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Implementation of Regulatory Information Management System – Update on Progress

Document History

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INTRODUCTION

We would like to provide a general update on the progress for the RIMS deployment that commenced at the end of March 2024.

We have completed our migration processes for all eCTD applications and the priority eSubmission applications that were work in progress – with some activities to complete the import of the balance of eSubmissions during the first half of May 2024.

The migration process has further highlighted some deficiencies and Best Practice challenges that have been experienced in the past with legacy submissions and some of these will be addressed by the eCTD 3.0 implementation. This potentially may require additional refinement of the specification and guideline if the Best Practice challenges persist with new submissions – for us to clean up data and process to effect more efficient operational processes.

The data challenges have unfortunately affected our planned time to complete vs actual time to complete slightly – and we highlight this, in the event that you note a week lag on normal processing. Please keep this in mind and allow the SAHPRA team time to recover processing capacity and pace – and kindly raise queries only for urgent matters as the influx of continuous inquiries further “jams the gears”.

The SAHPRA team has however made good progress in adapting to the new software tool, and despite the teething issues during the first two and a half weeks of April, has started to settle in a rhythm. We will be aligning efforts and bringing activities back up to the previous processing speeds as we have seen an expected slow-down as part of the transition as this certainly has been a significant change for the organization.

With such a major change we will track the progression through the learning curve over the next 3 months and will continue to engage Industry to provide you updates and where required have the webinars to ensure we provide clarity and training that may be required to ensure we remain aligned in our understanding and approach with the applications processes.

Regards

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COO