

The rules governing medicinal products
in the European Union

Volume 7A

Guidelines

Veterinary medicinal products

General, efficacy, environmental risk
assessment

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THE RULES GOVERNING MEDICINAL PRODUCTS IN THE EUROPEAN UNION

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These notes for guidance have been prepared by the Committee for Veterinary Medicinal Products, in consultation with the competent authorities of the Member States, to assist applicants for a marketing authorisation for a veterinary medicinal product. In case of doubt, reference should be made to the relevant EC Directives.

FOREWORD

Directive 81/852/EEC describes the requirements for the demonstration of the quality, safety and efficacy of veterinary medicinal products. The conduct of tests and studies for such demonstration has been harmonised, both within the European Union and internationally. Volume 7 of “The rules governing medicinal products in the European Union” incorporates testing guidelines prepared within the European Union.

It is presented in two parts:

- Volume 7A – General, efficacy, environmental risk assessment
- Volume 7B – Immunologicals, quality

These guidelines serve a two-fold objective. Firstly, they are intended to provide a basis for a practical harmonisation of the manner in which the Member States and the European Agency for the Evaluation of Medicinal Products interpret and apply the detailed requirements for the demonstration of quality, safety and efficacy contained in the Community directives. Secondly, they are intended to facilitate the preparation of applications for marketing authorisation which will be recognised as valid by all Member States and the European Agency for the Evaluation of Medicinal Products.

The use of guidelines, which are not legally binding, rather than a formal legal instrument, such as a directive, has been preferred in order to maintain an element of flexibility and not to place undue legislative restraints on scientific progress. It is recognised that in some cases, as a result of scientific developments, an alternative approach may be appropriate. However, where an applicant chooses not to apply a guideline, that decision must be explained and justified in the Expert Reports submitted by the company in support of the application. By their very nature, the guidelines must be updated in the light of scientific and technical progress. Moreover, further guidelines are currently under discussion, thus it is intended that this volume should be updated and revised as necessary.

These notes for guidance, which have no legal force, have been prepared by the Committee for Veterinary Medicinal Products of the European Agency for the Evaluation of Medicinal Products, in consultation with the competent authorities of the Member States, to assist applicants for a marketing authorisation for a medicinal product. In case of doubt, reference should be made to the text of the relevant EEC Directives.

The CVMP has recognised as suitable for veterinary medicinal products a series of guidelines on the quality of medicinal products for human use adopted by the Committee for Proprietary Medicinal Products (CPMP). These guidelines are listed at the end of this Volume. Some specific guidelines also relevant for veterinary medicinal products will be published in Volume 8 (Maximum residue limits for veterinary medicinal products) and Volume 9 (Pharmacovigilance for medicinal products for human use and veterinary medicinal products).

For ease of reference, and by kind permission of the Organisation for Economic Co-operation and Development (OECD) this volume also contains the OECD principles of good laboratory practice (GLP) which must be complied with during the conduct of safety tests on medicinal products.

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