European Medicines Agency

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Practical considerations on the impact of the new pharmaceutical legislation on Marketing Authorisation Applications via the Centralised Procedure and Centrally Authorised Medicinal Products for Veterinary Use

This guidance outlines practical considerations concerning the phasing in of Regulation (EC) No 726/2004[1] and Directive 2004/28/EC[2] to medicinal products for veterinary use authorised or applied for via the centralised procedure. It provides an overview of those key-procedural elements affected by the new legislation, which will have an impact on ongoing applications or existing marketing authorisations, as appropriate.

The guidance in this document represents the view of the EMEA, but the document does not have any legal force. In case of doubt reference is given to the above-mentioned Community Directive and Regulation.

Applicants/MAHs are advised to systematically discuss the consequences for their product(s) with their Project Manager, especially for Regulatory Procedures affected by the new legislation which will start or finalise around November 2005.

For general regulatory guidance on the interpretation and implementation of the new pharmaceutical legislation, please refer to the updated Notice to Applicants published by the European Commission as well as to relevant guidance documents / operating procedures published on the EMEA Website.
http://pharmacos.eudra.org/F2/eudralex/vol-6/home.htmhttp://www.emea.eu.int/htms/general/direct/legislation/legislationintro.htm

An overview of the relevant legal provisions in relation to the procedural elements listed in this document is provided in Annex I.

1. Ongoing marketing authorisation applications with Commission Decision expected as of 20 November 2005 (i.e. with a CVMP opinion as of September 2005)

In general, all marketing authorisation applications for which a Commission Decision will be granted as of **20 November 2005** will have to comply with all relevant provisions set out in the new Regulation and the amended Directive. The guidance below relates to specific aspects of the marketing authorisation which will have to be addressed by applicants, but cannot be considered as an exhaustive list.

Product Information:
Product information Annexes to Commission Decisions on new marketing authorisation applications will have to comply with the new legislation as of 20 November 2005. Consequently, the updated QRD templates will apply to the SPC, Annex II, labelling and package leaflet of new marketing authorisation applications for which a CVMP opinion will be adopted as of **September 2005**.

For all other ongoing applications, applicants will have to amend their draft product information at Day 121 (if the assessment procedure is before Day 120) or at the latest at Day 181.

[1] Repealing Regulation (EEC) No 2309/93/EC; O.J. L 136 of 30.4.2004
[2] Amending Directive 2001/82/EC; O.J. L 136 of 30.4.2004

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Dossier requirements:
For ongoing applications which are before Day 120 on 20 November 2005, the additional information required by the new legislation needs to be provided by Day 121. Applicants are advised to contact their Project Manager to discuss further practical aspects of this process. For all other ongoing applications for which a marketing authorisation will be granted as of 20 November 2005, submission and review of the required additional information needs to be discussed with the EMEA on a case-by-case basis.

Conditions and restrictions
The Commission can adopt decisions addressed to the Member States for the implementation of conditions or restrictions with regard to the safe and effective use of a medicinal product, as recommended in the CVMP Opinion on the medicinal product, as of **20 November 2005** (i.e. as of Opinions adopted in September 2005).

Publication on withdrawals
Any withdrawal of a marketing authorisation application occurring as of **20 November 2005**, will result in a 'Press Release' announcing the withdrawal on the EMEA website. Depending on the stage of the procedure at the time of withdrawal, a withdrawal public assessment report will be published at the latest 2 months after the announcement, after deletion of commercially confidential information.

Post-Opinion:
The shortened post-opinion linguistic checking procedure will apply to Opinions adopted as of the **November 2005** CVMP meeting. For Opinions adopted in October, the current linguistic checking timelines continue to apply. Any subsequent decision-making steps however (e.g. standing committee consultation) will follow the new legal timeframes, when such a step starts after 20 November 2005.

Re-examination
Any request for re-examination (appeal) of a CVMP opinion received* as of 20 November 2005 will follow the new legal provisions, resulting e.g. in appointment of a (Co-)Rapporteur different from those appointed for the initial opinion.
* *within 15 calendar days after receipt of the opinion.*

Post-authorisation:
EPAR summaries for the public will be published for medicinal products for which a Commission Decision will be granted as of 20 November 2005 (i.e. for CVMP Opinions granted as of **September 2005)**. The summaries will be developed in a process parallel to the production of the scientific EPARs.

The requirement to inform the EMEA of the **dates of actual marketing** of the medicinal product in the EEA and of any temporary or permanent interruption of such marketing, will apply to all authorised medicinal products as of **20 November 2005**.

The new PSUR cycle (reports every six months until placing on the market; reports every six months during the first two years following the initial placing on the market; reports once a year for the following two years; thereafter reports at three-yearly intervals) will apply to all medicinal products with a Commission Decision as of **20 November 2005.**

2. New marketing authorisation applications submitted as of November 2005

Eligibility for the centralised procedure
Applications for a new marketing authorisation, submitted as of 20 November 2005, will have to comply with the eligibility criteria set out in the new Regulation.
Applications submitted before this date will follow the eligibility criteria of the current Regulation.

Data and market exclusivity
The new periods of protection will only apply to applications for a new marketing authorisation submitted as of 20 November 2005.

Dossier requirements
All new marketing authorisation applications submitted as of 20 November 2005 need to comply with the new requirements. For applications submitted before that date, see section 1.

Assessment Timetable
The possibility for an accelerated assessment (opinion within 150 days) will apply to new marketing authorisation applications for which the **assessment** will **start after 20 November 2005**.
Where possible, the applicant should submit the request for such an accelerated assessment procedure at least 2 months in advance of the submission of the marketing authorisation application (i.e. as of September 2005).

Product Information:
Applicants submitting a new marketing authorisation application as of 20 November 2005 should follow the updated QRD templates for SPC, Annex II, labelling and package leaflet. The package leaflet shall be written in terms that are comprehensible to the general public and in the official language or languages of the Member State in which the medicinal product is marketed.

For applications submitted before that date, see section 1.

3. Existing marketing authorisations granted by the centralised procedure

Information on marketing of the product
The requirement to inform the EMEA of the **dates of actual marketing** of the medicinal product in the EEA and of any temporary or permanent interruption of such marketing, will apply to all authorised medicinal products as of **20 November 2005.**

MAHs will therefore have to provide the EMEA with the current marketing status of all various presentations per member state. MAHs shall also notify the EMEA of any temporary or permanent interruption of such marketing.

Renewals
The new renewal submission deadline (6 months before expiry) will apply to marketing authorisations expiring as of 20 May 2006.

Marketing authorisations, which have already been renewed under the system in force before the amendment of the Regulation, should be renewed once more under the new system before the authorisation may gain unlimited validity.

For marketing authorisations expiring after 20 November 2005, CVMP may recommend renewal with unlimited validity or may require one additional 5-year renewal **as of September 2005**. The renewal dossier of such applications should be in line with the updated CVMP guideline on renewals. **Product information** for renewal opinions should comply with the updated QRD templates (see also paragraph below).

Product Information:
Product Information of authorised medicinal products will have to be amended to reflect the new legislation by using the updated QRD templates **within 2 years** as of the application of the new legislation (i.e. by November 2007). The changes should be made at the occasion of a variation affecting the annexes, an extension procedure or the renewal of the product.
For products which have no regulatory activity during these 2 years, the update should be performed at the occasion of the renewal, even if it takes place later.

The update should be clearly included in the scope of the corresponding procedure. Neither notifications to the Commission nor 6-monthly Type I updating procedures will be used for this purpose.

For **extension** applications for which an opinion will be adopted in September 2005 or October 2005, MAHs may apply the new templates to the extension Annexes only. In such case, the already existing presentations will be updated as described in the previous paragraphs.

Data exclusivity

The extended period of protection (13 years) in the case of veterinary medicinal products for fish or bees or other species designated as such in accordance with the procedure referred to in Article 89(2) of Directive 2001/82/EC shall apply only to those medicinal products for which the initial marketing authorisation application is submitted as of 20 November 2005.

The additional period of protection (+1) for extensions of the marketing authorisation to additional food producing species in the case of veterinary medicinal products intended for food producing species and containing a new active substance that has not been authorised by the Community by 30 April 2004 shall apply only to those medicinal products for which the initial marketing authorisation application is submitted as of 20 November 2005.

The 3 year period of protection for extensions of a marketing authorisation to additional food producing species (where the marketing authorisation holder applied for the MRL extensions) shall apply as of 20 November 2005.

Publication on withdrawals

From 20 November 2005, any withdrawal of an application for an extension or variation relating to an indication or a change or addition of a target species, will result in a 'Press Release' announcing the withdrawal on the EMEA website. Depending on the stage of the procedure at the time of withdrawal, a withdrawal public assessment report will be published at the latest 2 months after the announcement, after deletion of commercially confidential information.

Post-Opinion:

The shortened post-opinion linguistic checking procedure will apply to relevant post-authorisation Opinions adopted as of **November 2005**. For Opinions adopted in October, the current linguistic checking timelines continue to apply. Any subsequent decision-making steps however (e.g. standing committee consultation) will follow the new legal timeframes, when such a step starts after 20 November 2005.

4. Referral procedures

Product Information:

Product information Annexes to Commission Decisions on referral procedures will have to comply with the new legislation as of 20 November 2005. In order not the delay the decision-making process, MAHs and/or applicants concerned are strongly advised to apply the annotated CMDv template* for SPC, labelling and package leaflet to referral procedures for which a CVMP opinion with product information Annexes will be adopted as of **September 2005**.

Any new referral procedure starting as of 20 November 2005 will have to address SPC, labelling and PL proposals (as appropriate) according to the annotated CMDv template*.

** A CMDv annotated template, based on the QRD annotated template, will be published in the near future.*

Annex I

Overview of legal provisions in relation to the procedural elements listed above.

Companies are advised to consult the EMEA and Commission website to obtain the (latest) guidance documents on the topics listed below or any other Review related topic. The following links may also be useful http://www.emea.eu.int/htms/general/direct/legislation/legislationintro.htm http://pharmacos.eudra.org/F2/pharmacos/new.htm and http://pharmacos.eudra.org/F2/eudralex/vol-6/home.htm)

Procedural element / topic	**Legal basis**
Product Information (SPC, labelling, PL)	Article 14, 58, 59, 60 and 61 of Directive 2001/82/EC, as amended
Conditions and restrictions	Article 34 (4) (d) of Regulation (EC) No 726/2004
Publication on withdrawals	Article 36 of Regulation (EC) No 726/2004
Post Opinion: Decision Making Process (PIPIT)	Article 34 and 35 of Regulation (EC) No 726/2004
Re-examination	Article 34 (2) of Regulation (EC) No 726/2004; Article 36 (4) of Directive 2001/82/EC, as amended
EPAR summaries for the public	Article 38 (3) of Regulation (EC) No 726/2004
Information on marketing of the product	Article 38 (4) and 39 (4-6) of Regulation (EC) No 726/2004
Eligibility for the centralised procedure: • Optional scope	Article 3 (2) of Regulation (EC) No 726/2004
• Mandatory scope indications	Article 3 and the Annex to Regulation (EC) No 726/2004
Legal basis & dossier requirements	Article 12 and 13 of Directive 2001/82/EC, as amended
Data and market exclusivity (10 years): • + 3 years for products for fish, bees or other designated species	Article 13 (1) of Directive 2001/82/EC, as amended
• +1 for an additional species	Article 13 (5) of Directive 2001/82/EC, as amended
• + 3 where MAH applied for MRL extensions	Article 13 (5) of Directive 2001/82/EC, as amended
Assessment timetable: • Standard timetable • Accelerated assessment	Article 31 (3) of Regulation (EC) No 726/2004; Article 39 (8) of Regulation (EC) No 726/2004
Renewals	Article 14 (1-3) of Regulation (EC) No 726/2004
Referral Annexes	Article 36 (5) of Directive 2001/82/EC, as amended

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