AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

EVALUATION OF MEDICINAL PRODUCTS TECHNICAL COMMITTEE (EMP-TC)

Pilot of the Continental Listing of Medicinal Products

Frequently Asked Questions

1. Are the draft guidelines considered final for the pilot or adjusted afterwards? What about additional requirements that might arise along the process, and are not captured explicitly in the drafts (e.g. some provisions foresee "any other information/document that might be requested")?
The published drafts guidelines are the ones to be used in this pilot. They are now being finalized in terms of designs only – no technical requirements will change.

2. When would the forms (e.g. cover letter template for Expression of Interest (EoI)) to be followed for applying for the procedure be published?
For a more detailed submission guidance and application forms and letter template. Please refer to the EMP TC Procedural Aspect Guidelines During Pilot. The Guidelines can be accessed at https://amrh.nepad.org/amrh-resources.

3. Timelines published for the whole procedure seem short, do you foresee some flexibility in terms of timelines and how?
Yes, timelines will be flexible and be extended (2 – 3 months extension tentatively).

4. How would the submission process to select NRAs (beyond application to SAHPRA) look like? E.g. after the joint assessment or at the same time as to SAHPRA; which format, what (additional?) requirements…?
SAHPRA is only providing a regulatory platform for the management of applications – these applications are not linked to SAHPRA's national process. The Technical Committees are in the process of developing continental platforms and specifications for their own platforms that will hopefully be used for the next phase of the pilot.

5. In case of an SRA-approved product, what are the required documents to be provided to enable reliance? How would the reliance be implemented?
Full dossier is required expected even for SRA-approved products, the EMP TC will determine this based on the nature of the product and the amount of information made available to the EMP TC (such as evaluation reports and proof of marketing authorization). Whether it's a reliance pathway or a full pathway, a full dossier is expected to be submitted. For reliance, the TC will need to have access to certain information, which is a standard process. Information such as redacted reports and proof of maximalization in the SRA countries as declared by the applicant.

6. Is the procedure applicable for New Indications/ Line Extensions (NI/LE)?
This will be a case-by-case basis; as long as it meets the Eligibility Criteria. It will have to be clear what is the new disease that will be targeted.

7. Is there a limit in terms of number of applications for the pilot?
Initially we are aiming for 20 – 30 applications, possibly expanding to 30 – 40. The pilot's objective is to test the procedures, and once it's established that the procedures are clear and effective, flexibility can be considered regarding the number of applications.

8. What are the overall timelines for initial ("continental") review?
Timelines are as follows:

Process	Time frame
Screening	15 calendar days
1st Evaluation of new applications	21 calendar days
1st evaluation query responses	14 calendar days
2nd evaluation – new application	14 calendar days
2nd evaluation – query response	7 calendar days
Quality assurance review	7 calendar days
Convening of virtual joint assessment meetings	14 calendar days
Communicating to applicants (query letters)	7 calendar days
Communicating to NRAs	14 calendar days
Implementation of decisions by NMRAs	60 days or 90

9. Can you clarify the provision to "comply with all national requirements," how the local country requirements would be handled? Some NRAs require documents/statements/declarations (beyond CTD, e.g. pricing certificates) that also require legalization etc. - is there any waiver foreseen in this regard? What about samples submission (and import licenses)?
NRAs specific requirements should be discussed with NRAs, the EMP TC guidelines have tried to address as many requirements as possible to cover many countries. The additional requirements are based on the laws of the countries.

10. What are the requirements to provide samples and testing?
The initial submission does not necessitate samples; they will only be supplied upon request.

11. Is there any limitation in terms of NRA selection (e.g. signed/not signed AMA Treaty, members of CoSP or not)? Is there any additional legal/regulatory activity needed to ensure adoption of continental listing decisions by NRAs?
This is important in terms of country selection, and also for the assessment of the overall continental pathway utilization.

12. We are targeting all 55 countries, and the Heads of National Regulatory Authorities (NRAs) have been consulted and expressed their willingness to consider the recommendations. We are currently collaborating with countries to formalize this process.Is it mandatory to market the products in all of the countries included in the expression of interest?
If a specific number of countries is mentioned in the Letter of Interest, the expected commitment is that the product will be marketed in those mentioned countries, and the criteria should be met as outlined in the call.

13. Is it acceptable to submit the same MAA at continental and at national level? What are the implications should we have both applications submitted in parallel?
Yes, the Secretariat will reach out to countries to request that it be processed through a continental pathway.

14. Since the continental decision is a recommendation, does the NRA have an option to reject the application or not implement the recommendation?
Yes, countries are sovereign and they can make their own decisions. It's a country level decision.

15. What are the benefits for the industry?
The advantage of a continental submission is the ability to centrally submit for a single decision rather than multiple markets in Africa. The Technical Committee (TC) will engage with other countries on behalf of the industry, and the assessment is conducted once and free of charge during the pilot. The industry can provide feedback to ensure that its needs are considered in the pilot process.

16. What would be the role of AMRH EMP TC? Would it be acting as facilitators of the review making sure that the different review steps and timelines are followed, including NRAs' adoption? (E.g., similar to WHO when a CRP is followed).
YES, countries who ratify the AMA treaty then the decisions made at the continental level would be bidding.

7. Is the pilot open for products already evaluated by an SRA i.e applying reliance (ex. EUM4All, MAGHP)?
Yes, as long as the product targets specific countries in the continent and meets the eligibility criteria. The targeted countries must be in Africa. If other countries are already included in the targeting, they are acceptable.

18. Regarding the samples: will testing be conducted?
It will be done on a case-by-case basis. If necessary, it will be implemented. The current process does not mandate the testing of samples.

19. Are the draft guidelines considered final for the pilot, and adjusted afterwards?
The guidelines are the ones currently being used for the pilot and considered final, but the TC is accepting comments to keep improving them even after the pilot.

20. What is the minimum number of countries that we need to apply in? Can we submit with only one market in the pilot?
You can start at the continental level and use the recommendation obtained from the EMP-TC to make your case at the national level and therefore in principle principle one market during this pilot may that should be acceptable. However priority will only be given to products targeting multiple countries in Africa.

21. Do you prefer WHO dossier or EMA, or any of those is ok?
Part of the CTE and the changes we expect is module 1. Any of those will work for the technical information. As part of the Common Technical Document (CTE) and the expected changes, particularly in module 1, the preference for either the WHO dossier or EMA is flexible. Both options are acceptable for providing the necessary technical information. The emphasis is on accommodating the diverse sources of information while adhering to the evolving CTE guidelines.

22. Why have selected SAHPRA's platform?
A call was made to NRAs and SAHPRA met the criteria and selected. A call was issued to National Regulatory Authorities (NRAs), and SAHPRA met the criteria and was selected.

23. What would be the timelines when applying abridged evaluation (reliance)?
The timelines will be shorter, but we don't know how much shorter. We cannot tell right now. It will be less than the 260 calendar days expected for a full review.

24. Does the pilot mechanism have the ability to follow the timelines and stage in which applications has reached? One you can log in and check your application?
We do not know if there a mechanism to follow the timeline in the system. What we know you can see what state the application is in and the status of the pre-qualification and what state the application is in. The Quantum system tracks the application from stage 1 until it is finalized, but it's not clear whether it provides public access to the industry so that you can track the publicly. We do not know if there is a public access for the status of the application.
We are uncertain about the existence of a mechanism to track the timeline within the system. While we are aware that the Quantum system allows visibility into the application's stage, pre-qualification status, and overall progress from stage 1 to finalization, it remains unclear whether it offers public access for industry stakeholders to track the application status publicly. The availability of public access for monitoring the application status is currently unknown to us.

25. Is it prerequisite for an applicant to have already lodged application(s) with a few African countries (if so, what is the minimum number?) before submitting the EOI or writing in a cover letter for EOI that there's a plan/intention to apply for MA in certain countries is enough/acceptable?
No, you can apply through this process and then take the recommendations to the countries for you to get market authorization using the recommendations.

26. Is it prerequisite for an applicant to have already lodged application(s) with a few African countries (what is the minimum no.) before submitting the EOI or writing in a cover letter for EOI that there's a plan/intention to apply for MA in certain countries is enough/acceptable?
No, you can apply through this process and then take the recommendation to the countries to get MA.

27. For vaccines in case of EMU applications how will the EMP TC be approving this? Eg. Covid 19 vaccines in case of pandemic?
Essentially the same process; provide a process from the EMP TC side and prioritize and speed up the process and prioritize products.

28. What will be the impact if duplicate applications are submitted with NRAs and for the Pilot?
It Will depend on the stage. At the national level, if the product is still in the evaluation queue, there is a possibility of engaging with the countries and obtaining consent from the applicant to pause the national evaluation, awaiting a continental recommendation and securing consent from the country. However, if the product has already entered the evaluation process, this might not be feasible. The continental process is expected to be quicker, and its recommendation can be utilized at the national level. The objective is to assist countries, and decisions will be made on a case-by-case basis.

29. If a company is submitting product registration outside Africa will reliance be implemented to fast track the applications because they will have been approved by the EMP TC?
Yes, a product has been approved by an agency that has been recognized (those agencies have been listed/noted), then it can be assessed will likely take a shorter time. Yes, if a product has been approved by a recognized agency (those agencies have been listed/noted), it can undergo assessment, and the process is likely to be expedited, resulting in a shorter timeframe.

30. Will WHO PQ products be considered in future for the continental pathway?
It will be treated as any other agency. Reliance will be used to avoid duplication.

31. Where are the links and resource page to the continental pilot?
https://amrh.nepad.org/amrh-resources.
https://amrh.nepad.org/publication/compendium-of-continental-guidelines-pilot-of-listing-of-human-medicinal-products.

32. Do applicants send the EOIs to the SAHPRA's online system or to the three emails listed on the call for applications?
Please send the documents to the SAHPRA online system and when you have any clarifying questions, please send any questions to the emails listed.

33. Will this process continue to the Post Approval Space?
Initially, we will focus on this process and then we will continue to develop the process to post approval, variations, ETC, and others as the process is honed. For now, it will be focus on current process only.