MINISTRY FOR AGRICULTURE, FISHERIES,
FOOD AND ANIMAL RIGHTS

Animal Health and Welfare Department

National Veterinary Laboratory
Abattoir Street, Albertown, Marsa, MRS 1123 - Malta

Variations for each Authorisation or Registration Type

1. Registrations through Regulation 7 of S.L 437.47

Registration holders must notify the Veterinary Medicines Section (VMS) of variations which have been approved in the source country. This can be made using the Notification of Change form.

The Veterinary Medicines Section does not issue approvals for notification of changes of these Registrations as it would have had no say in the granting of the Marketing Authorisation in the first place. The Veterinary Medicines Section just updates its records. Registration Holders can consider the submission as closed if they do not here from the Veterinary Medicines Section within 45 days.

There is no need to submit an application form for a notification of change for each and every variation approved in the country of source. Only those variations that in some way or another affect the information present on the Summary of Products Characteristics (SmPC), Package Information Leaflet (PIL), package and certificate need to be notified to the Veterinary Medicines Section. For example, there is no need to submit a variation updated Certificate of Pharmaceutical Product (CEP) or new Active Pharmaceutical Ingredient (API) manufacturer; but there would be a need to submit a application for notification for an added indication or change in a withdrawal period

It is important that the notification of changes are submitted to the Veterinary Medicines Section as soon as they are approved in the country of source.

In the annual extension Registration Holders are requested to provide a list of all variations that have been approved in the country of source in the preceding year. Please note that what is requested is a list of variations and not the actual application forms. If none were approved the applicant should just indicate so.

2. Authorisations through Regulation 4 (2) of S.L 437.47

Changes in the Authorisations through Regulation 4 (2) can be applied through Notification of Change form. This is the same form used for a Registration in accordance with Regulation 7 of S.L 437.47. All kind of changes need to be applied for.

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3. Marketing Authorisations (National/DCP/MRP)

Marketing Authorisation Holders (MAHs) must submit a variation to the terms of Marketing Authorisation using the appropriate form obtained from the EU commission website in the Eudralex section, Volume 6.

Variations are classified as either minor Type IA or Type IB, or major Type II.

Regulation (EU) No 1234/2008 regulates variations to the terms of Marketing Authorisation in the EU.

If the changes in the terms of Marketing Authorisation have affected the PIL, SmPC or labelling the updated Product Information must accompany the Variation Form.

Detailed information on the submission of variations through the MRP/DCP can be found in the Variations Section on the Committee for Medicinal Products for Veterinary Use (CMDv) website.

Where applicable, electronic approval letters are sent to the Marketing Authorisation Holders.

4. Community Marketing Authorisations

These variations are managed by the European Medicines Agency (EMA). Market Authorisation Holders (MAHs) submits the application forms to EMA for its evaluation. By virtue of its membership in the Committee for Medicinal Products for Veterinary Use (CVMP) the Veterinary Medicines Section receives the variation package for its comments. Its nominee within CVMP discusses the issues during the CVMP meetings on a monthly basis.

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