REGULATORY NEWS

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Conditional marketing authorisation in the EU: an improved regulation if properly applied

● **No early approval for drugs that fail to offer major therapeutic advantages.**

In late 2004 the European Commission released a consultation paper on the draft Regulation governing "conditional marketing authorisation", i.e. market approval granted on the basis of incomplete assessment data. This consultation paper suggested that some drugs might be approved too prematurely, for situations in which there was no special urgency justifying early approval (1-3). The version of the Regulation finally adopted in March 2006 represents an improvement (4).

Stricter criteria. Conditional marketing authorisation will be granted only if:

"*- the risk-benefit balance of the medicinal product is positive*;

- unmet medical needs will be fulfilled;

- the benefit to public health (…) outweighs the risk inherent in the fact that additional data are still required".

'Unmet medical needs' "*means a condition for which there exists no satisfactory method of diagnosis, prevention or treatment authorised in the Community or, even if such a method exists, in relation to which the medicinal product concerned will be of major therapeutic advantage to those affected*" (article 4) (4).

Transparency obligation. The European Medicines Agency (EMEA) is required to publish the list of obligations that recipients of conditional marketing authorisation must fulfil (clinical trials to be completed, further studies "*with a view to confirming that the risk-benefit balance is positive*"), along with the deadline for meeting each obligation (article 5) (4).

The summary of product characteristics (SPC) and patient information leaflet must mention the 'conditional', 'provisional' nature of market approval, as well as its expiry date (unless renewed).

Conditional marketing authorisation is valid for one year (article 6). Requests for renewal must be accompanied by an interim report on how the company has dealt with commitments to carry out required additional research. The licensing committee will then decide whether the authorisation should remain conditional, and whether the obligations and/or deadlines should be modified. If conditional marketing authorisation is maintained, it becomes valid until the decision is made to grant or refuse full approval (4).

We will be keeping a close eye on the proper implementation of these measures.

Selected references from Prescrire's literature search.

1- Prescrire Rédaction "Le projet de règlement sur l'autorisation conditionnelle de mise sur le marché des médicaments met en danger les populations" 22/12/2004.Website Prescrire www.prescrire.org.

2- "Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use" *Official Journal of the European Union* 30 April 2004: L136/34-L136/57.

3- "Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use " (and replacing annexe I) *Official Journal of the European Union* 27 June 2003: L159/46-L159/94.

4- "Commission Regulation (EC) N° 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) N° 726/2004 of the European Parliament and of the Council "*Official Journal of the European Union* 30 March 2006: L92/6-L92/9.