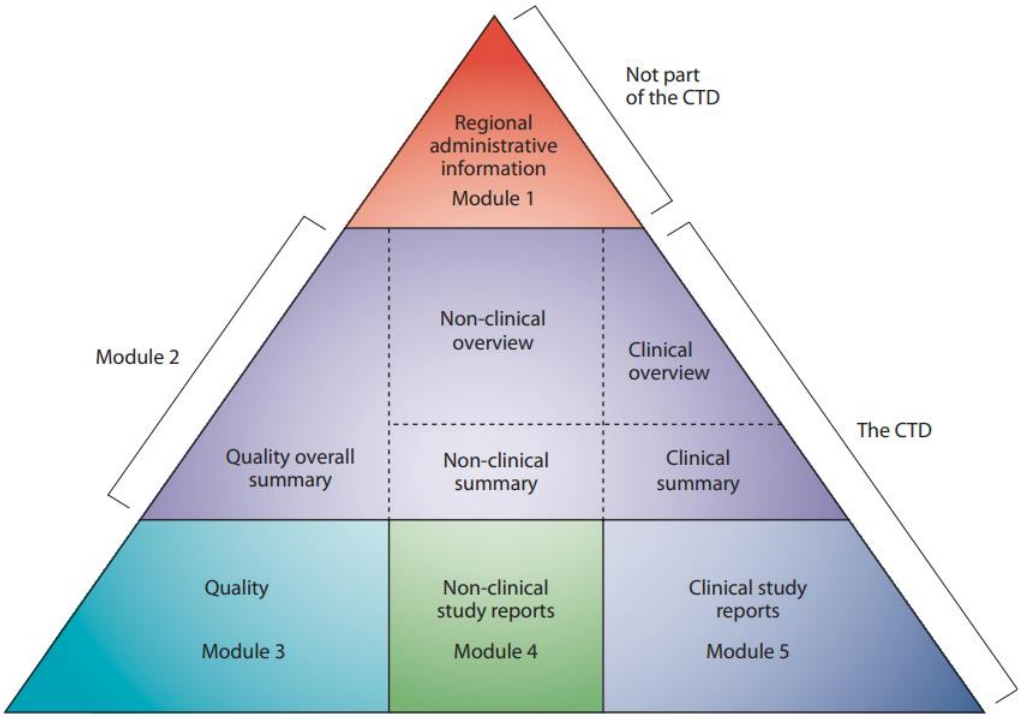

Figure 1- ICH CTD triangle- The CTD is organized into five modules. Module 2 contains the quality overall summary[4].

Copying this information into another document format requires additional time and resources, introduces transcription errors, delays the preparation of dossiers for submission and consequently the start and approval of regulatory procedures, contributing to the delay in access to medicines to patients. Furthermore, managing lifecycle updates to multiple documents with the same or similar information does not add value, neither for assessing authorities, nor for patients.

Additionally, for reliance procedures some national regulatory authorities (NRAs) require submission of a completed country specific SRA QIS templates which mandates endorsement by the stringent regulatory authority (SRA). This is required in addition to standard (WHO format) QIS template and QOS-PD. SRAs usually do not have a legal mandate to endorse these templates for other countries' use, which may create resource bottlenecks and delays.

[4] For more on the ICH Common Technical Document (CTD), see ICH website. Date accessed: 18 July 2023

Industry perspective

The ICH M4Q(R2) Expert Working Group (EWG) is focusing on the revision of CTD Quality sections in Modules 2 and 3 to capture quality information for the registration and lifecycle management of pharmaceuticals for human use. One of the main objectives of M4Q(R2) as the main source of the structure and location of regulatory quality information in line with the modern quality guidelines ICH Q8-Q14.

We believe that the ongoing revision of ICH M4Q provides an important opportunity to achieve standardised and aligned presentation of dossier information. Country specific information/ formatting needs should ideally be discussed with all regulators during development of this guideline to optimize use of the fit-for-purpose standard dossier information and avoid any duplication. Additional QIS and QOS-PD documents containing duplicative information should not be required as the CTD Quality sections in Modules 2 and 3 contain all appropriate information required for dossier evaluation. WHO, as a standing observer to ICH, may play a role in facilitating this discussion with input from African NRAs.

Industry recommendations

In order to reduce duplication and provide value adding data to registration processes, in line with the principles of clarity and efficiency, industry would like to recommend the following:

- → In line with the goal of global harmonization and convergence, it is recommended that the ICH EWG for M4Q (Rev 2) & WHO work closely to align on their guidance for Mod 2.3, so as to limit the need for both Mod 2.3 & QOS-PD template within the same submissions.
- → For innovator molecules, CTD Mod 2.3 and 3 should be accepted by all NRAs, without mandating an additional QIS/ QOS-PD template. Where QOS-PD and QIS templates are stipulated in a guideline, we ask for these templates to be an optional requirement for new chemical entities. Module 2.3 can also be provided in Word format to facilitate review by the regulator.
- → For reliance procedures, the focus should be on the MAH's declaration of sameness of the product dossier under review and on the identification and justification of any differences, as per WHO Good Regulatory Practices Document and International Pharmaceutical Regulators Programme (IPRP) Reliance statement. Submission of QOS-PD/national QIS submission documents should not be mandated for reliance pathways.
- → Further engagement between industry and health authorities to support harmonisation and capacity building for evaluation of ICH CTD could be beneficial. This will also contribute to implementation of reliance procedures at national level.