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FAQs

Mutual Recognition Procedure for the registration of Veterinary Medicines in the East Africa

Revised October 2021

Foreword

This version was issued in October 2021 to incorporate changes adopted as a result of a survey conducted in June-July 2021 whose objectives was to obtain feedback from industry, National Regulatory Agencies (NRA) and the EAC secretariat on regulatory obstacles around the implementation of MRP in areas such as adherences to MRP timelines, communication during the MRP process, GMP inspections, MRP sustainability, Stakeholders involvement and national regulatory fee policy. The results were subsequently discussed by the EAC MRP Technical Working Group (TWG) who recommended extension of MRP timelines to reflect internal NRA approval processes. The revised timelines are more realistic as they include the internal time taken by NRA Boards and Councils to ratify the recommendations of the technical staff/committee regarding issuing MAs, which had not been factored in during the setting of previous timelines.

TWG also noted the importance of continuous stakeholders' involvement during the implementation of MRP.

A consultative workshop was held with the global animal health industry in February 2021 during which questions were raised and clarifications provided. This version seeks to be comprehensive and incorporates the questions raised by industry and the answers provided by the EAC -MRP Technical Working Group (TWG).

The EAC Mutual Recognition Process for the registration of Veterinary Medicines

Obtaining approval to place veterinary medicines on the market requires a Marketing Authorisation (MA) from the National Regulatory Authority in each Partner State where the product is to be sold.

Up until now this involves applying for MAs separately in each country.

The new Mutual Recognition Procedure (MRP) overcomes this lengthy and often unpredictable process.

When can the MRP be used?

1. For new product applications
2. For expansion of markets into other EAC Partner States

How does MRP work?

In each EAC Partner State the regulatory authorities have nominated a representative to be a member of the Coordination Group for Mutual Recognition (CGMR).

For a new product

One regulatory authority is chosen by the applicant to be the Reference Country (RC). Other countries where MAs are sought are named as the Concerned Countries (CCs).

For expansion of markets into other EAC Partner States

The applicant chooses a country that has already issued a MA for the product to be the Reference Country (RC). Other countries in which the applicants intend to expand its market into becomes the CCs.

For a product that went through the MRP process, the applicant asks the same Reference Country (RC) for the licenced product, to act as the RC for the Repeat-Use MRP in the new market. In case a CC was withdrawn from the first procedure, the applicant can reapply.

The MRP runs to a specific timetable

The applicant discusses their application with the regulatory authority in their chosen RC.

Once the RC is satisfied that the product is eligible for MRP, the applicant sends identical application forms and dossiers to the RC and CCs, paying each of them the required fee.

The EAC Mutual Recognition Coordinator (MR-C) starts the clock.

Only the regulators in the RC assess the dossier and write the assessment report. The CCs may review the dossier if they wish.

The RC sends the assessment report to the CCs within 90 days of the clock start.

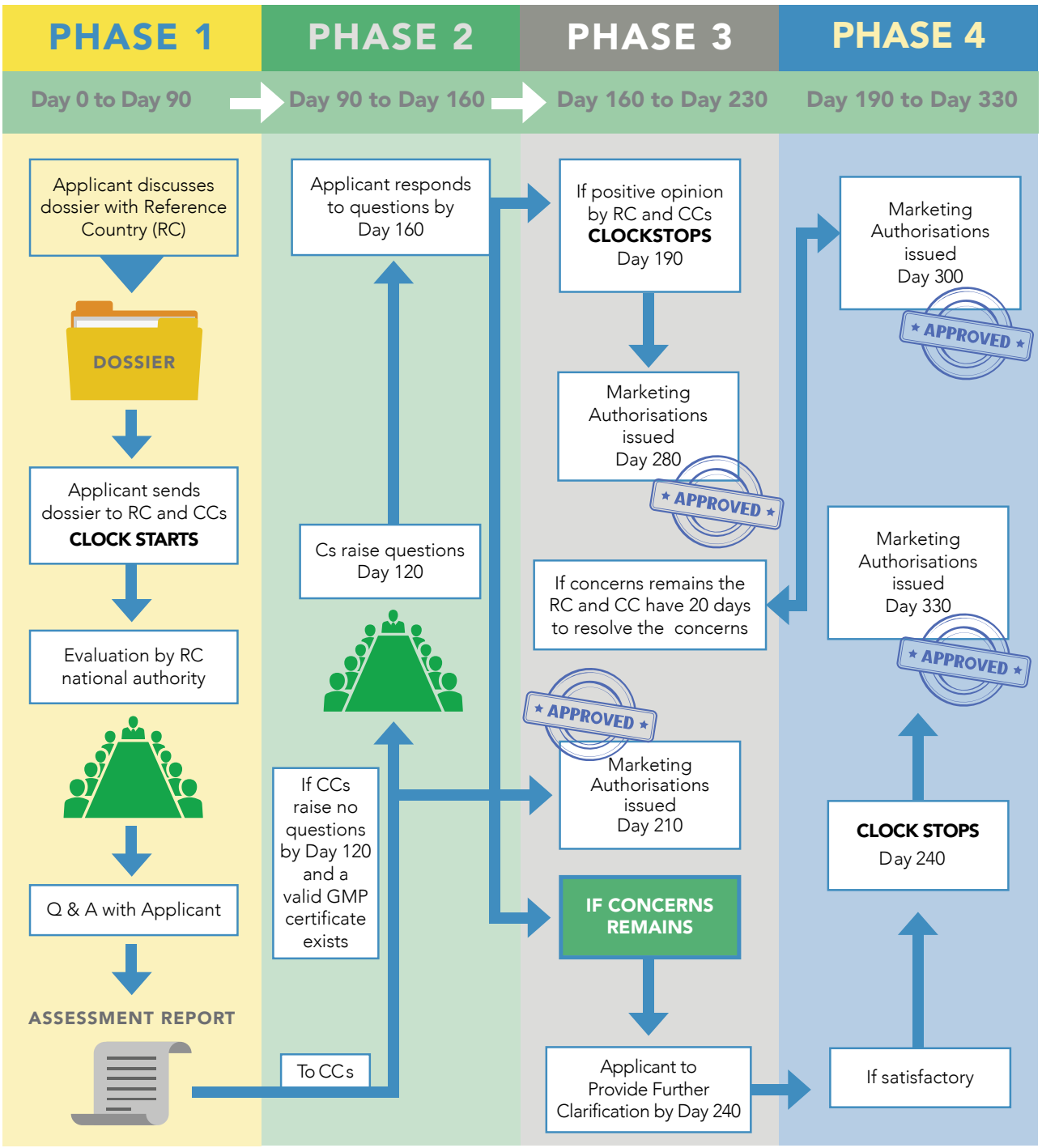
The CCs review the report and may ask questions about it on the grounds of safety, quality, and efficacy. If they do not have any questions, the clock stops, and MAs are issued **by Day 210.**

If the RC and CCs raise questions, the applicant responds to the questions **by Day 160.** Then the RC evaluates the responses and shares with the CCs. The RC and CCs have 30 days to agree on the evaluation report, bringing the procedure to Day 190. If the RC and CCs are satisfied with the answers and the manufacturer has a valid GMP Certificate, the RC, and CCs they issue Marketing Authorisations **by Day 280.**

If the RC and CCs do not reach an agreement, they have an extra 20 days to agree. If after this time they reach an agreement, MAs are issued **by Day 300.** If they still have concerns, the applicant is asked to provide further clarification on area of concern.

This must be done **by Day 240**. If the applicant provides satisfactory clarification, packaging changes are checked, and the MAs are issued **by Day 330.**

Detailed specific MRP timetable can be found in the Best Practice Guide (GL5) published on the EAC website:
https://www.eac.int/documents/category/livestock



Types of Veterinary Medicinal Products eligible for MRP

The requirements for registering veterinary vaccines and pharmaceutical products have been harmonised in all EAC Partner States.

The EAC Council of Ministers have directed National Regulatory Authorities to implement MRP for Immunological and Pharmaceutical Veterinary Products.

Although the current MRP covers Veterinary Medicinal Products, it is anticipated that the system will be extended to cover Veterinary Pesticides in due course.

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The Application

1. Is the EAC handling pharmaceuticals or are you focusing on immunological products only?

The EAC is reviewing and approving both Veterinary Pharmaceuticals and Immunological Products.

2. What is a Repeat Use MRP application?

Repeat Use MRP is an application made by the applicant who wishes to expand marketing authorization of the product to include Partner States that were not included in the previous process or that withdrew from the previous process.

3. Who decides which country will be selected as the RC and CC?

The RC and CCs are chosen by the Applicant. The applicant will choose a RC where a good market exists and whom they know is competent, experienced, and stringent. The CCs are selected because they are the other countries where the applicant wants to sell the product.

4. How do companies decide which country to select as the Reference Country (RC)?

All EAC Partner States with systems of registration of Veterinary Medicinal Products qualify to act as the Reference Country. Applicants who feel that they require further guidance on the choice of the Reference Country can contact the EAC Mutual Recognition Coordinator or their Local Technical Representative (LTR) in the Partner States (PS) where they have interests.

EAC Secretariat will continuously update Applicants on the status of preparedness of the remaining EAC countries without systems for registrations of Veterinary Medicinal Products when systems are established and become functional. Currently, Kenya, Rwanda, Tanzania and Uganda have fully functional agencies and are participating as RCs and CCs.

5. In what format are the dossiers submitted?

The pharmaceutical dossiers are submitted in a CTD format while the immunological dossier structure can be downloaded from the EAC website

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6. In which presentation must dossiers be submitted: hard copy or electronic?

Electronic copies: Rwanda, Tanzania, and Uganda
Hard copies and electronic copies: Kenya

7. How many copies of the dossier must be submitted to each country?

For Kenya one electronic and one hard copy, United Republic of Tanzania one copy, Uganda, and Rwanda two electronic copies on CD or USB drives.

8. When submitting MRP dossiers to different countries, must they be submitted at the same time?

Yes, EAC recommends simultaneous submissions of product dossiers, registration samples and relevant fees to each of the countries participating in the Mutual Recognition Procedure. Failure to do this results in delays in commencing the procedure.

9. Does the applicant need to send the dossier to each of the EAC countries they want to register the product, or will the Reference Country share the dossier with the Concerned Countries?

Identical dossiers should be submitted to the RC & the CCs together with samples and relevant fees.

10. Can submissions be done via online portals?

Submissions via online portal are recommended in Tanzania, but there is no online submission portal available in Kenya, Rwanda, and Uganda. In the absence of online submission portals, electronic copies on CD and USB drives are accepted in Kenya, Rwanda & Uganda.

11. To whom does the applicant submit their dossier?

The applicant submits the dossier to the selected RC and CCs either directly or through their LTRs.

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12. Is there a requirement for the submission of samples, together with the dossier?

Yes, samples must be submitted with the dossier. If the samples and fee do not accompany the dossier, the procedure will not commence.

13. As an applicant, can I use MRP to extend registration to other countries in the case where I already have my product registered in one country? How would I do this?

This is one of the functions of the EAC MRP. If an MA already exists in one Partner State, the applicant asks the NRA that issued the MA to be the RC for an MRP, selecting the other markets where they want MAs issued as the CCs. The RC may request that the dossier is updated to comply with current requirements before agreeing to act as RC in the MRP.

14. For dossiers already submitted to one or more of the countries- is it possible to request that those applications be reviewed through the MRP although it was not applied for under MRP initially?

Yes, it is possible. The applicants are advised to ask one of the countries where the product is already licensed to act as the RC.

If none of the countries have registered the product yet, one of the countries should be asked to act as the RC. Applicants will be required to align their dossiers and Summary of Product Characteristics (SPC) with the MRP documents before the commencement of the procedures. The Mutual Recognition Coordinator (MR-C) will issue the MRP application number to the product(s) and record that those products have become part of the MRP and will be administered as MRP products in future.

15. Once I have successfully registered a product in two countries through MRP, how can I register it in other EAC countries afterwards?

There is a process called “Repeat-Use MRP” (RUP) which can be used following a successful MRP. The applicant uses the same RC as in the original MRP and initiates an RUP to obtain MAs in other EAC Partner States. It is a quick process.

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16. In some EAC Partner States, injectables of different pack sizes (e.g. 1 ml /10 ml) are considered separate submissions. This is not the case in all other countries. What is the EAC stance?

Tanzania requires separate submissions for different pack sizes for the parental preparations while non-parentals are considered as a single application. For the rest of the Partner States of Kenya, Rwanda and Uganda, different pack sizes of the same strength and dosage form are considered as one application. The MRP guidelines provide minimum requirements, though some countries may request for additional requirements.

17. Must samples for all pack sizes applied for be submitted? Or would one pack size be sufficient?

Applicants are advised to submit samples of all the pack sizes that will be placed in the market and the requirements are as follows:

Kenya and Rwanda require 3 samples per pack size Tanzania and Uganda require 2 samples per pack size.
Applicants are however advised to confirm sample sizes with their LTRs prior to the submission of applications.

18. What does the sample testing of products involve? Can samples be tested by only one laboratory for instance AU-PANVAC?

For pre-registration immunological samples, EAC Partner States requires Certificates of analyses from any accredited OIE laboratories. However, for those products manufactured within the African Region, AU-PANVAC certificate of analyses will be required. See section 2F in Guideline 1 (GL 1) on the Dossier Structure for IVP (Immunological Veterinary Product) and similar section of GL 2 on the Technical Documentation to be included in the Registration Dossier on the EAC website using the link:
http://www.eac.int/documents/category/livestock
For sample testing after registrations, AU-PANVAC is the preferred laboratory.

19. Once the product receives EAC MRP approval, does the registration number have to appear on commercialised pack?

Tanzania is the only country which require the registration number on the packaging.

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20. Is it possible to get one registration certificate and one GMP certificate from the EAC for a product submitted through the MRP?

No. EAC is not a registration authority, and no legal framework exists to anchor such requirement. Registration is by the Reference and Concerned Countries which issue their own national Marketing Authorisation and GMP certificate once a positive decision has been made.

21. What is the lead time for approval of the application using MRP?

In uncomplicated/Straight forward cases with no queries on the submitted dossiers, the dossier review phase ends by Day 120 of the procedure and MAs are issued 90 days thereafter. (i.e., 210 days).

If questions are raised by Day 120, the RC and CC have 10 Days to consolidate questions and send to the applicant by Day 130. The applicant has up to Day 160 to respond. Between Day 160 and Day 190, the RC and CCs evaluates the responses from the applicant.

If the RC and CCs agrees to the responses from the applicant by Day 190, Marketing Authorization is issued 90 days after, bringing the procedure to Day 280.

However, if the RC and CC don't agree with the applicants' response, they have 20 calendars days to resolve the concern by Day 210. The MR-C informs the CGMR of the RC, CCs, and the Applicant that Marketing authorizations will be granted within 90 Calendar days thereby ending the Procedure on Day 300.

If responses to some of the questions are still un-satisfactory by Day 210, the RC requests the applicant to provide addition clarification to the questions by Day 240. Once the applicant provides satisfactory response, Marketing Authorization is issued within 90 days, bringing the Procedure to Day 330.

22. What is the validity of Marketing Authorization (MA) and GMP issued under MRP?

MAs are valid for 5 years and GMP certificates are valid for 3 years.

23. In the year renewal payment is made, is the retention fee also payable?

In Kenya and Rwanda, renewal fees are payable every 5 years after registration, while retention fee is paid annually.

In United Republic of Tanzania, retention fee is paid annually, but in the year of renewals of product license, both retention and renewal fees should be paid. In Uganda, renewal is free, retention is annual. Please visit the NRAs websites provided below for the fee structures as outlined in their respective regulations https://www.vmd.go.ke/downloads, https://www.tmda.go.tz, https://www.nda.or.ug and https://www.rwandafda.gov.rw

24. Is a percentage of the fees paid to NRAs shared with EAC MRP process?

EAC Secretariat does not get any portion of the registration fees paid to the EAC Partner States.

25. What are the requirements for efficacy trials for acaricides? Will this still be done per country, or will it be in one country in the region?

The EAC Partner States have not yet embarked on the harmonised registration of veterinary pesticides. The EAC Sectoral Council of Ministers on Agriculture and Food Security (SCAFS) directed Partner States to harmonise requirements for registration of veterinary pesticides. The MRP Technical Working Group is currently working on the process for harmonisation of registration of veterinary pesticides.

26. Are EAC guidelines available for registration of pesticides, nutritional supplements, and feeds?

The process of expanding the MRP TWG's mandate to include harmonising technical documents and processes for registration of veterinary pesticides has been initiated.

Nutritional supplements and feed and feed additives are outside the remit of EAC MRP.

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27. Are there EAC guidelines for registration of MUMS (Minor Use Minor Species) products?

There isn't a separate guideline for the registration of MUMS.

28. Do you also consider MRP and reliance on other countries outside of the EAC?

No.
EAC MRP is exclusively for the EAC Partner States. EAC is aware of countries outside its region that have adopted EAC MRP documents and are using them for registrations of veterinary medicine products although these countries cannot be included in the EAC Mutual Recognition Process.

29. Where will I find the fees schedule/structure for Marketing Authorisations?

Each NRA publishes their fees structure on their respective websites. A guideline is available on the EAC's website (GL11) indicating the links to the websites of all NRAs in the EAC.
https://www.eac.int/documents/category/livestock.

The Local Technical Representative

30. Appointment of a Local Technical Representatives

Applicants must appoint an LTR in each country where they wish to seek a Marketing Authorisation, by giving the appointed LTR power of attorney to act on their behalf.

31. What happens if I do not have a Local Technical Representatives (LTR) in a country included in my MRP application?

If you have not provided the details of your appointed LTR for a country indicated in your application form, that country's NRA will not accept the application. However, in countries where the applicant has a company office, then that office will carry out the some of the roles of the LTR.

32. Do Local Technical Representatives (LTR) get trained on the EAC MRP?

Yes, LTRs receive formal and informal training on the EAC MRP and other regulatory matters by their respective national regulatory authorities.

33. Can an applicant have more than one Local Technical Representative (LTR) in a Partner State for a single product?

No, the applicant names one LTR in each Partner State included on the Marketing Authorisation application form for each product. The applicants that have registered more than one product in a country may wish to appoint a different LTR for the other product(s), but NRAs do not permit more than one LTR to handle one product. LTRs are registered with the NRAs. In each country there could be other licensed distributors of the product as well as the LTR.

34. What would you list as the LTR's roles and responsibilities within the context of MRP?

i. Representing applicants in all communication with the National Regulatory Authoritiesin each Partner State. One LTR should be nominated per product per country.

ii. The LTRs are responsible for delivering fees, dossier, samples, etc. to the NRAs, on behalf of the applicant, for every application.

iii. LTRs liaise with the regulators on all pre-market and post-marketing activities and are routinely sensitised by the regulators on all procedures.

iv. Monitoring the distribution of the product in the Partner States on behalf of the applicant.

v. Instituting product recalls in case of market complaints or where the regulators require that the product be withdrawn or destroyed.

vi. Regulators normally ask the importer to ensure that an import document is endorsed by the LTR in that country before they are granted a licence/ permit to import from the manufacturer. This ensures that the LTR is fully aware of all transactions taking place between applicant and other companies within the country.

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35. Is there any timeframe for the LTR/Applicant to apply for MRP?

Yes, once the Reference Country screens the technical documents and are satisfied that an applicant's dossier meets the requirements of the EAC guidelines, the RC informs the applicant who sends identical applications to their LTRs in the CCs. The MRP cannot start until all CCs have received the dossiers, the samples, and the fees. Once all participating countries have received complete applications, the MRP clock is set at Day 7 to screen the dossiers for completeness. Upon receiving positive screening report from the RC and CCs the Mutual Recognition Coordinator announces the commencement of the procedure and sets Day 0 to start the procedure. It is important that LTRs do not delay submissions of MRP applications once they have received them from the applicant.

The MRP

36. Does MRP cover all veterinary products?

MRP currently covers registration of veterinary immunological and pharmaceuticals. EAC is in the process of harmonizing registration requirements for veterinary pesticides.

37. When does the clock start?

The MRP clock starts after the RC and CCs have confirmed with the MR-C that they have all received a valid application, dossier, product samples and the MA fees.

38. Does the applicant pay the licence fee to the RC as well as all the CCs?

Yes, the national fees are paid to both the RC and the CCs.

39. Does the CC have an opportunity to review the applicant's dossier?

Yes, the CCs receive the dossier and may review it themselves. They may find they want to ask the applicant some additional questions which should be included in the RC's assessment report for the applicant to respond.

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40. Can a CC reject the assessment report if the CC disagrees with the RC's assessment?

No, if a CC disagrees with something in the RC assessment report, they can raise this as a question in the relevant sections of the dossier and discuss it with the RC and other CCs before Day 120.

41. Are all countries in EAC ready to be Reference Countries?

At present, not all Partner States are ready to act as the RC in an MRP. Some NRAs have agreed to act as CCs for the moment to gain experience in the process.

42. Does MRP replace the national registration process?

No, national registrations may still take place when an applicant seeks an MA in only one EAC country. MRP may be used for applications to two or more NRAs in the EAC.

43. Who coordinates the process?

The Mutual Recognition Coordinator coordinates EAC MRP. The coordinator is stationed at the EAC Secretariat in Arusha.

44. In what language do the labels and package leaflet/insert need to be written?

The official language is English. Some countries may want another language as well e.g., Burundi and Rwanda may require French as well as English. Kenya and Tanzania require Kiswahili (in the case of pesticides) as well as English.

45. Can I use the same label in the RC and CCs once I have received MAs in those countries?

Yes. The text will be identical in each country included in the MRP. See 44 above.

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GMP requirement

46. For the GMP inspections, does the applicant pay the GMP inspection fees to the RC as well as all the CCs?

Yes, the applicant pays the GMP inspection fee to the RC & the CCs.

47. Will there be a list of manufacturers that are GMP approved by EAC?

The EAC does not 'approve' manufacturers, this is done by the respective NRAs, and they publish this information on their national websites.

48. Who issues the GMP certificate?

Currently, following a positive decision on issuing a GMP certificate, the RC and the CCs all issue national GMP Certificates.

49. Is the GMP certificate valid in the RC as well as all the CCs?

At present, each NRA issues their own national GMP Certificate once a positive decision on GMP status has been agreed.

50. What is the duration of validity of the GMP certificate and is this standard in all the countries (RC as well as all the CCs)?

The period of validity of GMP Certificates has been harmonised in all EAC Partner States as 3 years. The period of validity of a Marketing Authorisation has been harmonised in all EAC Partner States as 5 years.

51. To eliminate bias and delay, why don't we randomise the member country to carry out GMP inspection?

According to the MRP project design, it is the RC alone who carries out the GMP inspection on behalf of the other EAC Partner States (PSs) participating in the procedure. The current joint inspections were a directive from the EAC Council of Ministers to encourage capacity and confidence building among its PSs and it was for the first few MRP applications only.

Eventually, the RC alone should conduct GMP inspections, prepare the report and share it with the other countries participating in the MRP.
If EAC should decide to randomise this activity, some mechanisms for randomisation need to be discussed and agreed upon by its PSs.

52. Would a desk review be an alternative for physical GMP inspections, particularly considering current Covid-19 travel restrictions?

Yes, some EAC PSs have already initiated GMP Desk Reviews instead of physical inspections to ensure staff safety during the Covid-19 pandemic.

53. How will variations work? Will we also submit through the MRP? And will that be allowed pre-registration or only post-registration?

Variation is a post-registration procedure. It refers to additional changes to the dossier, samples, manufacturing site etc of a registered product from that submitted at registration.

Any variations that the applicant subsequently applies for, are processed through the original RC and, if successful, are approved simultaneously in the RC and CCs. The applicant approaches the RC who in turn informs the CCs and the MR-C of the change(s) applied for. The applicant is required to pay the variation fees to all the MRP Partner States and submit the changes.

Note that changes made to the product dossiers before the product is registered and/or placed in the market are taken as dossier updates and are therefore not channelled to the Variation Committee since the process of assessment would still be going on. As such, these pre-registrations changes do not attract Variation fees.

It should also be noted that some EAC Partner States consider changes in the manufacturing sites as new registration applications, therefore, such changes will not be processed as Variations.

54. What is being done by the EAC regarding counterfeit products?

Counterfeit products is outside the remit of the EAC MRP, which currently only addresses MA award.

However, each EAC national authority independently has systems of assessing products in the market and it is during such activities that counterfeits, sub-standard drugs and expired drugs are identified and removed from the market.

Additional:

Link to EAC Guidelines and Application forms:
https://www.eac.int/documents/category/livestock

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