



East African Community

**GUIDANCE FOR
THE APPEAL PROCESS
DURING A MUTUAL RECOGNITION APPLICATION
FOR THE REGISTRATION OF IMMUNOLOGICAL
VETERINARY PRODUCT(S)
IN THE EAST AFRICAN REGION**

Draft agreed by Technical Working Group	10 th October 2016
Draft released for consultation by representatives of East African region regulatory agencies	28 th October 2016
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EAC code	EAC/PSS/AGRI-LIV/IVP-REG Appeal/Ver.1
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The Appeal Process During MRP

Advice for Applicants and Regulatory Authorities concerning the Appeal Process.

Introduction:

During a Mutual Recognition Procedure (MRP) in the EAC, if the Reference Country and/ or any of the Concerned Countries cannot agree to issue Marketing Authorisations for an immunological veterinary product (IVP) by Day 200, the Applicant has the right to request an APPEAL. The appeal must be heard and the result notified to the Applicant by Day 240.

Procedure for the Applicant:

If the Applicant is not satisfied with a negative outcome of a MRP by Day 200, or by Day 220 if a second attempt has been made by the Partner States' regulators to reach a positive decision on the application, the Applicant may request an Appeal.

1. The Applicant notifies the Reference Country (RC) that they wish to appeal against the negative decision.
2. The Applicant may provide new information to support their appeal.
3. Any new information should be presented to the RC one week before the date of the Appeal.
4. Once the date of the Appeal is known by the Applicant they must notify the RC of the names of any experts they wish to bring to the Appeal.

Procedure for the RC:

Following a negative outcome of a MRP by Day 200, or by Day 220 if a second attempt has been made by the Partner States' regulators to reach a positive decision on the application, the Applicant may request an Appeal.

1. As soon as the RC receives notification from the Applicant that they wish to appeal against the negative decision the RC will notify the MR-Coordinator and the Concerned Countries (CC) that an appeal has been triggered.
2. The RC and MR-C will agree a suitable date and location for the Appeal to take place.
3. The MR-C will notify the Applicant and the CCs of the date and location of the Appeal. The date of the Appeal will be within 40 days of the negative opinion being announced.
4. Any additional supportive data presented by the Applicant will be distributed to the respective TWG members (RC and CC representatives) before the date of the Appeal by the MR-C.
5. The Appeal will be heard by the Technical Working Group representatives of the Partner States involved in the MRP (RC and CCs). The RC and CCs may bring other experts to the hearing if applicable.
6. The final decision on the MRP will be notified to the Applicant by the 40th day following the negative opinion.