

Team Meeting

20 April 2021

Backlog Working group/SAHPRA Teams meeting

Attendees: Abeda Williams, Deepa Maharaj; Anita Smal, Lynette Terblanche, Lorraine Danks, Bianca Baxen, Luyanda Mahlanza, Sibongile Ratlhogo, Mankiti Khaebana

Discussion:

Abeda introduced the meeting and requested an update on the Backlog.

SAHPRA confirmed that the current throughput for registrations is increasing. Internal challenges within particular units are being resolved, however finalization of registrations in earlier Resubmission Windows (RW) remain a challenge.

PI/PIL:

Clinical evaluations are lagging behind. Allocations are being done for RW 6 and 7.

The current projection for clearing the backlog is March 2022.

Abridged review has been implemented and approximately 157 applications have been accepted for abridged review.

There are approximately 900 new Registration Masters in evaluation.

In order to manage resource constraints, resources will be reallocated/deployed to other areas as required when the backlog in the specific unit has almost been cleared. (e.g., Inspectorate)

Unfortunately, reliance and more progressive ways of working have not been accepted across the regulator.

Industry 4 a-side is addressing the fact that the resubmission process has contributed to a new backlog being created. (AW)

Industry is being challenged by the lack of implementation of reliance and acceptance of the EMA approved SmPC. This is contributing to multiple cycles of queries and could further prevent the clearance of the backlog within the given timeframe. In addition, BAU is also being impacted.

The "over and above" requirements are limiting the rate of progress; therefore, these matters will be escalated to the 4-a-side for discussion (The requirement for BMR is a case in point).

It was suggested and agreed by the industry representatives that a different intervention is required, such as direct dialogue with evaluators. Such direct interface would provide the evaluators' perspective on matters. Industry will request representation from evaluators and chairpersons of committees on ITG Working Group meetings.

Distrust between the regulator and industry remains a challenge that needs to be addressed and will be by the 4-a-side.

LD confirmed that the app for the upload of sequences has been changed. Applicants are complaining that the submissions seem to remain on the tracker but in fact these have been downloaded on the SAHPRA side. In the past, once SAHPRA downloaded the sequence it would disappear in the applicant side. This is no longer the case. Applicants are requested to look at the industry-facing tracker before sending emails to SAHPRA querying the downloads.

SAHPRA requests applicants to refrain from continuous and frequent follow up emails on the same topic as this wastes time and it detracts the SAHPRA staff from being able to finalise matters.

Applicants are also requested to ~~re~~-check the naming conventions of response and correction sequences prior to submission.

The new email address for the PI/PIL Repository uploads for BAU can now be directed to:

pipilrepository@sahpra.org.za

For backlog updated PI/PILs they can still be sent directly to Bianca Baxen.

This information will be contained in a newsletter to be sent out by the Backlog unit.

The Backlog Newsletter will be sent to the BLWG for alignment prior to distribution.