



Brussels, 3 October 2005

**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**

Article 24(4)-(6) of Directive 2001/83/EC as amended by Directive 2001/27/EC, Article 28(4)-(6) of Directive 2001/82/EC as amended by Directive 2001/28/EC and Articles 14(4)-(6) and 39(4)-(6) of Regulation (EC) No 726/2004 introduce a so-called “sunset clause” in the Community legal framework for pharmaceuticals.

According to these provisions, any marketing authorisation which within three years of its granting is not followed by the actual placing on the market of the authorised product in the authorising Member State or on the Community market shall cease to be valid. When an authorised product previously placed on the market in the authorising Member State or in the Community is no longer actually present on the market for a period of three consecutive years, the authorisation for that product shall cease to be valid. The competent authority may, in exceptional circumstances and on public health grounds grant exemptions.

In accordance with Article 3 of Directives 2004/27/EC and 2004/28/EC, the Member States are to transpose these directives into their national legal orders by 30 October 2005 at the latest. In turn, pursuant to Article 90 of Regulation (EC) No 726/2004, Articles 14 and 39 of that regulation apply from 20 November 2005.

Directives 2004/27/EC and 2001/28/EC and Regulation (EC) No 726/2004 do not contain any transitional rules for the application of the mentioned provisions to medicinal products authorised before these new legal texts start to apply.

In such circumstances, it is appropriate to clarify how the mentioned provisions shall apply to existing products, as agreed by the Member States, the EMEA and the Commission in the Notice to Applicants group. In this regard, the three year period referred to above shall be counted, in the case of medicinal products authorised before the new rules start to apply, from:

- 20 November 2005 in the case of centrally authorised products; and
- the date when the national measures transposing Article 24(4)-(6) of Directive 2001/83/EC as amended by Directive 2001/27/EC and Article 28(4)-(6) of Directive 2001/82/EC as amended by Directive 2001/28/EC start to apply in each Member State, in the case of nationally authorised products. As stated above, Member States are under an obligation to ensure transposition of the new directives into their national legal orders by 30 October 2005.