The new EC Financial Penalties Regime - a bridge too far?

Peter Bogaert, Covington & Burling LLP, Brussels


The Commission has publicly stated that the Penalties Regulation will only rarely be applied. Even so, the new regime implies a significant change to the regulatory framework within which pharmaceutical companies operate and it may also prove to be a difficult tool in such a complex environment as the regulation of medicines.

Against this background, this article examines the following:

- Why a Penalties Regulation?
- Main elements of the Penalties Regulation.
- Regulatory obligations.
- Procedural guarantees.
- Extension under the Penalties Regulation.
- Practical recommendations.
- A bridge too far?

WHY A PENALTIES REGULATION?

The adoption of a Penalties Regulation is mandated by Article 84 of Regulation (EC) No. 726/2004 on the authorisation and supervision of medicinal products and establishing a European Medicines Agency (EMEA Regulation), which governs the centralised procedure for marketing authorisations. Article 84.1 requires member states to “determine the penalties to be applied for infringement of the provisions of this Regulation or the regulations adopted pursuant to it” and “to take all measures necessary for their implementation.” It further specifies that the penalties must be “effective, proportional and dissuasive.” In addition, Article 84.3 for the first time envisages a Community regime of financial penalties:

“At the Agency’s request, the Commission may impose financial penalties on the holders of marketing authorisations granted under this Regulation if they fail to observe certain obligations laid down in connection with the authorisations. The maximum amounts as well as the conditions and methods for collection of these penalties shall be laid down in accordance with the procedure referred to in Article 87(2).”

The Commission shall publish the names of the marketing authorisation holders involved and the amounts of and reasons for the financial penalties imposed.”

The structure of Article 84 clearly reflects the basic Community law principles of enforcement, which is in the first place a responsibility of the member states. This is also in line with the principle of subsidiarity, which is laid down in Article 5 of the EC Treaty and limits Community intervention to actions for which the objectives cannot be sufficiently achieved at the member state level. Under the centralised procedure, however, a marketing authorisation granted by the Commission is automatically valid throughout the EU and any infringement of related obligations also has, at least potentially, a Community wide dimension.

In addition, the traditional regulatory tools for addressing acts of non-conformity relate to the marketing authorisation and include, in particular, imposing variations, or suspending or withdrawing the product approval. These tools do not allow to impose sanctions for elements of non-compliance that ultimately do not affect the quality, safety or efficacy profile of the medicine in question. In addition, they automatically impact third parties, including patients and health professionals. In that light, it was considered necessary to establish an EC penalties regime that provides for financial sanctions that can be imposed on the marketing authorisation holder without necessarily affecting the status of the medicines concerned.

MAIN ELEMENTS OF THE PENALTIES REGIME

The key elements of the Penalties Regulation can be summarised as follows:

Scope

The Penalties Regulation first identifies what infringements can result in financial penalties. It only applies when the infringement “may have significant public health implications in the Community,” or “has a Community dimension by taking place or having its effects in more than one Member State,” or when other “interests of the Community are involved.” These criteria reflect the subsidiarity principle but are very vague and there is a risk that they could be invoked in almost every instance of non-compliance with regard to a centrally-approved product.

The Penalties Regulation also lists, and paraphrases, 17 regulatory obligations that it seeks to enforce. The list is exhaustive and covers obligations for both human and veterinary medicines. It has been the subject of significant debate and it is discussed further below (see below, Regulatory obligations),
Cross-border

Procedure

An infringement procedure is initiated by the European Medicines Agency (EMEA), on its own initiative or at the request of the Commission or a member state. The agency must notify the marketing authorisation holder of the initiation and specify the evidence that supports an alleged infringement. It then starts an inquiry, which can involve requesting information from the company or requesting member states to conduct inspections or to take other supervisory action. The agency can also ask third parties to provide information. Third parties are not legally bound to provide the information asked for and it would seem appropriate for the agency to clarify in requests to third parties that compliance is voluntary.

After having offered the company an opportunity to submit written observations, the EMEA prepares a report with the outcome of the inquiry. If the report concludes that penalties should be imposed and the Commission decides to continue the infringement procedure, the Commission issues a statement of objections. The company can again submit written observations and can ask for an oral hearing, which the Commission can invite third parties to attend.

The Commission can also request information from the company, the EMEA, member states or third parties (which again are not legally obliged to respond) and if need be return the file to the agency for a new inquiry. A final decision is only explicitly required by the Penalties Regulation when the Commission wishes to impose fines. That decision is made public, based in general on a “naming and shaming” principle, but also with respect for proper protection of business secrets. The decision can be challenged before the EC Court of First Instance.

Fines and financial penalties

The Penalties Regulation allows the Commission to impose fines of up to 5% of the EU (and normally also EEA) turnover of the marketing authorisation holder, provided there is an intentional or negligent infringement. There is no specific provision on how to determine the turnover of the marketing authorisation holder if the latter is expressly operating as a branch of a company or as an EEIG (European Economic Interest Grouping), but the general principles of corporate law will normally apply.

In setting the fine, the Commission must take account of the general standards of “effectiveness, proportionality and dissuasiveness” and also several specific criteria, such as:

- The seriousness of the infringement (for example, the possible risk for patient safety or public health in general).
- Good faith of the company in the interpretation of the rules in question.
- The company’s conduct during the infringement procedure.
- The turnover of the medicine in question.
- Possible repetition of infringements.
- Penalties already imposed at the national level.

Initially, the Commission had proposed even higher fines, namely up to 10% of the worldwide turnover of the marketing authorisation holder. That threshold was borrowed from the anti-trust rules, which have been enforced through EC penalties for many years. Even after the reduction to 5% of EU/EEA turnover, the maximum level could still be very high and often widely exceeds the maximum of penalties currently envisaged under national law, but the Commission argued that the protection of public health justifies penalties that are comparable to those imposed for economic infringements.

The Commission can also impose periodic penalties if the infringement continues, as well as fines and periodic penalties for non-compliance with requests for information from the EMEA or the Commission.

Balance with national responsibilities

The Penalties Regulation seeks to balance Community enforcement with the national enforcement responsibilities. To do so, it does the following:

- Imposes the above-mentioned, but vague, Community interest threshold (see above, Why a Penalties Regulation?),
- Seeks to stimulate close co-operation between the national authorities, the EMEA and the Commission,
- Requires the EMEA and the Commission to take national actions into account when considering or conducting infringement procedures and when fixing fines.

It also, however, envisages that national authorities will use their supervision and inspection powers to assist the EMEA and the Commission in their investigations.

REGULATORY OBLIGATIONS

Article 84.3 of the EMEA Regulation provides for penalties in case of failure “to observe certain obligations laid down in connection with the authorisations” granted under the centralised procedure. This limits the regulatory obligations that can be enforced through the new regime and Article 1 of the Penalties Regulation provides a limitation list. It focuses on:

- The completeness and adequacy of data contained in the applications for marketing authorisation and any updating of them (be it through submission of new data or by means of applying for variations or responding to a request to show that the risk-benefit profile of the product remains positive).
- Restrictions, conditions and obligations laid down in the marketing authorisation.
- The various obligations related to pharmacovigilance and post-marketing surveillance.

The obligation to notify the EMEA of starting or ceasing commercialisation and to provide quantitative data on sales and prescriptions on request is also included, as is the detection of residues of veterinary medicines.
Initially, the Commission proposed a wider material scope of application, but this was ultimately reduced, mainly for legal reasons. For example, the obligations related to compassionate use programmes, under Article 83 of the EMEA Regulation were taken out of the scope because Article 84 of the same Regulation clearly only envisages financial penalties for obligations "laid down in connection with" a Community marketing authorisation, while the compassionate use rules apply when there is no authorisation yet.

There was extensive debate in relation to obligations that arise from Directives as opposed to Regulations. The debate related to the rules on manufacturing and importation, but also, and especially, the rules on advertising. The latter are laid down in Articles 86 and following of Directive 2001/83/EC on the Community code relating to medicinal products for human use (Code for Human Medicines Directive), which is binding on member states and not on companies and individuals. Legal obligations for marketing authorisation holders, or other legal or natural persons, with regard to advertising of medicines, therefore arise under provisions of national law that implement (and often supplement) the EC provisions and cannot be enforced through an EC penalties regime.

In addition, the advertising rules in the Code for Human Medicines Directive expressly require member states to put in place adequate enforcement mechanisms at the national level, and this is clearly an area where the subsidiarity principle is relevant. In light of these aspects, the advertising rules were, together with the rules governing manufacturing and importation, ultimately excluded from the scope of application of the Penalties Regulation. This was, however, the subject of intense debate because of the growing importance of more international media, such as the internet.

**PROCEDURAL GUARANTEES**

During the various rounds of consultation of interested parties, heavy emphasis was placed on the need for adequate procedural guarantees. This is particularly relevant because there is for the moment no Community code on administrative procedures by the Commission and EC agencies that establishes general standards for investigative and decision making procedures.

The guarantees that currently exist result from specific rules in the substantive rules, general principles that are recognised by the European Court of Justice or are laid down in the Charter of Fundamental Rights of the European Union, and self-discipline by the administrative bodies. The EMEA Regulation does not contain any procedural guarantees for the new EC penalties regime, which explains the attention devoted to the issue during the consultation rounds. This was considered significant in light of the potential financial impact of the new system (fines of up to 5% of the EU/EEA turnover) and also in light of the important reputational impact which negative decisions may have. In addition to the basic principle of the right to be heard after access to the file, the Penalties Regulation now also explicitly recognises the right to legal representation, a burden of proof of alleged infringements for the Commission, the right to remain silent, and so on.

The Penalties Regulation also provides for more realistic time limits for the marketing authorisation holder to present its defence. Other suggestions, however, were not taken aboard. One relates to legal privilege, which is recognised by the Community courts, but, at least in the competition sector, remains limited to communications with outside counsel following the ruling in the Akzo case (joined Cases T-125/03 and T-253/03, Akzo Nobel v Commission, decision of 17 September 2007). Another related to the need to be able to obtain a suspension of the Commission decision based on a balance of interest (including the strength of the legal arguments), without having to comply with the standard test of irreparable harm. That would probably, however, have required an amendment to the general rules governing the Court of First Instance.

Additional suggestions to put in place a panel of independent adjudicators within the Commission, and operating a standard of intent or serious negligence before a fine can be imposed, are discussed below (see below, A bridge too far?).

**EXTENSION UNDER THE PAEDIATRICS REGULATION**

In December 2006, the European Parliament and Council adopted Regulation (EC) No. 1901/2006 on medicinal products for paediatric use (Paediatrics Regulation). The aim of the new Regulation is to cure the lack of adequate data on the potential use of medicines in children and to stimulate the development of specific paediatric forms. This is implemented through a combination of paediatric obligations and incentives.

The paediatric obligation applies, subject to transitional provisions, to all applications for a marketing authorisation for a new medicine, other than through the specific approval procedures for generics, biosimilars, well-established medicines, traditional herbal medicines and homeopathics. It also applies to the application for many line extensions for existing products that still benefit from a supplementary protection certificate (SPC) or a patent that qualifies for an SPC. The obligation involves the need to apply for approval of a Paediatric Investigation Plan (PIP), which may include a waiver (or deferral) of certain data, for example, of paediatric data in a specific age group or for a specific therapeutic indication, and to ultimately submit data in compliance with the PIP.

The paediatric incentive consists of a six-month extension of the SPC or of a two-year extension of the market exclusivity for orphan medicines. The incentives are, however, only available when the detailed conditions laid down in the Paediatrics Regulation are met.

Article 49 of the Paediatrics Regulation provides for penalties at the national and EC level in terms that are similar to those used in Article 84 of the EMEA Regulation. The penalties also have to be "effective, proportionate and dissuasive" and will apply in case of infringements of the Paediatrics Regulation or implementing measures. It does, however, separate these powers by allocating the penalties powers to the member states for products that are approved nationally or under the decentralised or mutual recognition procedures, and to the EMEA and the Commission for centrally-approved products. This deviates from the subsidiarity principle and illustrates an increasing trend of centralisation. Article 49 will have to be implemented through an amendment to the Penalties Regulation or, less likely, through a new Paediatric Penalties Regulation.
PRACTICAL RECOMMENDATIONS

The Penalties Regulation does not impose specific obligations on companies before they are the subject of an inquiry, but it is clearly advisable for companies to take certain preparatory measures. Even if the chance of an inquiry is probably in most cases fairly small, important steps can be taken, especially to allow a prompt and substantiated response to allegations of infringements. These steps can include, among others:

- Preparing a detailed overview of how the regulatory obligations that are covered by the Penalties Regulation are being complied with for all centrally-approved products. This should include details of the various legal entities involved, contractual documentation supporting the delegation of tasks, names and contact details of key personnel and persons replacing them in case of absence, and so on. Special attention may have to be given to situations where certain regulatory obligations are delegated to third parties, such as local distributors or co-promotion partners.

- Reviewing the standard operating procedures (SOPs) and compliance procedures for the specific obligations concerned.

- Training of staff, followed by audits and testing procedures for information gathering and analysis that would have to be relied on in case an inquiry or investigation is started.

A BRIDGE TOO FAR?

The Penalties Regulation is an entirely new component of the regulatory framework within which pharmaceutical companies have to operate. It allows the Commission to impose sanctions for breaches of obligations without necessarily affecting the status of the products concerned. Although in practice the Penalties Regulation may only sparsely be used, it will have an important impact on how companies operate. In particular, it will probably change the dynamics of the interaction between the companies and the EMEA and the Commission.

The revision of the pharmaceutical legislation in 2004 and the new Paediatrics Regulation already increase the discretion regulators have and this will be reinforced by the new penalties regime. In that context, one can wonder whether the penalties regime has been put in place too soon, or at least without sufficient guarantees. The pharmaceutical legislation is complex and also too often unclear, as illustrated by the many referrals to the European Court of Justice and the problems of interpretation of certain parts of the revisions of 2004.

In addition, applying the rules to concrete situations can require complex assessments of a scientific and technical nature. Linking compliance with these rules with potentially very tough penalties will present very specific challenges. Especially when the EC pharmaceutical rules in question are not clear, the imposition of penalties will be problematic, and this will be even more clearly so with regard to compliance with the Paediatrics Regulation. This is even more important because the Commission did not accept two important procedural safeguards that were proposed during the consultation process on the new Regulation: the limitation of penalties to cases of intentional or seriously negligent breaches, and an independent panel of adjudicators within the Commission. These safeguards are important because the Commission already has very broad tasks under the pharmaceutical system. For example:

- It proposes new pieces of basic legislation and plays an important role in the legislative process.
- It adopts implementing provisions in the form of Commission Directives and Regulations.
- It issues important guidance (in the form of the Notice to Applicants and ad hoc guidelines) that interprets the legislation.
- It supervises application of the legislation by member states.
- It issues Community marketing authorisations and decisions following referrals to the CHMP.

It is important that when financial penalties are imposed, this happens through a panel that is independent of the division that is responsible for these numerous and important other tasks related to pharmaceuticals, and against a standard that is higher than simple negligence. That is not yet, however, the case.
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