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## Implementation of Regulatory Information Management System – Responses to queries in eSubmission format

### Document History

First Publication – Version 1	06 March 2024
Version 2	26 April 2024
Version 3	26 April 2024

### INTRODUCTION

During the recent webinar engagements, we have had a number of applicants raise questions seeking clarity around the appropriate process to follow for submitting Responses to queries that have been shared by SAHPRA for their review, action and response – for either new medicine applications or variation applications.

A number of internal discussions have been concluded and we would like to provide clear guidance on how to proceed with your responses.

Responses that are due now, post the Admin Freeze, must be submitted in one of the following ways in eCTD format:

#### Scenario 1:

- Baseline (0000) – full and up to date
- Sequence 1 - Open Variation – for the relevant variation
- Sequence 2 - Response to the query related to the open variation submission

#### Scenario 2:

- Baseline (0000) – full and up to date
- Sequence 0001 - Open Variation 1 (e.g Quality) – still under review
- Sequence 0002 - Open Variation 2 (e.g Clinical) – which resulted in query
- Sequence 0003 – Response to the query related to the open variation 2 submission

#### Scenario 3:

- Baseline (0000) – full submission as reflected in the original eSubmission and any subsequent follow-up sequences (responses) for new medicine applications
- Sequence 0001 - Response to the query related to the new medicine application.

This process ensures that the Baselines received reflect the full information for applications – approved up to the point in time when the variation or prior pre-reg responses were submitted so that the information is complete and comprehensive for the variation/pre-reg query and related response and baseline at a point in time.

Regards

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