FAQs

Mutual Recognition Procedure for the registration of veterinary medicines in the East African Community

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 the Concerned Countries (CCs).

For an existing product

The applicant chooses a country that has already issued a MA for the product to be the Reference Country.

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.

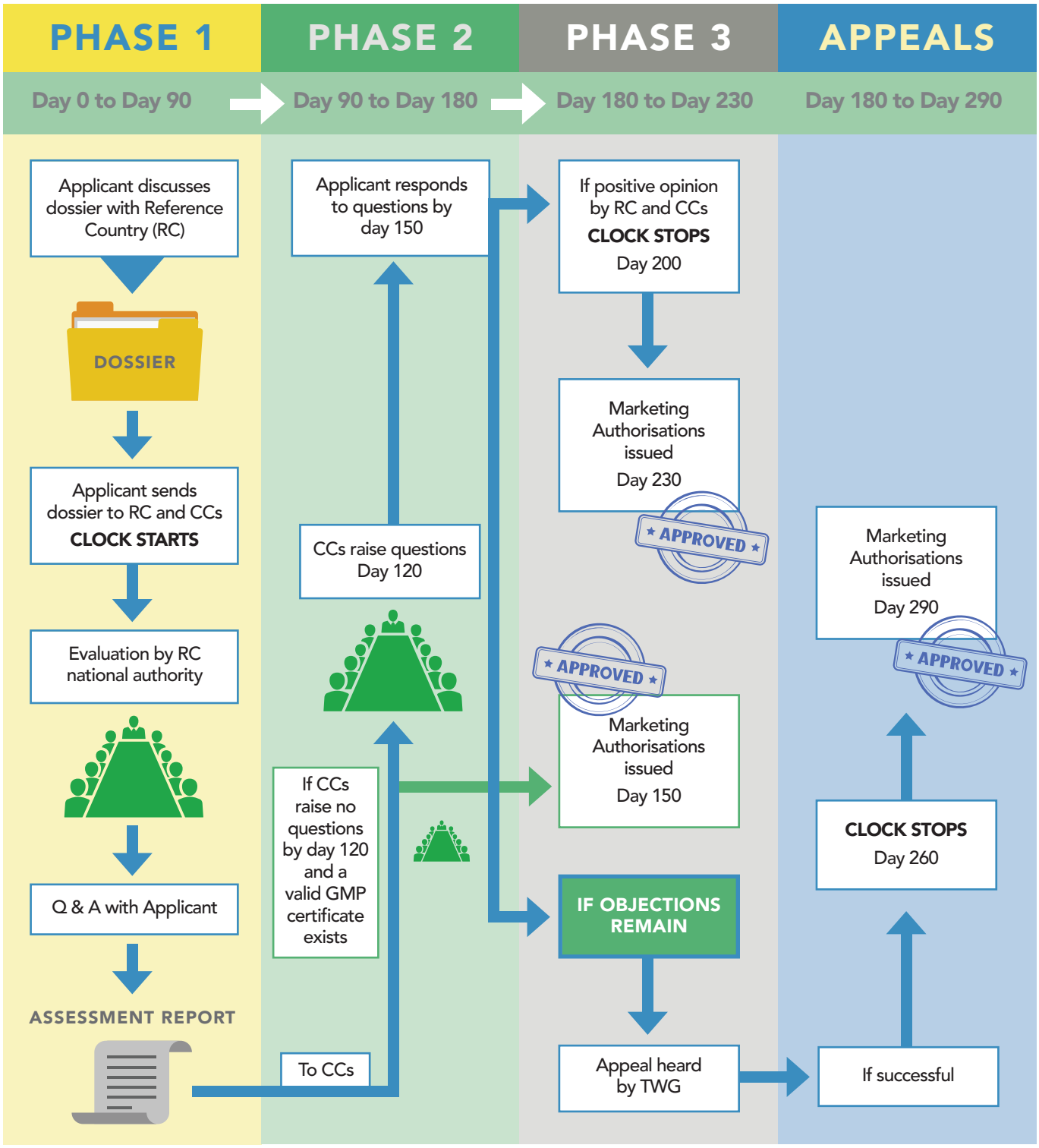
Only the regulators in the RC assess the dossier and write the assessment report. The CCs may review the dossier if they wish.

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 150**.

If the RC and CCs raise questions, the applicant responds to the questions **by day 180**. If the RC and CCs are satisfied with the answers and the manufacturer has a valid GMP Certificate, the RC and CCs check any revisions requested to the labelling by day 200 and issue Marketing Authorisations **by day 230**.

If the RC and CCs do not reach agreement they have an extra 20 days to agree. If after this time they reach agreement, MAs are issued **by day 250**. If they still have objections the applicant appeal and request a hearing. This must be held by day 240. If the applicant is successful, packaging changes are checked and the MAs are issued **by day 290.**



Types of veterinary Medicinal Products eligible for MRP

At present, the requirements for registering veterinary vaccines have been harmonised in all EAC Partner States.

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

Although the current MRP covers veterinary immunologicals, it is anticipated that the system will be extended to cover veterinary pharmaceuticals in due course.

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The Application

1 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 an RC where a good market exists and whom they know is competent, experienced and stringent so that the CCs are more likely to accept the assessment report without asking their own questions. The CCs are selected because they are the other countries where the applicant wants to sell the product.

2 To whom does the applicant submit their dossier?

The applicant submits the dossier to the selected RC and CCs through their LTRs. The LTRs are also responsible for paying the fees to the NRAs and submitting any samples that are requested.

3 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.

4 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 procedure 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.

5 What happens if I do not have an 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 might refuse to accept the application. If they agree to be part of the MRP you may not be able to market the product until you have appointed an LTR. See response to Q7

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6 Where will I find the fees 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

7 Why do applicants need Local Technical Representatives?

Applicants must appoint an LTR in each country where they wish to seek a Marketing Authorisation. If an applicant includes a country in an MRP application but has not yet appointed an LTR in that country, they might receive a licence for the product after a successful MRP outcome but will not be authorised to sell the product in that country until they can prove that they have appointed an LTR there.

8 What is the role of the LTR?

The LTR is the applicant's representative in communications with the national regulatory authority. The NRAs do not communicate directly with the applicant when raising questions about applications. They send their requests to the LTR appointed by the applicant. The applicant's responses are sent to their LTR who forward them to the NRA. The LTR's are responsible for sending fees, dossier, samples, etc. to the NRAs, on behalf of the applicant, for every application.

9 Does the LTR have a role to play in selecting the Reference Country?

The LTR should provide advice to the Manufacturer on the suitability of their choice of RC.

10 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. LTRs are registered with the NRAs. They are responsible for interacting between the NRA and the applicant and would be the first point of call by NRAs if any problems occur with the product once marketed such as adverse reactions, faults, etc. In each country there could be other licensed distributors of the product as well as the LTR.

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11 Is there any timeframe for the LTR to submit an application for MRP?

Yes, once the Reference Country is 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 the LTRs in all CCs have submitted the dossiers and the fees and samples to the respective NRAs. Once all concerned NRAs notify the MR-C that applications have arrived the MRP clock is set at Day -7, giving the NRAs 7 days to check that they have been sent everything required to verify that they have a complete application. After that the clock is set at Day 0 and the MRP starts. It is important that LTRs do not delay submissions of MRP applications once they have received them from the applicant.

The MRP

12 Does MRP cover all vet products?

At the moment MRP can only be used for registering veterinary vaccines. It could also be used for veterinary medicines once harmonisation of the registration requirements for veterinary pharmaceuticals has been achieved.

13 When does the clock start?

The MRP clock starts after the RC and CCs have confirmed that they have all received a valid application and the MA fees.

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

Yes, the national fees are paid by the applicant, through their LTRs, to all the countries where Marketing Authorisations are sought.

15 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 questions that are not included in the RC's assessment report.

16 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 assessment report they can raise this as a question and discuss it with the RC and other CCs before day 120.

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17 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.

18 Does MRP replace the national registration process?

No, national registrations may still take place when an applicant seeks an MA in only 1 Partner State. MRP must be used for applications to two or more NRAs in the EAC.

19 Who coordinates the process?

The Mutual Recognition Coordinator coordinates EAC MRP. This role will become an office of the EAC.

20 In what language do the labels and pack leaflet need to be written?

The official language is English. Some countries may want another language as well, e.g. Burundi and Rwanda require French as well as English. Tanzania wants English and Kiswahili. In Tanzania the Package Leaflet may include other languages in addition to English and Kiswahili.

21 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.

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GMP requirement

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

At present, the applicant only pays the GMP inspection fee to the NRA that carries out the inspection. This will normally be the RC.

23 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.

24 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.

25 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 questions that are not included in the RC's assessment report.

16 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.

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