

COMMUNICATION TO STAKEHOLDERS

Issue No.: PEM03-2022/23

23 May 2023

Implementation of the QOS & QIS

INTRODUCTION

This document is intended to provide guidance to stakeholder on the use of the newly implemented QOS & QIS.

General

- The QOS & QIS is required for all new registration applications, to facilitate evaluation by SAHPRA, and should be submitted with applications at the time of submission.
- For quality variation application, only a complete QIS is required unless major changes are made to the content of module 3 or a new API source with full details of the API are submitted.
- For renewals, the QOS & QIS is required.
- For submissions already in compilation with the SCoRE documents, not yet submitted to SAHPRA, a grace period of until 30 June 2023 will be granted.
- For applications still in the evaluation process and not yet approved, a QIS should be submitted with your response prior to registration.
- For applications which have been approved (no more query rounds for quality), registration will continue with the SCoRE document, and an updated QIS should be submitted once a variation application have been made.
- When updating a QOS & QIS for a variation, any changes should be marked in track changes, however, the document submitted to SAHPRA must be **highlighted in yellow**. Information should be included for all strengths. The following is applicable:
 - For variations to applications registered with a SCoRE, the complete QIS only should be submitted.
 - For variations to applications registered without a SCoRE/ QIS, a newly completed QIS should be submitted.
- The PDF version of the document should be included in Module 2.3 and 3.2.R.8 (Other) of the CTD submission.
- An additional MS Word text version (i.e. editable) of QOS & QIS should be included in the working documents folder.

- The default text is Arial, size 11.
- As per revised SAHPRA APIMF Procedure, if information is in the closed part of the APIMF, reference to the closed part should be made (where applicable) with the understanding that the API manufacturer submits the closed part directly to SAHPRA, together with a Module 2.3.S for the restricted parts of the APIMF.
- Do not change or delete the titles and the numbering (add “Not applicable” if necessary)
- Add additional rows to tables where required.
- Please duplicate Module 3.2.S and Module 3.2.P for multiple API and FPP in the product.

Please note that hyperlinking or referencing sections of the dossier is **not acceptable**; information should be summarised in the QOS & QIS

For information on submission requirements for renewals, please refer to the renewal’s guideline.

Digitally Signed by:
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CEO
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SAHPRA Chief Executive Officer (CEO)