Mutual Recognition Procedure for Veterinary Vaccines in the EAC

Short and Medium Processing Times (150 – 230 days)

GALVmed
Protecting Livestock – Improving Human Lives

Application process begins here

Applicant selects Reference Country (RC). Sends them dossier and list of Concerned Countries (CCs)

RC checks dossier. During pre-submission meeting RC advises Applicant if product is eligible for Mutual Recognition Procedure (MRP) and if Good Manufacturing Practice (GMP) inspection is necessary

When dossier compliant, Applicant sends identical Application & Dossier to CCs

CCs screen application then advise Mutual Recognition Coordinator (MR-C) that dossier has been received

DAY 0: **CLOCK STARTS**

RC starts to prepare Assessment Report

(RC and Applicant discuss and resolve any issues)

DAY 90:
RC sends Assessment Report to CCs to review (Takes up to 30 days)

DAY 120:
Two scenarios

SCENARIO 1
CCs inform RC they have no objections and confirm approval

CLOCK STOPS

DAY 150:
Marketing Authorisations issued by RC and CCs

SCENARIO 2
CCs send their own questions to RC

DAY 150: Applicant sends responses to questions to RC and CCs

DAY 180:
RC and CCs review and accept responses

Applicant sends final SPC and labelling to RC and CCs

DAY 200:
RC and CCs confirm approval
CLOCK STOPS

DAY 230:
Marketing Authorisations issued by RC and CCs

Number of days to process scenario 1

7 days

90 days

30 days

30 days

150 days to complete scenario 1

Number of days to process scenario 2

30 days

30 days

30 days

20 days

30 days

230 days to complete scenario 2