The European Union Penalties Regulation explained by Hogan & Hartson lawyers

After much debate about its contents, purpose and legal basis, the European Commission Regulation on Penalties relating to new drug approvals was finally adopted on June 14 and entered into force on July 5. As a consequence of the Regulation, the European Commission can now impose fines on companies whose medicinal products have been authorized in accordance with the central procedure laid down in Regulation 726/2004 for breaches of specified obligations. The centralized procedure allows for a single application, a single evaluation and a single authorization allowing direct access to the single market of the European Union, explain Elisabethann Wright and Susan Jane Clement of international law firm Hogan & Hartson.

Provisions could render drugmakers doubly exposed to fines by EU member states and by European Commission

Article 84(1) of Regulation 726/2004 provides that each EU member state shall determine the penalties to be applied to infringement of the provisions of the Regulation. Such penalties must be effective, proportionate and dissuasive.

Penalties at EMEA request

In addition, however, Article 84(3) of Regulation 726/2004 provides that, at the request of the European Medicines Aency (EMEA), the Commission may also impose financial penalties on the holders of marketing authorizations granted under the centralized procedure if they fail to observe certain obligations laid down.

The combined application of these two provisions could render companies doubly exposed to fines, facing infringement proceedings and penalties in EU member states and to infringement proceedings and penalties imposed by the Commission. Dual infringement proceedings and imposition of penalties at both national level in EU member state and by the Commission level for what may be the same infringement would arguably be tantamount to a breach of the right not to be tried or punished twice. Given that member states' penalties must be effective, proportionate and dissuasive, this breach could be further aggravated as a result.

The Penalties Regulation, which was the result of the application of Article 84(3) in practice, addresses this possibility of double exposure concern only to a limited extent. The Regulation limits the general circumstances in which the Commission can impose fines on marketing authorization holders to specified circumstances identified in Article 1 to the Regulation. These circumstances relate to cases in which an infringement may have significant public health implications in the EU, or where it has a Community dimension by taking place or having its effects in more than one member state, or where interests of the Community are involved. The purpose of this approach is, according to the third preamble to the Regulation, to ensure the effective enforcement of the EMEA Regulation by an appropriate management of the resources available at Community and national level.

The Penalties Regulation allows the Commission to impose fines for infringements of a wide range of obligations. However, according to the second preamble, infringements related to a marketing authorization should relate to the content of the approval and post-marketing requirements linked to an MA, including requirements relating to pharmacovigilance and market surveillance.

Article 1 of the Regulation permits the Commission to impose fines on MA holders arising from 17 different identifiable breaches. These include failures relating to the following:

- the completeness and accuracy of information in the application or other information submitted to the EMEA;
- conditions or restrictions included in the MA, *eg*, concerning the supply or use of the medicinal product;
- the supply of information that may entail a variation to the MA and the variation;
- notification of any prohibition or restriction imposed by the competent authorities of any country in which the product is marketed, or the supply of any information that may influence its risks and benefits evaluation;
- placing on the market in accordance with the content of the summary of the product characteristics and the labeling and package leaflet as contained in the MA;
- notification to the EMEA, *eg*, of the dates of actual marketing and when the product ceases to be on the market;
- the appropriately qualified person who is responsible for pharmacovigilance;
- recording and reporting of suspected serious adverse reactions, suspected serious unexpected ARs, and suspected transmission of infectious agents;
- detailed recording of all suspected ARs and submission of such records in the form of periodic safety update reports;
- communication of information relating to pharmacovigilance concerns to the general public; and
- collation and assessment of specific pharmacovigilance data.

Infringement procedure

The decision to initiate the infringement procedure is taken by the EMEA. This can be either on the Institutes own initiative or following one from the Commission

or a member state. It is unclear which conditions would have given rise to this last type of request, nor how action in such circumstances would be reconciled with that by a member state in accordance with Article 84(1) of Regulation 726/2004. The EMEA may approach the MA holder before initiating an infringement procedure, but is not obliged to do so.

There are two stages to the infringement procedure. In the first, the EMEA conducts an inquiry during which it may request the MA holder to submit written or oral explanations, or particulars or documents. Natural or legal persons may also be asked to provide information related to alleged infringements. Although the terms "request" and "ask" are used, the Commission has the power to impose fines on MA holders who do not cooperate with this investigation.

Prior to adoption of the EMEA report, the MA holder has a right to submit written observations . The EMEA then reports to the Commission and, if the agency considers that the MA holder has committed an infringement, requests the Commission to fine the applicant. The EMEA can take up to 18 months from initiation of the procedure to adoption of its report.

The second stage, the decision-making phase, is conducted by the Commission. If it decides to continue with the infringement procedure, it will set out its case against the MA holder in writing in a statement of objection. Where this is not forthcoming within 18 months it is required to provide an explanatory statement if it has not done so within 18 months. The MA holder then has the right to be heard in writing and orally. Despite the absence of strict time limits on the Commission, the institution can impose a time limit for response on the MA holder although this must be at least four weeks on the applicant for its written response. Moreover, it can set the date of the oral hearing at a time of its choosing .

Financial penalties

The Penalties Regulation provides that MA holders that are held to have intentionally or negligently committed a breach of obligations identified by the Regulation can face high fines. However, the Regulation sets out circumstances which the Commission must take into consideration when imposing fines. These provisions are clearly influenced by the Commission's Guidelines on the method of setting fines in antitrust cases. However, they provide much less guidance on how the Commission will set fines. They set out circumstances which the Commission must take into consideration, where relevant, however, they omit key provisions such as taking into account the company's inability to pay in exceptional cases and imposing a symbolic fine in certain cases.

The Regulation provides for two types of financial penalties: fines and periodic penalty payments. Where the MA holder has committed, intentionally or negligently, an infringement, the Commission may impose a fine of up to 5% of the MA holder's turnover in the preceding year. It provides that, in determining whether to impose fines and in determining the appropriate fines, the Commission shall be guided by the principles of effectiveness, proportionality and dissuasiveness.

Where the MA holder does not terminate the infringement, the Commission may impose periodic penalty payments per day not exceeding 2.5 % of the holder's average daily EU turnover in the preceding business year.

Unlike in the Commission's Guidelines on the method of setting fines in antitrust cases, the Regulation does not expressly provide for a reduction in fines where the undertaking concerned effectively cooperates with the Commission beyond its legal obligation to do so. Instead, it says in its preamble that, while the Commission should be entitled to compel MA holders to provide the necessary information and documents relating to a presumed infringement, the right to silence in situations where the holder would be compelled to provide answers which may involve an admission on its part of the existence of an infringement, as developed by the European Court of Justice, should also be respected.

Level of fines viewed as high

While the level of the fines, at 5% of the MA's EU turnover in the preceding business year, is lower than the 10% in the Commission's Guidelines on the method of setting fines in antitrust cases, it is still considered to be extremely high, particularly taking account of the obligations and procedure that the holder had to pursue prior to grant of the MA. Furthermore, the terms used "the holder's Community turnover" suggests that the MA holder's turnover in all sectors will be taken into account, and not only that related to the medicinal product that is the subject of the MA in dispute.

The Penalties Regulation also permits the Commission to impose fines on marketing authorization holders not exceeding 0.5 % of their Community turnover in the preceding business year where, intentionally or negligently they do not comply with requests by the EMEA or the European Commission during the investigation or they supply incorrect or misleading information in response such a request.

Moreover, where non-cooperation of the MA holder continues, the Commission may also impose periodic penalty payments *per* day not exceeding 0.5 % of the holder's average daily Community turnover in the preceding business year.

Few would dispute the need to ensure that MA holders should respect post-marketing authorization obligations. However, it remains to be seen whether fear of high fines will be either sufficient or appropriate to ensure that they do so, the lawyers conclude.