

BACKLOG CLEARANCE COMMUNICATION

AUGUST 2020

Backlog Clearance Programme Update

The Backlog Clearance Programme has received applications for Re-submission Windows 1 to 9. The quality of submissions has improved significantly. We are receiving all applications submitted on the Document Uploading System via the FTP site and all queries from applicants regarding the FTP site are being handled and addressed accordingly by our Backlog Mailbox and our IT department. We would like to extend our gratitude for your co-operation thus far. A total of 267 new registration applications have been approved by the Programme to date.

While the quality of submissions has improved significantly in the recent past, we are still facing a few challenges and would urge Industry to assist with the following:

- There is a significant number of applicants who do not include the required batch manufacturing records, and this is often identified at technical screening where it contributes to significant delays with the processing of applications.
- Non-compliance with guidelines is also a challenge, and applicants are reminded to strictly adhere to eCTD and eSubmission guidelines and any applicable policies and regulations, as this will help limit back-and-forth interactions between the applicant and SAHPRA. This will culminate in the reduction of the time to process an application.
- We have also noted that applicants do not include the hyperlinks specified in relevant guidelines.
- Furthermore, some of the applications for Reliance review are of poor quality or incomplete and miss supporting documents, such as unredacted reports and the closed part of the DMF. This delays the review of these applications as the onus then falls on SAHPRA to source these documents on behalf of the applicant.

Backlog Programme New Joiners

We are pleased to inform you that we have welcomed 4 new employees to our SAHPRA Backlog family, some of whom have already been on-boarded and have commenced with their duties.

These new employees consist of

- 1 Technical Screener (planning to employ 4 additional ones),
- 2 Evaluator Coordinators and
- 1 Finance Accounting Officer to the Project.

These additions were made to assist for the duration of the Programme.



Variations Portal (Full Launch)

Please note that with effect from 1st of September 2020, all variations portal queries to be directed to the following email: dvp@sahpra.org.za

We would also like to alert you to the delayed deployment of the Variations Portal for enhancements and upgrades to support acceptance of type II variations applications. We have encountered some unforeseeable internal glitches that have caused the go-live for the full launch to be deferred to a future date. We will keep you informed on progress and updates about the new launch date.

Zazibona Applications

For any backlog applications where an applicant is applying for the Zazibona process, applicants are to submit directly to BAU and **not** to the Backlog team.

PI/PIL for Generic Applications

SAHPRA urges applicants with generic applications to use the PI/PIL repository on SAHPRA's website. This is important and will help evaluators apply standardised approaches to the evaluation of similar APIs and reduce the time required to evaluate products.

Submission of Type II Variations Applications

We have noted that some applicants are submitting their type II applications together with type I variations as one application via the FTP/eCTD. Please note that we will not be accepting type I applications as part of the type II submissions. ALL type I variations applications must be done via the Variations Digital Portal.

Confirmation of successful electronic submission uploads on FTP site

The Backlog Clearance Programme is successfully receiving all submissions made via the Document Uploading System. To lighten the administration burden on the numerous electronic submissions we are receiving on a daily basis, we would like to bring to your attention that after the successful transfer of submissions via the FTP Document Uploading System, SAHPRA proof of submission or confirmation receipts for uploads will not be issued. Once the submission is uploaded it will automatically appear on SAHPRA's side.

Applications which have completed evaluation

Be advised that your allocated Portfolio Coordinator (PC) will notify you once your application has completed evaluation and requires for you to pre-populate the registration certificate(s). Once the template is sent, you will be required to return the completed version within 1-2 working days of receipt. Take note that the longer it takes to return the completed template, the longer it will take to process the certificate(s) – which will be done in batches – and applicants could miss the next batch if the requests are not responded to within the specified time period.



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Extension of Response Times to Technical Screening & Evaluation Queries

The Backlog Clearance Programme recently communicated an extension of Industry query response timelines (24 June 2020). In the above communication, the timeline for Industry to respond to screening and evaluation recommendations was extended from ten (10) to 20 working days (i.e. one (1) month) from the date of receipt by the applicant. This amendment was made to allow Industry time to sufficiently address the queries raised at screening and at evaluation.

It has, however, come to the Backlog Unit's attention that applicants are using the above response timeline for both first and second query rounds and for both Clinical and P&A (and sometimes also for N&S and Inspectorate), thus significantly delaying the process. Backlog has, therefore, decided to cap the second query round at five (5) working days for minor queries and ten (10) working days for major queries. We believe that by this stage in the process, the applicant has had an opportunity to address the queries raised at technical

screening and evaluation. SAHPRA will try to minimise additional queries raised during the second query round.

Thus, 20 working days' response time will be allowed for the first query round and five (5) working days' (for minor queries) and ten (10) working days' (for major queries) response time will be allowed for the second query round.

Please note these timelines are only applicable to Backlog applications, and not for BAU applications.

Furthermore, in order to facilitate administrative processes within the Programme, we kindly ask that applicants inform their relevant PCs, should they be unable to respond within the above timelines (which will result in an automatic deferral of the application to the additional Re-submission Window in December 2020). This will reduce the number of follow-ups to be done by the PCs.

Additional Re-submission window in December 2020

The Backlog Clearance Programme has been receiving quite a number of extension requests to respond to queries. SAHPRA has since introduced an additional Re-submission Window in December 2020 to address these extension requests, NOTE; the additional Re-submission Window is only for submission of responses to screening/evaluation queries and not for new registration dossier submissions.



Request to submit new applications/variations prior to scheduled Re-submission Windows

This will not be allowed, unless the product is deemed an essential medicine for assisting with the COVID-19 pandemic and is supported by motivation to this effect.

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Common screening queries that cause delays in the end-to-end process

To ensure a seamless end-to-end process, we have compiled a list of common screening deficiencies that result in screening queries that delay evaluation. Kindly ensure that the list of queries below is attended to before submission to prevent a rejection.

GENERAL QUERIES

- To ensure swift navigation of the dossier, please ensure that hyper-linking and book-marking complies with the prescribed eCTD and Module 1 guideline.
- Follow the instructions in the validation template to ensure all requirements are complied with.
- To ensure that the correct pathway is used, please utilise the Quality and Bioequivalence and Clinical guidelines for the required information.
- Use only the stipulated RRA's when choosing the proposed review pathway.
- Include all prior recommendations, responses and approvals in Module 1.0 and an amendment schedule, if applicable.
- All submitted information is to be legible and in the English language.
- Please make use of the prescribed letter of access template in the General Information guideline and the sameness declaration template in the Quality and Bioequivalence guideline.

MODULE 1 QUERIES

- Use eCTD and Module 1 guideline to compile 1.2.2.3.
- In section D (Technical Screening (Pre-clinical and Clinical)) of the validation template, ensure that question 1.9 summaries are complied with.

MODULE 3 QUERIES

- Applicants are to provide signed, dated and version-controlled API specifications for both the API manufacturer/s and FPP manufacturer/s.
- Batch analysis and Certificates of Analysis (CoAs) are to be submitted from both the API manufacturer/s and FPP manufacturer/s.
- The inclusion of executed Batch Manufacturing Records (BMR) and blank/master BMRs is compulsory. We will only accept an executed BMR that has NOT been translated into English if a signed English version of the blank/master BMR is included in the submission.



Concluding Notes

We will continue to provide regular progress updates and will continue to incorporate learnings and improvements to our processes along the way. We appreciate your ongoing engagement and support during this pandemic.

Keep safe.

Yours faithfully
BACKLOG CLEARANCE TEAM