European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

London, 3 May 2006
Doc. Ref. EMEA/243280/2005 – Rev 2

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

This guidance outlines practical considerations concerning the phasing in of Regulation (EC) No 726/2004[1] and Directive 2004/27/EC[2] to medicinal products for human 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 Product Team Leader, 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 Applications 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-2/home.htm
http://www.emea.eu.int/htms/general/direct/legislation/legislationintro.htm

An overview of the relevant legal provisions and EMEA/Commission guidance documents in relation to the procedural elements listed in this document is provided in Annex I.

This guidance document will be updated regularly to reflect the ongoing implementation discussions at EMEA, CHMP and Commission level:

Table of revisions

Date	Section	Scope
Rev 01 November 2005	1 – Dossier requirements	Included clarification on additional information required.
	3 – Marketing	Updated to reflect the revised Chapter 1 of NTA and EMEA guidance documents.
	3 – PSUR	Amended PSUR transitional requirements.
	3 – Data exclusivity	Updated to reflect the revised Chapter 1 of NTA
	Annex I	Included latest published guidance documents

[1] Repealing Regulation (EEC) No 2309/93/EC; O.J. L 136 of 30.4.2004
[2] Amending Directive 2001/83/EC; O.J. L 136 of 30.4.2004

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Date	Section	Scope
Rev 02 May 2006	1 – Withdrawal	Updated to reflect latest EMEA guidance document
	2 – Assessment TT	Updated to reflect latest EMEA guidance document
	2 – Conditional MA	Updated to reflect Implementing Regulation
	3 – Marketing	Updated to reflect latest EMEA guidance document
	3 – Withdrawal	Updated to reflect latest EMEA guidance document
	Annex I	Included latest published guidance documents

1. Ongoing marketing authorisation applications with Commission Decision expected as of 20 November 2005 (i.e. with CHMP 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 CHMP opinion will be adopted as of **September 2005**.

Applicants will therefore have to amend their draft product information to reflect the new QRD templates in time for opinions to be adopted in September and October 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.

The requirements to include **braille** on the packaging of medicinal products and to make the package leaflet available in formats for the blind and partially sighted, will apply to new marketing authorisations for which a Commission Decision will be granted as of 20 November 2005. Applicants are therefore advised to address Braille already for applications for which a CHMP Opinion will be adopted as of **September 2005,** as outlined in the relevant guidance document published on the Commission Website (see Annex I).

Consultations with target patient groups (‘**user consultation’**) on the draft package leaflet will apply to marketing authorisations for which a Commission Decision will be granted as of 20 November 2005. Applicants are therefore advised to address ‘user consultation’ for applications for which a CHMP Opinion will be adopted as of **September 2005.**
For ongoing applications which are before Day 120 on 20 November 2005, the required information needs to be provided by Day 121. For all other ongoing applications for which a marketing authorisation will be granted as of 20 November 2005, submission and review of the required ‘user consultation’ information needs to be discussed with the EMEA on a case-by-case basis.

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 Product Team Leader 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.

The additional information to be provided relates to

- a detailed description of the pharmacovigilance system
- a detailed description of the risk-management system, where appropriate
- a statement on application of ethical standards in clinical trials conducted outside the community
- 'user consultation' of the package leaflet, new product information and braille requirements (see paragraphs above)

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 CHMP 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, followed by the publication of a "Questions and Answers" document.

Depending on the stage of the procedure at the time of withdrawal, a withdrawal public assessment report (WPAR) 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** CHMP 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 CHMP 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, possibility for Scientific Advisory Group consultation etc ...

* *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 CHMP 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** 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.

Applications containing an **orphan designated substance** or a **new active substance** for which the therapeutic indication is within the mandatory scope of the Regulation and which have been submitted (but not yet approved on 20 November 2005) via a national procedure, must be re-submitted via the centralised procedure. Any applicant in this situation must contact the national competent authority concerned and the EMEA as soon as possible.

Applications containing an **orphan designated substance**, which have been approved via a national or mutual recognition procedure (MRP) before 20 November 2005, can not continue to obtain further national marketing authorisations via a MRP or a repeat-use MRP, and must be re-submitted via the centralised procedure. Any applicant in this situation must contact the national competent authority concerned and the EMEA as soon as possible.

Data and market exclusivity
The new periods of protection will only apply to applications for 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 new CHMP assessment timetable (Day 80 Rap Assessment Report) and 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**.
The request for accelerated assessment should be made as early as possible before the actual submission of the marketing authorisation application. The timing of the request should be at least 10 working days in advance of the CHMP plenary meeting preceding the intended start of the centralised procedure.

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 requirements to include **braille** on the packaging of medicinal products, to make the package leaflet available in formats for the blind and partially sighted, and to perform **consultations** with target patient groups (‘user testing’) will apply to all new marketing authorisation applications submitted as of 20 November 2005.

For applications submitted before that date, see section 1.

Conditional marketing authorisation:
The possibility for CHMP to recommend the granting of a “conditional marketing authorisation”, following consultation of the applicant, will apply to new marketing authorisation applications for which a CHMP opinion will be adopted as of the April 2006 CHMP meeting.

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.**

For existing medicinal products, the 3-year period of non-marketing, which may lead to the marketing authorisation ceasing to be valid ('sunset clause') will start to be counted from 20 November 2005.

MAHs will therefore have to provide the EMEA with the current marketing status of all various presentations per member state.
MAHs should also notify the EMEA of any temporary or permanent interruption of such marketing where the MAH identifies that there might be a public health concern with a cessation.

PSUR

- *Marketing authorisations not yet renewed before 20 November 2005*:

PSURs will currently be submitted at either six-monthly or yearly intervals depending on the date of authorisation and the agreed international birth date of the product. It is considered in the best interests of public health protection for these products to maintain their current PSUR submission periodicity up to their first renewal. Thereafter, PSURs should be submitted every three years, unless other requirements have been laid down as a condition of the marketing authorisation.

In addition, for medicinal products that are currently not marketed, once the product is placed on the Community market, the PSUR should be submitted at least every six months during the first two years of marketing and once a year for the following two years thereafter. Subsequently, the PSURs should be submitted at three-yearly intervals, or immediately upon request.

- *Marketing authorisations already renewed before 20 November 2005*:

The next PSUR should be submitted no later than three years after the date of application of the revised legislation i.e. 20 November 2005 for centrally authorised products. In order to respect existing birth dates agreed with the EMEA/CHMP and to avoid duplication and overlap of PSUR submission the following principles should be applied:

- For marketing authorisations that will be renewed within three years of 20 November 2005 the next PSUR should be submitted with the renewal application, unless otherwise agreed with the EMEA/CHMP. Thereafter, PSURs should be submitted every three years, unless other requirements have been laid down as a condition of the marketing authorisation.
- For marketing authorisations where the next renewal is more than three years from 20 November 2005, a PSUR should be submitted within three years i.e **before 20 November 2008**. The precise date of submission of the next PSUR should be agreed with the EMEA/CHMP. Thereafter, PSURs should be submitted every three years, unless other requirements have been laid down as a condition of the marketing authorisation.

In addition, for medicinal products that are currently not marketed, once the product is placed on the Community market, the PSUR should be submitted at least every six months during the first two years of marketing and once a year for the following two years thereafter, unless otherwise agreed with the EMEA/CHMP. Subsequently, the PSURs should be submitted at three-yearly intervals, or immediately upon request.

Renewals

The new renewal submission deadline (6 months before expiry) will apply to marketing authorisations expiring as of May 2006. Consequently, the new timetable for assessment (90-days) will apply to renewal applications starting after 20 November 2005.

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, CHMP may recommend renewal with unlimited validity or may require one additional 5-year renewal **as of September 2005**.

The renewal dossier content of such applications should ideally be in line with the updated CHMP guideline on renewals. **Product information** for renewal opinions adopted as of September 2005 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 and updated QRD templates, at the occasion of a variation affecting the Annexes or extension procedure **within 2 years** of the application of the new legislation (i.e. by November 2007), unless the marketing authorisation is renewed earlier, in which case the renewal procedure should be used for the update.
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.
Article 61(3) notifications or 6-monthly Type I updating procedures will not 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.

The requirements to include **braille** on the packaging of medicinal products and to make the package leaflet available in formats for the blind and partially sighted, will not apply immediately to authorised medicinal products. Nevertheless companies are encouraged to apply the provision to all medicinal products as soon as possible.

Companies are advised to contact the Product Team Leader to discuss the best timing for updating of the product information and inclusion of Braille, as appropriate, for their product(s) concerned.

Consultations with target patient groups (‘**user consultation’**) on the draft package leaflet will not be required for medicinal products authorised before 20 November 2005. Nevertheless, companies are advised to discuss with the EMEA the need to undertake consultations with target patient groups for authorised medicinal products, taking into account that such a consultation may be required at the time of variations introducing major changes to the package leaflet (e.g. use in a new target patient group, novel presentation with critical administration issues).

Data exclusivity

The additional year of protection (+1) further to a new indication granted within the first 8 years of authorisation adding to the new (8+2) data exclusivity periods shall apply only to those medicinal products for which the initial marketing authorisation application is **submitted** as of 20 November 2005.

Similarly, new indications **submitted** as of 20 November 2005 may benefit from the one-year data exclusivity period for a new indication for a well-established substance (see definition in Chapter 1 of the NTA).

A change of classification **authorised** as of 20 November 2005 may benefit from the one-year data exclusivity period for such a change.

Publication on withdrawals

Any withdrawal of a new indication application (Type II variation or as part of an Extentions application) occurring as of **20 November 2005**, will result in a 'Press Release' announcing the withdrawal on the EMEA website, followed by the publication of a "Questions and Answers" document.

The product EPAR will be updated at the latest 2 months after the announcement, after deletion of commercially confidential information, to reflect the withdrawal. Any other Extension application withdrawal information will be published as part of the EPAR update only.

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 CMDh template* for SPC, labelling and package leaflet to referral procedures for which a CHMP 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 CMDh template.

Annex I
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Overview of legal provisions and respective EMEA and Commission guidance documents / operating procedures in relation to the procedural elements listed above.

Note: Links to relevant guidance documents published at the time of release of this document, are included for convenience. However, 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.
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-2/home.htm

Procedural element / topic	Legal basis	EMEA / Commission guidance documents
Centralised Procedure	Regulation (EC) No 726/2004	Chapter 4 (European Commission – NTA – Volume 2A) http://pharmacos.eudra.org/F2/eudralex/vol-2/A/Chap4rev200604%20.pdf
Product Information (SPC, labelling, PL)	Article 11, 54, 55, 59 and 63 of Directive 2001/83/EC, as amended	QRD product information templates http://www.emea.eu.int/htms/human/qrd/qrdplt/24530905en.pdf
Braille requirements	Article 56a of Directive 2001/83/EC, as amended	Guidance concerning the Braille requirements for labelling and the package leaflet (European Commission – NTA) http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2005/04_05/Braille_text20050411.pdf
Handling of consultation with target patients groups	Article 59 (3) and 61 (1) of Directive 2001/83/EC, as amended	Guidance concerning "consultations with target patient groups" for the package leaflet (European Commission – NTA) http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2005/08_05/USERTESTING_20050817.pdf Operational procedure on Handling of "Consultation with target patient groups" on Package Leaflets (PL) for Centrally Authorised Products for Human Use http://www.emea.eu.int/htms/human/qrd/qrdplt/27737805en.pdf
Conditions and restrictions Risk management	Article 9 (4) (c) of Regulation (EC) No 726/2004; Article 127 (a) of Directive 2001/83/EC, as amended	Guideline on risk management systems for medicinal products for human use http://www.emea.eu.int/pdfs/human/euleg/9626805en.pdf
Publication on withdrawals	Article 11 of Regulation (EC) No 726/2004	Reflection Paper on publication of withdrawals http://www.emea.eu.int/pdfs/human/euleg/23935005en.pdf

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Procedural element / topic	Legal basis	EMEA / Commission guidance documents
Post Opinion: Decision Making Process	Article 9 and 10 of Regulation (EC) No 726/2004	Guidance concerning the implementation of Art 10 (European Commission) http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2006/02_2006/finalproposal_pipit.pdf Decision making procedure for the adoption of Commission Decisions (European Commission – NTA – Chapter 6) http://pharmacos.eudra.org/F2/eudralex/vol-2/A/vol2a_chap6_2005-11.pdf Operational procedure on "The new Linguistic Review Process of Product Information in the Centralised Procedure" http://www.emea.eu.int/pdfs/human/regaffair/554202en.pdf
PSUR cycle	Article 24 (3) of Regulation (EC) No 726/2004	Transitional measures for submission of PSURs for centrally authorized products for human and veterinary use http://www.emea.eu.int/pdfs/human/euleg/33861205en.pdf
Re-examination	Article 9 (2) of Regulation (EC) No 726/2004; Article 32 (4) of Directive 2001/83/EC, as amended	Guideline on Procedures for re-examination of CHMP opinions http://www.emea.eu.int/pdfs/human/euleg/5074505en.pdf
EPAR summaries for the public	Article 13 (3) of Regulation (EC) No 726/2004	Reflection paper on EPAR Summary for the Public http://www.emea.eu.int/pdfs/human/euleg/12675705en.pdf
Information on marketing of the product	Article 13 (4) of Regulation (EC) No 726/2004	Marketing Authorisation – section 2.4.2 (European Commission – NTA – Chapter 1) http://pharmacos.eudra.org/F2/eudralex/vol-2/A/vol2a_chap1_2005-11.pdf Questions and answers on notification to the EMEA of actual marketing and cessation of placing on the market for centrally authorised medicinal products http://www.emea.eu.int/htms/human/postguidance/18007805en.pdf

Procedural element / topic	Legal basis	EMEA / Commission guidance documents
'Sunset-clause'	Article 14 (4-6) of Regulation (EC) No 726/2004	Marketing Authorisation – section 2.4.2 (European Commission – NTA – Chapter 1) http://pharmacos.eudra.org/F2/eudralex/vol-2/A/vol2a_chap1_2005-11.pdf Application of the "sunset clause" in the review of the pharmaceutical legislation to medicinal products authorised before Directives 2004/27/EC and 2004/28/EC and Regulation (EC) no 726/2004 start to apply (European Commission) http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2005/10_05/sunsetclause_10-2005.pdf Questions and answers on the application of the so-called "sunset clause" to centrally authorised medicinal products http://www.emea.eu.int/htms/human/postguidance/18007905en.pdf
Eligibility for the centralised procedure: • Optional scope	Article 3 (2) of Regulation (EC) No 726/2004	Guideline on the application of Article 3.2 of Regulation (EC) No 726/2004 - Optional scope of the centralised procedure - Human medicinal products (European Commission) http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2005/12-05/Optional%20scope%20publ%2021%2012%2005.pdf
• Mandatory scope indications	Article 3; Annex of Regulation (EC) No 726/2004	Guideline on therapeutic areas within the mandatory scope of the centralised procedure for the evaluation for marketing authorisation applications with reference to Article 3 and point 3 of the Annex of Regulation (EC) No 726/2004 http://www.emea.eu.int/pdfs/human/regaffair/28295405en.pdf Operational measures for the submission to the EMEA of ongoing national marketing authorisation applications for medicinal products for human use falling within the mandatory scope of the centralised procedure. http://www.emea.eu.int/pdfs/human/regaffair/35461105en.pdf
Legal basis & dossier requirements	Article 8 and 10 of Directive 2001/83/EC, as amended	Marketing Authorisation – section 5 (European Commission – NTA – Chapter 1) http://pharmacos.eudra.org/F2/eudralex/vol-2/A/vol2a_chap1_2005-11.pdf Module 1 of EU-CTD (European Commission – NTA – Volume 2B) http://europa.eu.int/comm/enterprise/pharmaceuticals/eudralex/homev2.htm#2b

Procedural element / topic	Legal basis	EMEA / Commission guidance documents
Pharmacovigilance (incl. description of PhVig system)	Article 8(3)(ia) and 8(3)(n)of Directive 2001/83/EC, as amended	Guideline on "monitoring of compliance with pharmacovigilance regulatory obligations and pharmacovigilance inspections (European Commission) http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2006/02_2006/v9_compliance-guideline_pubcons_03-2006.pdf Volume 9a - Guidelines on Pharmacovigilance (European Commission) http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2005/12-05/draft%20of%20Volume%209a_12_2005.pdf
Data and market exclusivity: • (8+2) +1 for a new indication	Article 14 (11) of Regulation (EC) No 726/2004	Marketing Authorisation – section 6 (European Commission – NTA – Chapter 1) http://pharmacos.eudra.org/F2/eudralex/vol-2/A/vol2a_chap1_2005-11.pdf Guideline on the elements required to support the significant clinical benefit in comparison to existing therapies of a new therapeutic indication in order to benefit from an extended (11-years) marketing protection (European Commission) http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2005/12-05/Guideline%20on%2014_11_%20for%20public%20consultation.pdf
• +1 for a well established substance	Article 10 (5) of Directive 2001/83/EC, as amended	Guideline on new therapeutic indication for a well-established substance (European Commission) http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2005/12-05/10%20_5_%20guideline%20for%20public%20consultation%2016%20December%202005.pdf
• +1 for a switch in legal status	Article 74 (a) of Directive 2001/83/EC, as amended	Guideline on changing the classification for supply of a medicinal product for human use (European Commission) http://pharmacos.eudra.org/F2/eudralex/vol-2/C/switchguide_160106.pdf
Assessment timetable: • Standard timetable • Accelerated assessment	Article 6 (3) of Regulation (EC) No 726/2004; Article 14 (9) of Regulation (EC) No 726/2004	Guideline on the procedure for Accelerated Assessment pursuant to Article 14 (9) of Regulation (EC) No 726/2004 (EMEA/419127/05) http://www.emea.eu.int/pdfs/human/euleg/41912705en.pdf
Renewals	Article 14 (1-3) of Regulation (EC) No 726/2004	Marketing Authorisation – section 2.4.1 (European Commission – NTA – Chapter 1) http://pharmacos.eudra.org/F2/eudralex/vol-2/A/vol2a_chap1_2005-11.pdf Updated CHMP guideline on the processing of renewals in the centralised procedure http://www.emea.eu.int/pdfs/human/regaffair/299000.pdf

Procedural element / topic	Legal basis	EMEA / Commission guidance documents
Referral Annexes	Article 32 (5) of Directive 2001/83/EC, as amended	CMDh annotated QRD templates http://heads.medagencies.org/mrfg/docs/pi/QRD_annotated_template_CMDh.pdf
Exceptional circumstances	Article 14 (8) of Regulation (EC) No 726/2004; Article 22 of Directive 2001/83/EC, as amended	Guideline on procedures for the granting of a MA under exceptional circumstances. http://www.emea.eu.int/pdfs/human/euleg/35798105en.pdf
Conditional MA	Article 14(7) of Regulation (EC) No 726/2004	Commission Regulation (EC) No 507/2006 on the conditional MA for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 http://pharmacos.eudra.org/F2/eudralex/vol-1/reg_2006_507/reg_2006_507_en.pdf