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COMMUNICATION TO STAKEHOLDERS

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Renewals Frequently Asked Questions

Document History

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Version 2 Update Section 49 to clarify the PI/PIL submission requirement for Renewals	15 December 2022
Version 3 Deleted section 6 Added section 48-67 based on the industry comments from the Renewals Feedback – conclusion session	21 April 2023
Version 4	30 June 2023

Added section 68-74 based on the industry comments from the Renewal Catchup session	

This document is set to provide the summary of the frequently asked questions regarding the Medicine Registration Renewals Process ensuring a consistent approach to benefit all stakeholders to ensure quality, efficacious and safe products are available to the public.

The document covers specific questions in relation to but not limited to the following:

- Inactive Products/un-marketed products
- Products registered before 2017 and not yet registered (old medicines)
- Variations review during renewal
- PI/PIL, GMP approval and CPP, PQRs, QIS and QOS
- Risk Benefit assessment report
- Product Schedule during renewal process
- Process timeline
- Renewals Workstream structure and Schedule

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INDUSTRY DISCUSSION – RENEWALS GUIDELINE FREQUENTLY ASKED QUESTIONS

FAQ / Applicant Questions	Response from Authority
1. Are the timelines provided for submission of applications for the review process prior to expiry date in working days or calendar days?	The timelines provided are in working days, i.e., 120 days. This corresponds to 6 months prior to the expiry date.
2. Will the timeline, in terms of days, allocated for each step in the process be included in the process map?	The timelines for the different steps will be established and refined during the pilot process. A more granular process map which will include the number of days for each step would be published once the pilot is completed.
3. Will a Portfolio Co-ordinator be linked to a company as was done in the Backlog Project?	The PC appointed in the Renewals workstream will be responsible for the end-to-end coordination of the process. The PC will not be linked to a specific portfolio of companies.
4. Which SAHPRA portal will be used for this submission of renewal applications?	Renewal applications should be submitted via the FTP system until further notice.

FAQ / Applicant Questions	Response from Authority
5. Considering that veterinary medicines applications were required to be converted to CTD from 1st Jan 2022, are applicants expected to convert the veterinary medicines to eCTD for the renewal applications?	From Jan 2022, all veterinary applications should be submitted in CTD format. Applicants should submit renewal applications in eSubmission CTD format via the FTP platform. Submissions for renewal of veterinary products will not be in eCTD format for now, until further notice.
6. Will the Type IA and IB be managed by DVP portal which cannot handle eCTD submissions? And once we submit the renewals in eCTD format, how will we manage those variations, will the DVP portal be updated or how will those Type IA and IBs be managed after the eCTD roll out?	SAHPRA is in the process of procuring a Regulatory Information Management System and the tool that we envisaged to deploy and we will be managing all of the documents through one of the industry tools. In future, variations will be submitted in eCTD format to then be recorded as the sequences on this software platform so that we have got all of the life cycle management and we have got all the information in eCTD format through this tool. Applicants are reminded that all new medicine applications in eCTD are submitted via the FTP and as such all those who are now submitting in eCTD, can submit type IA; IB and II via the FTP.
7. Should applicants submit Modules 1-5 or Modules 1-3 when it pertains to the submission of a full	Module 1-5 will be required fora baseline dossier for all applications that are currently not in eCTD format. An application for renewal which will be a follow-up sequence should only consist of the information that is requested in the Renewals Guideline.

FAQ / Applicant Questions	Response from Authority
eCTD baseline dossier?	
8. Please advise of a solution in the case of TOAs where new applicants do not have visibility of previous submissions on the DVP but are required to provide a history of amendments in the application for renewal of the relevant products. .	This will be well taken care of by the RIMS which will ensure we have all the history in one place provided we have received a baseline dossier in cases where we do not have. However, in the interim, the DVP outcome report date can be used. For variations implemented following 37 working days, calculate the date by adding 37 days to the date of submission.
9. Are eCTD baseline dossiers only required for those products not in eCTD format?	Yes, correct. This requirement does not apply to Veterinary medicines, as current CTD is the requirement.
10. What is the consensus regarding old medicine where Module 4 and Module 5 information is not available?	At this point the old medicines will not comply with Module 4 / 5 and this will be discussed in the consultation sessions that will be starting next year as the framework is firmed up.

FAQ / Applicant Questions	Response from Authority
11. How do we submit baseline dossiers in eCTD format if applicants have already submitted a variation in eSubmission format?	Applicants are required to convert the variations in eSubmission format to eCTD and submit the eCTD baseline.
12. What is the process regarding grandfathered/ old medicines that do not meet the requirements for application for a renewal	Further information regarding grandfathered/old medicines will be communicated in due course.
13. What measures will be in place to ensure that we do not have Backlog of applications for renewal?	The roadmap spans across 13 years and accounts for the large number of products that would have to be reviewed. The applications will not be processed at one go. The roadmap allows SAHPRA to start with products registered in2018, then 2019, then 2020 and so on. We will then slowly build up capacity internally to ensure that we do not start running into a backlog. We would have enough time to bring relevant resources on board and train them so they can look after the renewals on an ongoing basis. This is something that will happen over the course of 13 years as there will be step changes at different intervals. The key is to make sure that the renewals requirements and the renewals evaluation process is very streamlined but still exercise due diligence in terms of renewing certain critical information and obviously ensuring patient safety.

FAQ / Applicant Questions	Response from Authority
14. It is not always possible to plan variation in advance of the process, Are there any exceptions With regards to variations submissions being made together with a renewal application	Variations should not be submitted together with a renewal application. Variation applications should be submitted as a follow up sequence via the FTP system.
15. How far in advance can an applicant submit for renewal, e.g. is 6 to 12 months in advance accepted?	Renewals should be submitted at least 120 working days (6 months) prior to the expiry date, which corresponds to 6 months.
16. Issue on the interface between eSubmission which were in CTD format but not on eCTD but in sort of NEES format, so far there is a lot of practical examples where bit Type II variation has been submitted in eSubmission format and now suddenly we are faced with providing a baseline eCTD.	For variations where eCTD baseline have not been submitted before, if there are these kind of variations coming through now, the requirement is for the baseline to be submitted along with the variation. For instance, if SAHPRA have got something that was previously submitted in a CTD or eSubmission format, if there is any significant variations right now, normally is eCTD baseline plus the sequence. Pending variations in eSubmission format –applicant should submit the renewal application once the variation is approved since the formats are different and to manage life cycle of the product information.

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And the issue for us then is do we go backwards and take out that variation because the timing of the renewal is not something that we can control. So the practical issue for the industry is where you have that transition; you have got very big Type II eSubmission which is already in the system and now you suddenly faced with baseline eCTD and what we were hoping would be entertained is that huge variation will be able to be integrated into the baseline eCTD. So this is the sort of the special case that we are going to have in many cases because of the eCTD baseline issue?	
17. If the applicant submits a renewal application, then it is understood that applicants can still send the variation through the FTP/DVP in	To re-confirm that, yes, that is the case. We then allow the normal process of amendments/variations to carry on and that also gives colleagues a period where we move to the good software platform that will allow us to have visibility across the teams and also to see amendments across the teams amendments that pending or has been reviewed etc. Yes indeed

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parallel if for example, Type IA/Type IB quality variation comes up from the manufacture?	we will still allow for those amendments to run through the normal process whilst we are busy doing the renewal in the other work stream. Note that the renewals process does not affect the normal or routine processes of the product. The renewal reviewers will look at information until the date of the renewal submission.
18. If baseline have already been submitted, does the renewal date move out?	Baselines submission do not have an impact on the original registration date, therefore, the renewal due date will also be not impacted by baseline submissions.
19. Is the EU also enforcing this renewal program or is it already in place?	Renewal process is already in place at EMA.
20. Can we submit the PI/PIL as was 5 years ago and the current one; and then attach all Labelling Variations which were submitted and approved?	Applicants are required to submit the Professional Information (PI)/Patient Information Leaflet (PIL) approved from 5 years prior to this renewal application submission, the current SAHPRA-approved PI/PIL (the latter if applicable) and the proof of approval of current PI/PIL.

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21. Which PI/PIL are we supposed to use SmPC or not?	Will stick with the SmPC while we are sorting out the regulation issue.
22. If the PI is in the SmPC format, does the PIL also have to be in the new format given that the regulations are not yet updated?	The current format of the approved PIL will be accepted until the regulations are updated and published for implementation.
23. Where a manufacturer source country no longer issue the GMP certificate, what would be a suitable substitute?	A suitable substitute will be a certificate from the Recognized Regulatory Authority (RRA) or from SAHPRA itself as per the GMP guidelines.
24. Does the resolution letter have an expiry date?	The resolution letters have an expiry date, it is noted in the resolution how long that resolution letter is valid for. Should you have any concerns around that and is affecting your renewal, you need to contact the inspectorate in order to say that the inspection needs to be planned for that particular site or if you have the reliance certificate that meet requirements in terms of GMP, you can submit that as well.

FAQ / Applicant Questions	Response from Authority
25. FDA does not issue GMP certificates and nor letters, please advise?	FDA does have the Establishments Inspection Reports (EIR) which we use for reliance. These reports, from the FDA, should be included in the application for the relevant sites.
26. Will the QIS and QOS replace the SCoRE?	Yes, the QIS and QOS (if the SCoRE has not been submitted already for the product) should be submitted for renewal applications. Note: QIS/QOS is required for all renewal applications.
27. Where in the CTD dossier will the QOS and QIS be inserted?	In Section 3.2.R.8
28. With regards to the PQRs, the requirement is that we need to conduct a review of 10 or 25 consecutive batches, in cases this is not possible, and will it be acceptable to use batches that were manufactured or maybe just released for other markets and not necessarily in SA?	The review should be conducted for export products as well, so we talking about the principal manufacturing in the country they are in and they are required to do periodic quality product review and the reason for this review is to verify the consistency of the existing process, the current specifications for both starting materials, finished products and to highlight any trends. So it would be value adding if you did include those batches because then it would give the Regulator an idea of whether the processes controlled at the point of manufacture.

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29. Will the SAHPRA template be issued for QOS/QIS?	QIS and QOS templates will be published after the pilot has concluded.
30. What are the phases for? Are we getting a list of product to be submitted according to therapeutic use during these phases?	Products registered in specific years and have been bucketed into different year groups which is a phase and within the phases is the subsections per quarter. The schedule will then inform the applicants when the renewal applications should be submitted.
31. If the duplicate registrations renewal date comes up before the master registration, which date will be used to plan for the renewal?	The renewals framework is at a line item level also when a product line has been registered it would then be due for renewal based on its individual registration date.
32. Will the renewal of all applications be once off and not every 5 years that pass, as it is reported that EU will do away with the renewal all together as of Jan 2022?	According to our legislation, that is section 15, subsection 6A, Registration is valid for 5 years, which means renewal applications has to be submitted within 5 years prior to the expiry date as indicated on the renewal certificate
33. Can we consolidate the master and	Yes, the master and the clone can be consolidated into one eCTD baseline, however the

FAQ / Applicant Questions	Response from Authority
clone into one eCTD baseline?	Renewal applications will be taken case by case depending on their respective dates of registration.
34. Have we identified the applicants that their products will be involved in Pilot?	Yes, the products for pilot have been identified. And communication with those applicants relating to these specific products will then be shared now after this workshop in early next week so that there will be enough time to set up further discussions with the respective applicants.
35. Based on past experience, the project where innovators and generics were not aligned for clinical, we suggest that innovators be renewed first.	There are specific areas that focus on the safety, quality and efficacy components that the team will look at. The approach is slightly different to what is being done in registration process.
36. Prioritising format, I know that it has been suggested that innovators be looked into first but is there going to be a process maybe, will it be like a FIFO type of thing or will there be a quality and efficacy portion attached to which	The renewal process will not follow any priority process but will be processed according to the registration dates as per schedule shared.

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ones do get reviewed or rather renewed first. So if there is the process, could that be share but if there is still going to be taking it back internally, kindly advice?	
37. Since the renewal include the approved information, does it require approval again or a check from SAHPRA?	Renewal process will not include the re-evaluate approved information. There will be specific areas that evaluators will focus on with respect to safety, quality and efficacy components of the medicine.
38. For products where there is no eCTD baseline for products called up for renewal, will the baseline submission on its own be acceptable for the purpose of renewal to be completed or the baseline need to be submitted with the separate variation sequence?	Baseline, sequence 0000, should be submitted and the renewal information should be submitted in sequence 0001

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39. What file name convention should be used for the renewal submissions?	Application number-REN-Sequence number Example: (i) When converting to eCTD the following naming convention should be used: 540000-REN-0000 (for the baseline) and 540000-REN-0001 (for the renewal information (ii) When the renewal application is submitted as a follow up sequence, the following naming convention should be used: 540000-REN-00XX where XX is the relevant follow up sequence number
40. If the dossier is very outdated, like dossiers in MRF format and it was never updated completely; as it has been said that old information will need to be changed would that not then be a variation? So will we need to put in a variation first before we do renewal or do we make those changes as part of the renewal?	Test methods that changed that are supposed to be submitted as an update and variations to them should have been submitted already in the dossier. What SAHPRA is avoiding is to have to deal with those issues because there are applicants that are not updating this information. At the time for submission for renewal, SAHPRA would require that applicants have updated or brought this in line with the current standards. Even if some of the guidelines requirements have not been met, these are things that should have been brought in line once these guidelines has been changed. In cases where this has not been done, it should be done before hand, ideally for renewals all of this should have been submitted already. These should have already been approved before hand, SAHPRA don't want applicant to have to submit an application where these are not done. If not done, it will results in the renewal being rejected as it will not be aligned to the latest Pharmacopeia.

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41. Please advise where is the guideline for template to be included in the renewal?	The guideline states clearly what will be required for renewal submission. It has stated that Module 1 and also stated the requirements for products dated 2017 prior. And other product from 2018 to date, the information is also indicated in the guideline.
42. At the time of renewal and the variation has not yet been approved by SAHPRA, is it possible to get an extension for renewal submission?	Applicants will be reminded of their renewal 6 months before the renewal due date.
43. Please confirm if the exemption will be retained for non-clinical and clinical data which were exempted at the time of registration?	No change in requirements for Non-clinical and clinical data for renewal. The renewal is based on the basis on which it was registered.
44. Will registration number stay the same on the registration certificate?	The registration number will remain the same.

FAQ / Applicant Questions	Response from Authority
45. On the PI/PIL issue; if the Amendment Schedule Format is not a reasonable Compromise; can we submit the PI/PIL as was 5 years ago and the current one; and then attach all Labelling Variations which were submitted and approved. At least those Variations will be on file with us & SAHPRA can compare the then.	Applicants are required to submit the Professional Information (PI)/Patient Information Leaflet (PIL) approved from 5 years prior to this renewal application submission, the current SAHPRA-approved PI/PIL (the latter if applicable) and the proof of approval of current PI/PIL.
46. What if you have amendments during the renewal process?	Variations should not be submitted together with a renewal application. Variation applications should be submitted as a follow up sequence via the FTP system. The Applicant should follow the Priority review request process for urgent variations.
47. When applications are transferred to a new HCR, will SAHPRA update the renewal roadmap accordingly and inform the new HCR when the dossier is due for renewal?	Applicant to notify renewal work stream and request that the application be moved from the previous road map of the old HCR to the new approved HCR.

FAQ / Applicant Questions	Response from Authority
48. What will the fee be for duplicates /clones?	Refer to the capping in response to question 49 below
49. Is there a cap on the fees for a particular strength? Example, maximum R90 000 per product irrespective of the number of strengths	See below proposed fees circulated to industry, any changes will be communicated accordingly: For NCE applications: NCE Master – R50 000 NCE Line Extension – R20 000 A maximum of 3 lines will be charged amounting to R90 000 for a renewal (R50 000 + R20 000 + R20 000) For Generic applications: Generic Master – R40 000 Generic Line Extension – R12 000 A maximum of 3 lines will be charged amounting to R64 000 for a renewal (R40 000 + R12 000 + R12 000)
50. Which fees are applicable to biological medicines? Do new biological medicines fall	All new Biological and Biosimilar renewals are charged as NCEs, refer to point 49 above.

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under NCEs and Biosimilar under generics or will there be separate categories?	
51. Will different strengths (for same product range) but possibly registered at different times - be submitted as one renewal (eCTD) - in line with Master and clone principle?	Yes, provided the relevant strengths and clones/replicas are due for renewal, i.e. registered in 2018 and before. This will be done on case-by-case bases.
52. Will there be an impact on the renewals schedule by inclusion of duplicates at the time of the master renewal?	There will be an impact as stated above in 51.
53. If the product has not been marketed, we will not have batch documents for the PQRs therefore PQRs will be problematic for dormant products.	This will be addressed accordingly, when the dormant renewal issue is finalized.

FAQ / Applicant Questions	Response from Authority
54. Are we permitted to assume approval if SAHPRA feedback is not received within the stipulated time frames?	Approval cannot be assumed. SAHPRA will have to provide feedback after 6 months.
55. For the risk-benefit assessment report, can we use a PSUR for period of 5 years or can the latest published periodic Risk Benefit Evaluation report be submitted, as all the necessary information is already included in the PBRERs?	A risk-benefit assessment report of the preceding 5 years is required as stated in the SAHPGL-HPA-04_v2 (Renewal Of Registration Of Human And Veterinary Medicines).
56. How detailed should the summary be? Is there a specific format? Is it simply summarizing PSURs that cover the 5-year period?	The detailed requirements for the risk-benefit assessment report of the preceding 5 years is specified in the SAHPGL-HPA-04_v2 (Renewal Of Registration Of Human And Veterinary Medicines).
57. Just to go back to the comment on Codes - do we not need to code our applications. Are the Codes no	The file name convention to be used for renewal applications submitted online would be sufficient to ensure the correcting routing of the applications.

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longer required?	
58. In Nigeria, if the renewal evaluation is still ongoing after expiry they issue a temporary renewal certificate for a period of one year. Very important to inform PEE and Port Health as shipments may be stopped and SEP will not be granted. Should this be qualified as a single extension?	Where there are delays, SAHPRA will issue a temporary registration certificate valid for one year. This will be considered on a case-by-case basis.
59. Can we still submit a CPP from the country of manufacture if the product is not registered in that country?	A CPP issued by the relevant Health/Regulatory body in the country of manufacture of the product or, if not registered in the country of origin, a CPP from a Health Authority of a country where the product is registered and marketed (legalisation/notarisation not required).
60. If the CPP is not available at the time of renewal submission due to	The commitment will not be acceptable for the renewals. The Road Map schedule shared has provided enough time to request these documents from the authorities in advance.

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delays from local authorities, can we submit the renewal application with commitment?	
61. For dossiers that have already transitioned to Baseline eCTD (Module 1-3) and submitted to HA, what would be the expectation for Renewals	The renewal sequence is expected to be submitted for the renewal in line with the SAHPGL-HPA-04_v2 (Renewal Of Registration Of Human And Veterinary Medicines).
62. Module 4 and 5 information is generally left untouched and is old and in old hard copy format and is likely to not be eCTD formatted & we will not easily be supported to have the docs reformatted. It will be an immense task for industry to redo products that has already been baselines as well as old products. Can these modules be excluded from the eCTD baseline?	Modules 4 and 5 will not be required for a renewal application if already submitted in the baseline. If Modules 4 & 5 were not included in the baseline, then submit in a follow-up sequence M1-5 will be required in the baseline submission.

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Note: Botswana only requires M1 - 3 for renewals where M4 + M5 are not available. Nigeria which is an WHO ML3 also only requires M1-M3 for baseline. And It is a same case for Tanzania as well.	
63. Can a global PQR from the manufacturing site be used or must it be a local specific one?	Global PQR can be used as it demonstrates consistency, provided the formulation is registered in South Africa, and has to comply with SA requirements which is aligned to the PICs requirements.
64. If a QOS is in the ICH format would that be sufficient	The SAHPRA published QOS template must be used.
65. In cases where only a partial SCoRE was submitted during variation applications, please confirm if a QOS will then be required during the License Renewal process.	Both QOS and QIS should be submitted.
66. According to the FAQs provided,	No transfer of registration certificate may be submitted while a renewal application is being

FAQ / Applicant Questions	Response from Authority
variations can be submitted in parallel with renewal applications, but in a separate sequence. Would this also apply to transfers of applicancy? If a ToA was submitted, but not yet approved by the time the renewal application must be submitted, must the renewal application be submitted by the proposed new HCR? Similarly, if a renewal application was submitted, and a ToA must be submitted, can it be submitted before finalisation of the renewal application and run in parallel?	processed. When products are transferred to a new HCR, it remains the previous HCR's responsibility to inform the new HCR of the renewal due date, as per the renewal roadmap. The roadmap will not be amended by SAHPRA to reflect transfers of applicancy.
67. Can SAHPRA please consider creating a space on their website for documents shared with	All documents shared with ITG are also uploaded on the SAHPRA website.

FAQ / Applicant Questions	Response from Authority
industry? A lot of the documents seem to not filter down from ITG/ other bodies.	
68. In the case where the BMRs were never submitted to SAHPRA, are these expected to be submitted with the renewals? If the BMRs are submitted, is it MBRs or eBMRs. In the case of multiple sites, do we submit BMRs from all the registered sites or only from the active site?	Yes, the BMR should be included in the eCTD baseline sequence. Both Master BMRs and executed BMRs should be submitted as stated in Module 3.2.R.7 in the Quality and Bioequivalence Guideline (SAHPRA-PEM-02) Master BMRs for each manufacturing sites should be submitted as stated in Module 3.2.R.7 in the Quality and Bioequivalence Guideline (SAHPRA-PEM-02).
69. What is the format of the PQRs required to be submitted? The renewals guideline requires at least 10 batches for the PQR. If less	For the PQR, please follow the requirement as stated under section 4.3 of the Renewals Guidelines (SAHPGL-HPA-04) Batches manufactured at a lower scale than that stated in the guideline will be handled on a

FAQ / Applicant Questions	Response from Authority
were manufactured during a review period, can we include only trending of at least 10 batches, but review only on the batches manufactured in the review period, or should the entire review be on the 10 batches? Is the renewal submission structure then going to look like: 1. Module 1, 2 PV, 3 PQR and subsections etc.	case-by-case basis and more extensive documentation may be required in such cases. For the renewal sequence requirements, please refer to section 4.3 in the Renewal of Registration of Human and Veterinary Medicines (SAHPGL-HPA-04).
70. Can we submit the renewal application earlier than our proposed deadline?	No. As per the renewal framework communication, the renewal application should be submitted as per stipulated time lines in the renewals schedule.
71. Regarding the dormant products, is the 18 month per dossier renewal or a general extension from a specific period?	The extension period start from the 1st of June 2023 to December 2024

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Further clarity is required on the grace period of 18 months as per the recent Renewals communication document. • Is the grace period only allowed for renewals of dormant dossiers due for submission in Phase 1 (2023) & Phase 2 (2024) dormant products?	See response above
• Do we have to notify SAHPRA of the intent to apply a grace period to a dossier?	Yes, the notification should be done by sending a letter in the company letterhead advising SAHPRA renewal their intent to apply for grace period with the details of the products.
• If yes, how long in advance of the renewal window should we notify SAHPRA that we will not be submitting a renewal dossier?	Could notify SAHPRA anytime but latest a month before the renewal submission is due.
• Is the grace period calculated as 18 months from the allocated	Grace period is calculated from the 1st of June 2023.

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window or can the renewal dossier be submitted at any point during the grace period? (i.e., renewals due in Phase 1, Q3 + 18 months grace period now fall in Phase 3, Q1). • Will we be able to submit dormant dossiers prior to the renewal date (i.e. prior to the 18m)? Do we have to notify SAHPRA in this scenario? • Advise if we will be allowed to cancel dormant products during the grace period.	All applications due in Phase 1 to Phase 2 Q4 are applicable for the grace period. Yes please notify the renewal team and the application will be slotted into the allocated submission window. Yes. The cancellation procedure should be followed as stated in the guideline.
72. What happens if the product is manufactured overseas specifically for supply to South Africa and it is not registered in the country of manufacture. Who will issue the	Refer to the response in FAQ number 59

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CPP for these products or will we be exempt from providing a CPP? Please could we obtain guidance on what is required in the CPP – in addition, is only FP site information required or FP and API (DS) site information?	The Certificate of a pharmaceutical product is issued by the relevant Health/Regulatory body in the country of manufacture of the product and should conform to the format recommended by the World Health Organization (WHO), see link below: *https://www.who.int/teams/regulation-prequalification/regulation-and-safety/regulatory-convergence-networks/certification-scheme/model-certificate-of-a-pharmaceutical-product*
73. Can mock-up Artworks be provided for the duplicate which is not launched?	Colour mock-ups of the packaging of the product, i.e., blister, label and unit carton in pdf format should be submitted. Facsimile of labels will be accepted for dormant dossiers.
74. In the renewals Guideline "SAHPGL-HPA-04_v2", the following is requested: "A declaration that data related to any commitments/compliance with conditions which the product was registered under, must be submitted."	This declaration is to confirm that the applicant has complied with all the conditions for registration and have fulfilled all commitments made during the registration process or lifecycle of the product. If there are any outstanding commitments like placing another batch on stability or doing a validation, which may have arisen as a result of variations made to the product, a list with including the proposed time to complete them should be provided. The applicant should also declare that all other commitments have been fulfilled. The declaration can be included with the QIS and QOS in Module 3.2.R.8 or as an annexure to the cover letter in Module 1.0.

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Will you please clarify what is meant with this declaration and what should be declared? And where should this declaration be included in 3.2.R.8 with the QOS and QIS? This is the 'conditions of registration' that SAHPRA does not issue an updated document when a ToA is approved - and the original applicant do not have a copy, what do we do?	All new registration certificates are issued with the conditions of registration. The original applicant should provide these to the new applicant.
Who should be contacted in case of any queries on the renewals process?	Enquiries can be made to the following dedicated mailbox: renewals@sahpra.org.za