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SAHPRA Communication **Feb 20**

SAHPRA - INDUSTRY COMMUNICATION FAQs

This document is intended to provide communication to applicants wishing to resubmit applications for new registrations as well as variations as part of the Backlog Clearance Program and Business as Usual. This is a "living document" and will be updated as experience is gained through the processing of the Backlog Clearance Program and new BAU processes. If any answers in this document contradicts previous answers to FAQs, information in the most recent communication supersedes previous answers. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of applications. This document should be read in conjunction with SAHPRA's revised guidelines and templates for Backlog and BAU, available from SAHPRA's website.

New FAQ's for Backlog, Business As Usual, Biologicals and General Questions	v1 February 2020

FREQUENTLY ASKED QUESTIONS: BACKLOG CLEARANCE PROGRAM

1 New registrations

1.1 Questions about submission process

1.1.1	Q: Can we please get some clarity on the requirement for the QP Declaration relating to API Variation submissions: The EU guideline mentions the requirement for submission of a QP in several places. 1. Does this QP Declaration replace the API declaration previously provided in 1.2.2.6 or is it an additional document that is required? 2. In which part of the dossier does one include the QP declaration? There is no indication in the Validation templates on where to include it. 3. If it is required, then in what format must we submit (Word or PDF)? 4. If required, do we use the EU template document for this declaration or will SAHPRA provide us with a ZA template document?
	A: The API declaration provided in 1.2.2.6 remains, PDF format to be used
1.1.2	Q: Will SAHPRA allow applicants to send PIs/PILs to the SAHPRA Backlog contact team to proactively request that they be uploaded onto the SAHPRA PI/PIL repository or can this only be done in the order of the resubmission windows?
	A: These should be submitted in the order of resubmission windows due to lack of resources inhouse. However these will be requested 1-2 months prior to the opening of the said resubmission window.
1.1.3	Q: The eSubmission guideline states in point 2.3 “Note: The entire eSubmission needs to be re-submitted each time the applicant makes changes.” Please confirm whether the entire eSubmission must be resubmitted when responding to minor screening queries.
	A: Submission of the entire dossier is not necessary only submit the compulsory document as per the guidelines and the amendment schedule as a follow up sequence.
1.1.4	Q: What are the timelines for Business Validation (A.3) to be completed from date of resubmission?
	A: 5 days
1.1.5	Q: Type II resubmissions. SAHPRA to provide more detail and clarity w.r.t. the no. of query rounds they will accept and also what timeframe will applicants be given to reply to any queries/deficiencies. Similar to the guidance provided on the new dossier resubmissions.
	A: This will be the same timelines as new registration timelines
1.1.6	Q: Regarding type II resubmission windows (section 5.3) – what would SAHPRA want as evidence to prove that a product is in stock-out?
	A: SAHPRA requires stock levels and historic data showing stock movement over a period of 3 months.

1.1.7	Q: Regarding the portal user account process, will there be a limit to the number of secondary users? Can secondary users be non pharmacists (scientists; administrative)
	A: RP will issue access to secondary users and per the guideline there are no restrictions Yes as delegated by the RP
1.1.8	Q: Regarding the pending decision on SCoRE for variations – SAHPRA to provide Industry their decision very soon, and not delay, since Industry has limited time to prepare these templates. If the answer is yes, SAHPRA to please advise if the SCoRE willl be required for all types of applications, i.e. Type Is and Type IIs
	A: SCoRE document is required for variations. No new SCoRE document will be issued. For variations, the applicant must only fill out the the section of the SCoRE that is relevant to the changes being amended must be completed. i.e. not the full score doc. Yes this is required for both type Is and II. As stated above, the relevant section needs to be completed
1.1.9	Q: Will a new version of the SCoRE and Variation Communication be issued to address this new requirement?
	A: There will not be a new version of the SCoRE doc (applicable to both variations and new registrations) and this will be communicated
1.1.10	Q: What advantages does SAHPRA see in completing the SCoRE template for variations? Module 1.5.2.1 in essence is a summary of the changes, Will there be benefits with respect to shortened timeline reviews for SAHPRA?
	A: SCoRE document is a lifecycle management doc i.e. one can determine the basis for approval for any change but this may not necessarily impact the timelines
1.1.11	Q: Regarding section 5.7 – unclassifed changes (z-codes) – is it the intent of SAHPRA to adopt EU article 5, and EMA recommendations, fully? Will SAHPRA accept “z” classification for uncategorised variations as this is not addressed in Guideline 2.08?
	A: z-codes=codes for unclassified changes. In our guidelines we stated that these should be classified as Type IIs. This will be considered in the future
1.1.12	Q: Proprietary names for backlog products. All applications from different applicants for a particular API are being submitted together in one resubmission window and the possibility of similar names being proposed by different applicants is high. The response time should a proposed proprietary name be rejected is not mentioned in the BCC v4. Please confirm what the response time to a proprietary name rejection would be.
	A: Response time will be aligned with the evaluation timelines.
1.1.13	Q: Please advise industry that for duplicates the tracker will only reflect the Master dossier but all duplicates will be reviewed. If not, do we assume that approvals are valid for both MASTER and Duplicate (specifically for naming and scheduling)?
	A: Yes the tracker will reflect the Master dossier, No. the approval is valid for the master dossier, the names will have to be approved separately i.e. the scheduling will be approved for all but the names will be approved separately.
	VARIATIONS
1.1.14	Q: For Type II Clinical Backlog re-submissions (to commence Feb/Mar 2020): will applicants be allowed to update to the SmPC format as well as update the PI/PIL to the latest safety information

	not previously submitted in order to ensure that the labelling has the most up to date safety information?
	A: Yes, applicants must reformat to SmPC format and consolidate and include all safety updates (those submitted previously, and those pending submission).
1.1.15	Q: Type II backlog variations involving safety updates such as additional Contra-indications are being requested to be submitted as a Type II, when the portal opens, however applicants already have additional safety updates which have not yet been submitted (these include both Type IB and Type II). To prevent a backlog of Type II safety variations, and to allow reliance approach in recognising the EU approved SmPC, SAHPRA to review the variation guidelines to allow addition of contra-indication to be included as a Type IB as well.
	A: These can be submitted as Type 1B. The variations guideline will be amended.
1.1.16	Q: Timeline for Type II variation approval needed please.
	A: Answered by Q2.1.2 of the Variations Communication v2 Nov 19
1.1.17	Q: Can applicants reach out to their Project Coordinator to follow up on the variations?
	A: Refer to the variation FAQ
1.1.18	Q: Backlog MAA (new application for registration) resubmission: Is Industry required to update the registered product PI/PIL to the new format and submit to SAHPRA (Type 1A); before resubmission of the line extension or clone applications in the resubmission windows? Or do we retain the PI/PIL of the registered product in the old format and submit the resubmission product in the new format? (in essence you cross reference to the old format PI in your resubmission).
	A: Answered by Q2.2.8 of the Variations Communication v2 Nov 19
1.1.19	Q: Review of the online tracker seems to indicate the dossier is being reviewed by one unit at a time instead of a parallel review. Applicants are receiving queries from individual units and request for a sequence response rather than SAHPRA consolidating all queries into one report for a single sequence submission. (Noted process has been ...)
	A: PCs will send individual query letters. The applicant to provide a consolidated response (follow-up sequence)
1.1.20	Q: Backlog variation resubmission: We have instances where we submitted a full dossier update with Type A, B, C amendments at the same time. We received approvals of the Type C and A amendments but SAHPRA requested clarity on the Type B amendment. We have responded to SAHPRA in 2018 with no response to date. (A side note: the Type B amendment was resubmitted independently prior to receiving the SAHPRA response and taken as approved after 30 days). In the Variations Communication it states that previously submitted Type B amendments can be taken as approved. Kindly advise whether we can continue with the approach or do we need to resubmit the variation during the Full Launch phase of the Digital portal?
	A: Partial approval-all applications which are not approved at the inception of the backlog project need to be resubmitted. Since there's a type C amendment- the application is then classified as a Type C which needs to be resubmitted at full launch. *Applicant specific queries should be communicated via the backlog email.
1.1.21	Q: The EU DCP procedure and EU MRP procedure do not have many differences and the MRP procedure shows to have more conditions required than DCP. Will SAHPRA consider recognising EU MRP procedure as a recognised regulatory authority?

	A: SAHPRA recognizes CP and DCP. SAHPRA recognizes specific agencies in EU. Inclusion of MRP, NP and other agencies is under consideration per the reliance proposal
1.1.22	Q: Will the applicants receive approval letters from each unit e.g. ME&R, once evaluation is complete?
	A: no, the tracker will reflect the outcome for each unit but a consolidated approval letter will be issued.

FREQUENTLY ASKED QUESTIONS: BUSINESS AS USUAL

New registrations

1.2 Questions about submission process

1.2.1	Q: Tohlang confirmed that applicants will not lose their place in the queue for BAU resubmissions, which is contradicting the information given in one of the Business calls. Clarity is required in terms of the process how BAU resubmissions will be handled.
	A: These will be handled on a first come first served basis.
1.2.2	Q: Tohlang confirmed that applicants will not lose their place in the queue for BAU resubmissions, which is contradicting the information given in one of the Business calls. Clarity is required in terms of the process how BAU resubmissions will be handled.
	A: These will be handled on a first come first served basis.
1.2.3	Q: A baseline needs to be done for transfers of applicancy for eCTD format. This is actually the 'old' Applicant's responsibility but is not of interest to them so can the 'new' Applicants rather do this baseline. Will this be permitted? We propose the following two options: a. The baseline (sequence 0000) is prepared by the current (old) HCR, and the ToA application (sequence 0001) by the proposed (new) HCR. Both sequences are submitted together on one CD / DVD b. The baseline (sequence 0000) is prepared by the proposed (new) HCR. All currently approved sections of the CTD is included, including scanned copies of the latest application forms (Module 1.2.1). The proposed (new) HCR adds the letter of application, application forms, electronic copy declaration and validation template. The ToA application (sequence 0001) by the proposed (new) HCR. Both sequences are submitted together on one CD / DVD
	A: Baseline is required regardless of who it is that prepares it.
1.2.4	Q: Some applicants have submitted paper CTD submissions within BAU and have not yet received an application number. The concern is that when Applicants resubmit in eCTD format or e-submission format, that they will lose their place in the submission queue. How will this be handled
	A: all application numbers have been issued for the paper dossiers
1.2.5	Q: Can BAU allow applications that have already been submitted in eCTD prior to the implementation of ScORE and other templates, to be evaluated as is and request any further documents during the question phase as this can be added as the next sequence.
	A: All applications previously submitted after Feb 2018 have to be recompiled and resubmitted, for eCTD (see previous FAQ)
1.2.6	Q: Backlog new submissions have an online application tracker and portfolio coordinators which are beneficial to industry - will a similar process be implemented for BAU new submissions?

	A: Yes, IT is working on the tracker
1.2.7	Q: BAU resubmissions – can we resubmit with the proof of payment as per the initial submissions (old fees) similar to backlog resubmissions
	A: Yes. Submit POP
1.2.8	Q: Must applicants apply for application numbers for applications that were submitted after 1 Feb 2018 in paper CTD format and where screening outcomes have not been received, or will SAHPRA send letters to those applicants with the application numbers and indicating the application fees payable? If SAHPRA will send letters, by when will they be sent
	A: For paper submissions the screening outcome letters were issued including information on the format in which applications should be submitted by 30 Nov 2019.
1.2.9	Q: Please can you consider that for eCTD (submitted in 2018-2019): sequence 1 (or the next follow-up sequence) be used to include any updates, assessments reports and additional documents rather than a resubmission.
	A: Yes; for BAU applications initially submitted in eCTD, applicants may submit an updated sequence instead of the entire dossier. The next sequence can be submitted to include any pending variations, as well as to comply with all the new requirements. SCoRE document to be included.
1.2.10	Q: Name change applications submitted in BAU were evaluated without resubmission – applicants are already compiling and resubmitting? How do we avoid duplication of effort on both sides
	A: If the relevant approvals for the variation application have been received by 25 October 2019, these certificates will be finalised. Variation applications which have not received approval will need to be resubmitted.
1.2.11	Q: The ITG concern is with the R15 000-00 for Type II variations. There are different levels of complexities for the different Type IIs and so some variations require less input by SAHPRA therefore in these cases is the R15000-00 fee really justified? The proposal is for SAHPRA to follow the UK MHRA model in this regard and limit this R15000-00 to only complex major technical variations.
	A: The new fee proposal has taken this into consideration. The UK MHRA model will be adopted. SAHPRA is finalizing the fees document. The fees document will be published for comment by Mid March 2020
1.2.12	Q: Please confirm when the amended Regulation 11 will be published in the Government Gazette. Safety updates done in the new SmPC format cannot be implemented until the amended Regulation has been published for implementation.
	A: SAHPRA has conceded on this that these regulations will be published end Feb 2020 and has updated their variations communication accordingly. Conversion to SmPC has been postponed.
1.2.13	Q: Can SAHPRA provide estimated timelines for approval of Type II variations?
	A: See Variations Communication Q2.1.2 v2 Nov 19
1.2.14	Q: Post 1 Feb 2018 – applicants have received responses from SAHPRA that applications have been distributed for review: • Confirm whether applicants must still resubmit? • When will applicants be notified whether resubmissions are required?

	A: If this is about priority products then it is correct that such applicants should not resubmit. Communication has been sent to the relevant applicants who do not have to resubmit. (Priority ring fenced products). There were paper products that were received and allocated prior. All those that did not receive communication should resubmit. Refer to the communication which was sent out in July 2019 on handling BAU.
1.2.15	Q: Resubmission of Transfer of Applicancy for which Inspectorate approval was received or post-registration name changes where naming approvals were received – only the revised registration certificate(s) is outstanding, will resubmission under BAU still be required?
	A: Transfer of Applicancy: Resubmit and include the Inspectorate approval letter, if received. Proprietary name change: If a name change approval was received and a variation to the registration certificate was submitted by end October 2019, these certificates will be finalised. Queries regarding these applications should be sent to the Certification Team.
1.2.16	Q: Can variations going to different units be combined in one sequence, e.g. a quality variation and a clinical variation or a transfer of applicancy and a proprietary name change? The working codes will indicate which units are involved, and as the applications will be in electronic format, the different units will be able to access the application at the same time. BCC FAQ 2.1.10 confirms that variations can be combined. Will this be true for BAU as well?
	A: Yes, they can be combined (eCTD or eSubmission). The code: VPA should be used for all variation Indicate, under the VPA code on the cover letter, what type of variation is submitted ie. Quality/ Inspectorate/Clinical/Veterinary/Biological/Certificate or any combination thereof. For backlog: indicate backlog and type of variation is submitted Quality/ Inspectorate/Clinical/Veterinary/Biological/Certificate or any combination thereof.
1.2.17	Q: The Government Gazette (GG) states the following: 1(a)(xii) Screening fee on receipt of an electronic Common Technical Document (eCTD) format application: R1760 per sequence; (pg 3) The validation templates for eSubmission and eCTD state: 2d Follow-up sequence: Validation fee (proof of payment, submitted in a separate envelope, with copy of the letter of application) (Module 1.2.2.1) (pg 2) 1. The GG only refers to eCTD and not eSubmission. Would the fee stipulated in 1(a)(xii) in the GG also be applicable to each follow-up sequence submitted in eSubmission format? 2. The GG refers to a screening fee, whereas the validation templates refer to a validation fee. Please clarify if the screening and validation fees referred to are the same, or clarify where the validation fee can be found. 3. If an application is submitted that is classified as a major technical amendment, that attracts a fee of R15 000 (1(b)(v) in the GG), is the R1760 fee for screening/validation also required?
	A: 1. Yes: For the first resubmission there is no validation but applicants will be charged for next sequence. 2. Yes, these are the same. Synonymous. 3. No screening fee required for variations currently
1.2.18	Q: BAU variations affecting registration certificates – how long will it take to issue amended registration certificates following approval, e.g. name change? Some of these are urgently required for tender purposes.
	A: Timelines for issuing registration certificates are to be determined when reengineered processes are implemented. To be determined in future. Clearly indicate on the application and include evidence, that the product is for tender purposes upfront.
1.2.19	Q: Please can SAHPRA advise on the response timelines to be adhered to for responses to deficiencies which are received for BAU submissions. For Backlog these are stated as follows: 5 working days for screening queries

	10 working days for Response 1 10 working days for Response 2 We assume that these will be different for BAU submissions? Please clarify
	A: BAU and Backlog processes are harmonised. The requirements are therefore similar. From date applicant receives the letter and take into account holidays.

FREQUENTLY ASKED QUESTIONS: BIOLOGICALS

1.4 General Biological Questions

1.4.1	Q: SAHPRA recently invited companies to make use of the WHO prequalification system. GBMSA were told at a meeting with WHO in October that a product passing the WHO PQ would be eligible for local registration within three months, especially biosimilars. Does SAHPRA support this?
	A: SAHPRA is looking into this, to be communicated at the end of the quarter
1.4.2	Q: Confirmation initially was that a backlog of 75 applications will be cleared by end Dec 2019 in the BMC unit. Is this estimate still on track? How many haves been approved thus far? What was the outcome of the survey done earlier this month?
	A: Based on the BMU workshop presentation, a commitment was made to register 44% of the 75 applications. 23 have been registered. From the survey, consolidated figures for the variation-all discrepancies were communicated with the applicants and corrected.
1.4.3	Q: Biosimilar applications have been with OPS and ADMIN, not allocated to BMC yet, after more than a year. When will the allocations happen to the various units? (N&S;BMC)?
	A: All biosimilar applications received were shared with BMU
1.4.4	Q: A process for review and communication from Biologicals unit need to be communicated to the industry.
	A: A workshop was held on 22 Nov 2019 to clarify
1.4.5	Q: Backlog has a tracker and portfolio coordinators- will a similar process be implemented for Biologicals?
	A: A tracker will be implemented for the BMU. The 75 applications are coordinated by BMU. All applications received post 1 Aug 2019 are handled through the project office.
1.4.6	Q: Do we need to align with requirements added in the backlog project for biologicals? Eg. do we submit PI in SmPC format, SCoRE document, executed batch records, master batch documents, Abridged & Verified review templates?
	A: Yes only for the SmPC. The other documents are still under discussion
1.4.7	Q: Must biological applications (backlog and BAU) be resubmitted?
	A: If applicants submitted paper submission previously, then eCTD submission/esubmission format is required.
1.4.8	Q: Must the validation template (6.16 or 6.30) be used for biological applications?
	A: under review
1.4.9	Q: Will BMU publish FAQs?
	A: Yes
1.4.10	Q: Please provide feedback regarding the guidelines applicable to biologicals/biosimilars.
	A: These are available on the website. New guidelines are still under discussion.

1.4.11	Q: Biological medicines will not be part of the soft launch for Type IA variations (MAH address change, FPRC name change, FPRC removal) (BAU variations) – could we perhaps be allowed to submit as part of the soft launch since these variations relate to Inspectorate?
	A: These can be submitted to BAU.
1.4.12	Q: Would the reliance model be considered for new indication applications for biological medicines?
	A: under discussion
1.4.13	Q: With SAHPRA moving electronic, how does the biologic unit envisage variations to be submitted and managed?
	A: BMU variations will be submitted like all other variation applications
1.4.14	Q: There are a set of codes for Biologicals on the SAHPRA website. This document does not have headers or footers or a version number. There are also codes in the General Information Guideline. Please clarify which set of codes must be used when coding submissions for Biological Medicines.
	A: To be confirmed
1.4.15	Q: How do we follow-up on older clinical submissions for Biological medicines that were previously submitted to the Clinical Unit?E.g. PI/PIL updates responses submitted where responses are still pending and holding up the submission of new clinical updates
	A: applicant to follow-up with BMU
1.4.16	Q: Will biologicals applications still be reviewed by ME&R - inspectorate, Names and Scheduling and Clinical Unit or will Biologicals complete the full review?
	A: BMU will complete the full review except for N&S and Inspectorate.
1.4.17	Q: Please can SAHPRA stipulate the timeframe to be expected for validation of an eCTD new biological entity submission which falls under the BAU process.
	A: under discussion
1.4.18	Q: Section 2.1: API Information - Biologic NCE often have no CEP, WHO Prequalification, APIMF, DMF etc nor found in monograph/pharmacopoeia or letter of access
	A: The use of the SCoRE document is still under discussion.
1.4.19	Q: Going forward, will we still need to use the Biological Amendments Guideline to assess variations on Biologicals or will the EMA variations guideline (together with the Variations addendum) be used?
	A: The current guideline is being used. Going forward, the EMA guideline will be used.
1.4.20	Q: Will EU variation approval letters be used to evaluate variations submitted for registered products? Like with the backlog and BAU process.
	A: still under consideration
1.4.21	Q: Does the WHO CRP expression of interest Oct 19 v1 apply to vaccines as well?
	A: to be confirmed

FREQUENTLY ASKED QUESTIONS: GENERAL

1.3 General and other Variation questions

1.3.1	Q: 1. Feedback on guidelines please that were published for comment and never finalised, e.g. (i) Section 21 [2.52] (ii) Exemptions from certain medicine registration requirements for Human Medicines [2.48] (iii) Post-marketing ADRs [2.33] (iv) Proprietary names [2.15]
	A:(i)comments are being consolidated in house (ii)comments are being consolidated in house (iii)comments are being consolidated in house (iv)Finalized
1.3.2	Q: Feedback on the website and where to get the latest guidelines (some are not on the website, some old versions are on the website and the new versions not)
	A: some new guidelines are uploaded under the news section on the website. The website is under construction and will be launched at the end of Jan 2020.
1.3.3	Q: Is there a replacement for the Head of Names and Scheduling Unit?
	A: No
1.3.4	Q: In the Reliance Model: Module 3 from RRA country maybe be deficient compared to SAPHRA requirements eg. as they don't have COA, how do we declare sameness?
	A: Either COA or batch analysis can be accepted. Highlight the differences in the cover letter.
1.3.5	Q: Abridged and verification templates requires a copy of specification which is expected to be version controlled. How is this attached to the word document or can we mention where to find the document?
	A: Through reference to the relevant section in the RRA dossier and/or eCTD/eSubmission
1.3.6	Q: Declaration template – when will this be available
	A: under review
1.3.7	Q: Biowaiver template Is this required as this a copy of comparative dissolution report and also a WHO document? Both a report and protocol are required – why? We should only be providing the report
	A: The biowaver template includes information from the comparative dissolution report however different conditions will require different templates e.g. BCS biowaver vs different strengths. In the absence of a report then a protocol may be required
1.3.8	Q: BTIF Do you need separate documents for each bio study? If there is more than one biostudy and the analytical methods are the same - do you need to repeat the information if a BTIF is required per study

	A:Yes, information per study should be included
1.3.9	Q: Amendment schedule for PI/PIL changes – why is this required when we provide annotated versions of documents
	A: The requirement for the amendment schedule is suspended instead a narrative of past variations should be included in the amendment history.
1.3.10	Q: Please can we get clarification from SAHPRA on the process to be followed to request amendments to the registration certificates issued by Backlog Variations / Certifications Clearance team.
	A: Applicants should email queries to backlog certification email address backlog.certification@sahpra.org.za
1.3.11	Q: Validation template: a. Section b 7a. Which API COA is required? (i.e. sample, COA of DMF, Bio batch) b. Section b 7 c and d. 7c declaration of BMR is required but 7d it is not specified
	A: The bio batch. Where there is no biostudy COA of the DMF may be submitted. Section 7d refers to the pivot batch e.g. bio batch
1.3.12	Q: Type IA's and the requirement to notify SAHPRA within 12-months following implementation: how is this envisaged by SAHPRA to be managed: a. Will an applicant log the Type IA on the online portal as and when they are received and then wait for a Type IB or Type II submissions to add the Type IA to these? h) Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product (*) | 1, 2, 3, 4, 7, 8 | 1, 2 | IA_{IN}
	A: Type IA can be submitted separately to Type IB/Type II onto the portal, they do not need to be combined. Type IAIN notifications must be submitted to SAHPRA and can be implemented once submitted
1.3.13	Q: Would a baseline eCTD/eSubmission be required when a Type 1AIN (= Type A for immediate notification) is submitted to SAHPRA via the on-line portal?
1.3.14	Q: The EMA Guideline refers to "current edition of Ph. Eur." When classifying variations see example below. h) Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product (*) | 1, 2, 3, 4, 7, 8 | 1, 2 | IA_{IN} Will SAHPRA accept reference to other well recognised pharmacopoeias with the same category and classification of the variation? i.e. update of the dossier to comply with the provisions of an updated general monograph of the BP/USP/JP?
	A: Please see items 4.3.2 and 4.3.5 of the Variations addendum for Human and Veterinary Medicines v2 Nov 19

1.3.15	Q: We have been requested to resubmit several TOA's in paper as we are told that the Inspectorate cannot access the systems for reviewing electronic submission. Given all the other communication from SAHPRA and knowing the intention is to stop ALL paper submissions, this is of grave concern on multiple levels. Could you please find out if other companies have received similar requests and address via ITG
	A: All variation applications need to be resubmitted in eCTD/eSubmission format
1.3.16	Q: "implementation of the outstanding general regulations relating to bonusing as published in gov gazette no.41287 (page161) dated 1 December 2017" Is this going to be implemented as the original notification (see Annexure above) stated (within three months i.e. after December 2017 ?) or not at all?
	A: Resolved through Is this required as this a copy of comparative dissolution report and also a WHO document? Both a report and protocol are required – why? We should only be providing the report ugh medical devices unit.
1.3.17	Q: API MFs: Is this applicable to only generic APIs?
	A: No, it is applicable to both generics and innovators
1.3.18	Q: The Addendum to the Variations guideline and the related Communication: Is not on the SAHPRA website. Furthermore, the guideline contains no update history and does not clearly link to the main guideline e.g. have sections been replaced, there seems to be duplication of some information.
	A: The addendum to the variation guideline is on the website. The website is still under construction To be looked into