SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Minutes of the
5th SAHPRA-ITG meeting
12th May 2020

Time	Venue
09H00 – 11H30	Virtual (Microsoft Teams)

	Action
1. Opening and Welcome – The CEO Dr Boitumelo Semete (Tumi) welcomed all to the 5th SAHPRA-ITG meeting since its inception. – The meeting accepted the minutes of the previous meeting of 25 February 2020. – Ms Abeda Williams introduced all industry groups/organisations represented in this forum. List of attendees will be sent to SAHPRA – The CEO introduced the new SAHPRA Office Manager, Mukona Mphidi to the ITG representatives. Going forward, ITG and PTG meetings will be coordinated and minuted by Mukona. Hayley to assist with the minutes of this meeting. – The CEO further highlighted the need to re-look at the format of the ITG meetings and engagements. The proposal is to rather ensure engagements that are more strategic versus operational to address issues that impact the Industry, to derive the most value. ITG working groups' engagements will also need to be re-looked at. SAHPRA will review the Terms of Reference (TOR) and share with industry for input.	SAHPRA

	Action

2. Attendance list

SAHPRA

Name	***Representing***
Present	
Boitumelo Semete	CEO of SAHPRA
Portia Nkambule	SAHPRA (PN)
Santhani Chetty (SC)	SAHPRA
Tohlang Sehloho	SAHPRA
Davis Mahlatji (DM)	SAHPRA
Sibongile Ratlhogo	SAHPRA
Silverani Padayachee	SAHPRA (SP)
Mukona Mphidi	SAHPRA
Khamusi Mutoti	SAHPRA
Momeena Omarjee	SAHPRA
Kaiser Thembo (KT)	SAHPRA
Bianca Baxen	SAHPRA
Mankiti Khaebana	SAHPRA
Connie Tloubatla	SAHPRA
Imtiaz Ibrahim	SAHPRA
Luyanda Mahlanza	SAHPRA
Shyamli Munbodh	SAHPRA
Susan Khoza	SAHPRA

	Action

ITG

Name	***Representing***
Present	
Connie Tloubata	BPIA
Leigh Gunkel-Keuler	DSA
Imtiaz Ebrahim	DSA
Muhammad Bodhania	GBMSA
Anita Smal	GBMSA
Samantha Jordaan	HPASA
Wayne Robinson	HPASA
Abeda Williams (AW)	ITG Chair and IPASA
Nicole Edelstein	PHARMISA
Hayley Eagar	ITG secretary and SAAHA
Ernest Schay	SAAHA
Tammy Chetty	SAAPI
Nicolette Stott	SACRA
Sarah Cohen	SALDA
Moira Ellie Jimba	SALDA
Tammy Pillay	SAPRAA
Nicola Brink	
Deepa Maharaj	SCA

		Action
No	**Matters arising from previous minutes**	
	Medical devices:	
	Andrea Julsing will provide feedback on the blocking of medical device consignments at Port Health.	AJ
	This issue requires a longer-term strategy which Portia will take forward.	PN
	SAHPRA extended the outstanding medical device licence applications to mid-April.	
	In vitro diagnostic (IVD) permits:	
	SAHPRA clarified that the end-user i.e. the laboratories are responsible for obtaining the import permits in line with the Tissue Act and National Health Act Chapter 1 requirements.	
	SAHPRA is involved with the licensing requirement only for IVDs so as such the other import requirements are not within its mandate.	
	Complementary medicines (CMs):	
	CMS were not discussed at this meeting because the CM meeting between ITG and SAHPRA CM unit has not taken place.	
	The portal has been updated to amend new CM licences,	
	ITG's proposal to uplift submitted dossiers to comply and align with new requirements will be considered at the forum on Monday 18th May.	SAHPRA
	SAHPRA will also consider ITG's proposal of Responsible Pharmacist versus Authorized Person on Monday 18th May.	
	SAHPRA plans to meet with the South African Pharmacy Council (SAPC) soon in order to align on this issue.	
	Clinical trials – Export permits:	
	Portia was not able to action this item due to the COVID-19 lockdown but is following up on this matter. This item will go to the next SAHPRA-ITG meeting as a matter arising.	PN
	Office move:	
	SAHPRA will move to the new offices much later than planned in May 2020 because of the COVID-19 lockdown.	
	API Master Files:	
	Silverani is working on this FTP interface with the assistance of HPA and IT.	SP

		Action
3	**Update on Backlog, BAU, Biologics including Reliance Model**	

	Action

3.1 Backlog clearance update

Total number of current applications -1517

Extensions were granted to Applicants due to the lockdown.

Application Status	Masters	Line Items
Screening	26	44
Inspectorate	50	111
Technical screening • Queries with applicant	204 On track - 145 Extension- 97 Overdue- 3	574 On track- 463 Extension- 248 Overdue- 7
Evaluation	281 On track - 102 Extension- 84 Overdue- 2	678 On track - 230 Extension- 188 Overdue- 4
Registered	49	110
Rejected	4	9

SAHPRA requested that Applicants that were able to respond to queries to please submit their responses as soon as possible, even if this is before the stipulated deadline.

- SAHPRA has adopted a different approach on ways of working and have made improvements such as additional capacity. More updates will be provided in the next meeting on improvements and progress made. — SAHPRA
- ITG cautioned SAHPRA regarding too many changes (e.g. templates) that the organisation takes ownership of its internal processes and not overburden the already saturated industry with too many template and resubmission requirements.
- SAHPRA committed to engage industry on any changes in compliance and administration requirements going forward. — SAHPRA
- Industry raised concern regarding no positive feedback regarding grace period on timelines and extensions. SAHPRA highlighted that too many deadline extensions will hamper service delivery and derail and delay the Backlog progress. Proposed to retain the current timelines of an additional one (1) month given for the bulk of submissions and SAHPRA will only consider written submissions that have reasonable challenges. SAHPRA will review these submission outliers on a case-by-case basis and on their individual merits/circumstances.
- Since April 2020, Variations are being addressed with additional appointed capacity. ITG requested timelines for the approval of variations. SAHPRA indicated that timelines were not yet determined, and feedback will be provided to Industry. — SAHPRA DM

		Action
	3.2 Reliance applications. Total number of applications are 35. Extension granted until 31 May 2020 due to lockdown.	

Registered	In Progress	In query (with applicants)
12	11	12

– SAHPRA has expanded its list to include other Regulatory Authorities within its Reliance Model. Furthermore, a consultant, Stuart Walker will be assisting to conduct a gap analysis of SAHPRA's processes, comparing these to other Regulatory Authorities. Stuart will then develop a framework and tools to optimize SAHPRA's Reliance Model processes. A Reliance workshop will be conducted in June/July this year and SAHPRA may also invite Industry to this workshop.

		Action
	3.3 Business as usual (BAU) for new registration applications (variations to be shared at the next meeting) FTP Uploading System – SAHPRA developed an online uploading system for receipt of applications. Uploading to the evaluation tool (EURS) has been more efficient and the timeline greatly reduced. BAU tracker (Phase I) – currently developing and optimizing an internal tracker for BAU. Phase two (2) will be the development of industry phasing trackers. Screening template has been revised to reduce screening time and will be shared with industry. SCORE and BTIF templates were updated and will be circulated to Industry for comment. SCORE – comments from Industry were reviewed; duplications, guidance comments and examples have been removed. BTIF – duplications have been removed. Outlined new process followed by new registration applications. Improved evaluation approaches by strengthening batch processing. BAU and Backlog have aligned in the end-to-end process to improve efficiencies. To increase evaluator capacity an Expression of Interest was issued. This process is at an advanced stage of finalization. Distribution of applications across the end-to-end process (line items) as at 30/04/2020: - • Total number of applications - 284 • Number in Admin Screening - 6 • Number awaiting Inspectorate review – 19 • Number in technical screening – 42 *(24 are queries with Applicant)* • Number in Evaluation – 178 *(80 are queries with Applicant)* • Number registered or rejected – 39 *(9 rejections)* Update on variations for BAU and Backlog will be included at the next meeting. – SAHPRA reported that plans and processes to digitalize the submissions and identify which appropriate tools to use is underway. – Clarity was sought on when can industry expect Type II variations tracker timelines to go live/be active. SAHPRA indicated that it was not clear on the timelines at this stage as Internal systems are working on verifying data. This will be prioritised for industry. – ITG highlighted that there was no guidance regarding timelines for response and request for extensions. SAHPRA had not issued communication in this regard. These extension applications are dealt with on a case by case basis by SAHPRA as requested.	SAHPRA SC SAHPRA SC

		Action
	– SAHPRA expressed the concern that there was confusion from Industry regarding the correct codes submitted for variations through the portal. SAHPRA highlighted to Applicants to use the correct codes. The cover letter needs to be very clear and to highlight the code. The prefix ANA must be used for nay new registration submission, including responses to SAHPRA recommendations for new registration submissions. – IITG requested an update on products that have been registered (Publication of registered products). It was clarified that this is part of SAHPRA's annual performance plan and IT will publish this on the SAHPRA website. The Quarter 3/2019 list was uploaded onto the website in January 2020 and that for Quarter 4/2019 should have already been uploaded. – It was suggested that going forward feedback be provided on new applications. – The stability guideline that is not version controlled was still on the website and causing confusion to Industry. SAHPRA will withdraw this guideline. Going forward, SAHPRA will look at the stability guideline versus the variation's guideline.	SAHPRA SAHPRA

	Action

3.4 Biologicals

- SAHPRA was experiencing delays in clearing the 75 applications due to the hybrid process of the project unique to each product as well as using the same Evaluators used for Backlog and BAU-Clinical. Applicants were informed through a formal communication explaining the process and possible requirements for additional documents.
- The number of rejections of 13 master applications were considered high. This was due to 6 x previous MCC rejections of which 4 were due to failure to demonstrate biosimilarity and 3 failed at QSE.
- Appointment of additional evaluators is under way.
- ITG requested that SAHPRA pay more attention to the status of variations. ITG requested clarity on how long it will take to complete the remainder of the applications. SAHPRA indicated that it can take up to four (4) months to complete.
- SAHPRA will establish a Biologicals tracker after Project 75 is completed.

BREAKDOWN OF BIOLOGICALS 75:

APPLICATIONS	MASTERS	LINE ITEMS
TOTAL SCREENING (NONE)	75 0	138 0
INSPECTORATE	4	9
EVALUATIONS IN PROGRESS	9	14
QUERY WITH APPLICANTS	9 **ON TRACK: 3** **EXTENSIONS: 5** **OVERDUE: 1**	11 **ON TRACK: 5** **EXTENSIONS: 5** **OVERDUE: 1**
REGISTERED	36	64
REJECTED	13	32
WITHDRAWN/NO RESPONSE	4 **WITHDRAWN: 1** **NO RESPONSE: 3**	8 **WITHDRAWN: 3** **NO RESPONSE: 5**

		Action
4.	**Outstanding FAQ responses** **I**TG will be sending SAHPRA a new list of questions asked by Industry and compiled by ITG.	
5.	**SHAPRA COVID-19 response** deferred due to time constraints	
6.	**COVID impact on matters**	
	6.1 Inspections – GMP inspections – priority will be on applications awaiting registration. Organisations (Sites) will need to ensure compliance with regulations on COVID -19. – GDP- this will only be done for applications of new licenses and those currently being processed. Will be done remotely. – During this level 4 lockdown due to COVID-19 site, inspections will only be conducted for local sites. For Gauteng inspections the team is working on a plan. Notice will be given four (4) weeks prior to the visits and published on the website.	
	6.2 Clinical trials: SAHPRA guidance on virtual monitoring – ITG asked SAHPRA for clarity on applying the COVID-19 EMA guidelines that allow for use of screen sharing and remote monitoring. – SAHPRA indicated that the clinical trial guidelines allow central monitoring, allow virtual monitoring at study site. Onsite monitoring. – Tohlang will review the terminology in these clinical trial guidelines to align with other Regulatory Authorities and refer to these other RAs.	TS

		Action
	6.3 PITE exemptions requested – It was highlighted that SAHPRA had issued many rejections for exemption applications from PIT by Applicants. New guideline was supposed to have been published end of March 2020. SAHPRA indicated that there was an increase in a number of PITE applications received in which Applicants were not providing motivation, or validation of transport systems and proof of payments. Some Applicants requested a waiver on the fees. These issues resulted in delays in processing applications. – Inspectorate will meet with the ITG Working Group to discuss the PIT exemption issue in a separate forum. – SAHPRA clarified to ITG that exemptions were a temporary measure implemented due to COVID-19. – Weekly newsletter is issued to industry.	
	6.4 Wholesaler/distributors S21 included on licenses – Distributors and wholesalers' licenses do not include Section 21 medicines. These facilities are therefore not authorized to distribute Section 21 medicines. This has serious consequences especially for Section 21 medicines for COVID-19. It was reported that more work still needs to be done to confirm whether the licence should include this kind of designation. The matter is still to be considered by the internal governance structures the outcome will be provided soon. The matter is in progress. This matter will also be discussed in the separate forum between SAHPRA and the ITG Working Group.	

		Action
7.	**S36 labelling exemption** – The background to this agenda item is that ITG applied for a blanket Section 36 labelling exemption from the labelling Regulations 10 and 11 gazetted 25 August 2017 but SAHPRA rejected this application on the grounds that SAHPRA had already submitted the Regulations for implementation to the Minister for publication. – However, in the context of the COVID-19 lockdown, it is unlikely that these regulations will be published soon so ITG would like to revisit this Section 36 exemption application. – This item will be taken up in a separate forum between SAHPRA and the ITG Working Group. – ITG requested clarity regarding Section 36 exemptions, whether Applicants can launch the products with the updated and aligned SmPCs and the reason for the delays in the publishing of the labelling regulations. SAHPRA reported that both formats of PIs/PILs versus SmPCs are accepted because they recognise this time period as an interim hybrid stage between the new and old labelling formats. Old format of PIs/PILs is permitted too. Complete migration to the SMPC format will eventually happen.	
8.	**Staff update and funding request to PHEF: CEO** Deferred due to time constrains	
9.	**Any other business (AoB)** – SAHPRA reported that the organisation was currently preparing for an audit and requests industry to assist in prioritising its requests. – Variations applications –Industry was requested to provide original dossiers/history that were previously submitted in hard copies to be in an electronic format via eCTD or e-submission format when submitting applications. This is because SAHPRA is still in a process to align/integrate its processes to digitalize and will communicate to request input from industry when the process is complete. Industry requested to be given more time to consider the request and will provide a response.	SAHPRA ITG