

The New EU Rules on Financial Penalties for Pharma Companies

January 10, 2019

Food, Drugs, and Devices

On January 7, 2019, EU Regulation 2019/5 was published in the Official Journal of the European Union. The Regulation is part of a [package](#) that makes numerous significant amendments to the EU's regime for veterinary medicines and medicated feed, and it also made some key changes to the EU financial penalties regime.

Under the EU financial penalties regime, the European Medicines Agency (EMA) can investigate and report on alleged breaches of the EU pharmaceutical rules by holders of a marketing authorization (MA) for centrally-authorized human medicinal products. The European Commission could then adopt decisions imposing significant financial penalties on infringing MA holders.

This alert outlines some of the key changes to this financial penalties regime, which apply from January 28, 2019.

Background

The previous financial penalties regime was based on Article 84(3) of Regulation 726/2004, which established the EMA and the centralized procedure for the approval and supervision of medicinal products. Article 84(3) allowed the EMA to request that the European Commission impose financial penalties on the MA holders and gave the Commission the power to adopt more detailed legislation specifying the "maximum amounts as well as the conditions and methods for collection of these penalties." In June 2007, the European Commission adopted Regulation 658/2007, laying down a procedure for the investigation of alleged infringements and the imposition of financial penalties on MA holders of up to 5% of their annual EU-wide turnover.

To our best knowledge, there has been only one infringement procedure against a pharmaceutical company, which Covington handled. The Commission closed the procedure on December 15, 2017 without a financial penalty. During that procedure, it became apparent that there were a number of legal and procedural issues with the penalties rules that arguably rendered the regime ineffective and any Commission decision imposing a fine amenable to challenge before the Court of Justice of the European Union ("CJEU"). The changes to the EU financial penalties regime aim to address these issues.

Affiliates Can Now Also Be Subject To A Fine

In the past, the rules implied that the European Commission was only permitted to impose financial penalties on the legal entity that holds the MA. To go beyond that, the European Commission would have needed to argue that the MA holder included not only the legal entity holding the MA, but also the parent company and other affiliates alleged to have been involved in the infringement. There were obvious legal objections to this.

The new rules now expressly state that penalties can be imposed on a legal entity other than the MA holder itself provided that such entities form part of the same economic entity as the MA holder.¹ That may include the parent company (whether or not established in the EU) or affiliates of the MA holder. In addition, one of two conditions must be fulfilled: (i) the other legal entity must have exerted a decisive influence over the MA holder, which is generally the case for a parent company; or (ii) the other legal entity must have been involved in, or could have addressed, the MA holder's failure to comply with its obligations. The preamble states that this amendment is necessary because "it is important that means exist to address the fact that [MA] holders could be part of a wider economic entity. Otherwise, there is a clear and identifiable risk that the responsibility for a failure to comply with those obligations could be evaded, which might have an impact on the ability to impose effective, proportional and dissuasive penalties."

Obligations That May Be Subject To A Fine

Under the old penalties rules, Article 84(3) of Regulation 726/2004 did not specify the obligations that could be subject to a financial penalty if infringed. The Commission sought to identify these in its implementing Regulation 658/2007. This was a problem, because Article 84(3) empowered the Commission only to set out the "maximum amounts as well as the conditions and methods for collection of these penalties." Under general principles of EU law and Article 84(3), the European Commission only has the power to adopt "non-essential elements" that supplement EU legislation. In principle, it was for the Council and Parliament to decide what regulatory obligations are to be enforced through financial penalties. As a result, any fine under the old rules would arguably have been invalid.

The new Regulation addresses this by adding a new Annex II to Regulation 726/2004, which specifies the 22 obligations that can be enforced through fines. They can be summarized as follows:

- The obligation to submit a complete and accurate dossier with an MA application;
- The obligation to comply with conditions or restrictions of an MA concerning supply or use of the product;
- The obligation to comply with conditions or restrictions of an MA concerning safe and effective use of the medicine;
- The obligation to apply for a variation if necessary to take account of technical and scientific progress, or to supply new information that may entail a variation to the MA or may influence the benefit-risk evaluation, such as any prohibition or restriction imposed by competent authorities anywhere in the world where the product is marketed;
- The obligation to keep product information up to date with current scientific knowledge;

¹ New article 84a(2) of Regulation 726/2004.

- The obligation to provide, at the request of the EMA, any data demonstrating that the benefit-risk balance remains favorable;
- The obligation to place medicines on the market in accordance with the SmPC, labeling and package leaflet as set out in the MA;
- The obligation to comply with the conditions attached to a conditional MA;
- The obligation to notify the EMA of the dates of actual marketing and of the date when the medicine ceases to be on the market, and to provide data relating to the volume of sales and the volume of prescriptions;
- The obligation to operate a comprehensive pharmacovigilance system, to operate a risk management system, and to submit, at the request of EMA, a copy of the pharmacovigilance system master file;
- The obligation to record and report suspected adverse reactions;
- The obligation to submit periodic safety update reports (PSURs);
- The obligation to conduct post-marketing studies, including post-authorization safety studies and post-authorization efficacy studies, and to submit them for review;
- The obligation to ensure that public announcements relating to information on pharmacovigilance concerns are presented objectively and are not misleading and to notify them to EMA;
- The obligations relating to Pediatric Investigation Plans (PIPs), namely to comply with the time limits for initiating or completing measures specified in the EMA decision on deferral following the initial MA and in accordance with the definitive opinion of EMA;
- The obligation to place the medicine on the market within two years of the date on which the pediatric indication is authorized;
- The obligation to transfer the MA or to allow a third party to use documentation contained in the file of the medicinal product, as provided for in the pediatric Regulation;
- The obligation to submit pediatric studies to the EMA, including the obligation to enter information on third country clinical trials into the European database;
- And finally, the obligation to comply with post-authorization requirements under the pediatric Regulation.

Unlimited Jurisdiction of the EU Courts

Under the old financial penalty rules, there was no provision stating that the EU Courts had unlimited jurisdiction to review any decision imposing a financial penalty and the size of the penalty. This was a legal flaw in the regime. As financial penalties are (at least quasi-) criminal in nature, article 6 of the European Convention on Human Rights and article 47 of the EU Charter on Fundamental Rights require effective judicial protection. This means that the decision imposing a penalty should be fully reviewable by the CJEU. Under the old financial penalties rules, this could have been a ground for challenge of any such Commission decision.

New article 84a(9) of Regulation 726/2004 closes this loophole by providing the CJEU with “unlimited jurisdiction” to review these decisions. The article expressly states that CJEU may cancel, reduce, or increase the fine or periodic penalty payment.

Going Forward

Based on the new article 84a of Regulation 726/2004, the European Commission will adopt a new delegated act containing the procedure that can lead to a fine. The new rules will contain provisions on initiation of the procedure, measures of inquiry, rights of defense, access to file, and confidentiality. It is conceivable that these rules could reduce the role of the EMA in the investigation of possible infringements and leave more responsibilities with the Commission. In the meantime, the procedure under Regulation 658/2007 remains applicable and new investigations under the new rules could in principle start from January 2019.

The Commission will also adopt further detailed rules on the imposition of penalties on legal entities other than the MA holder. The Commission will probably publish a draft of this delegated act later this year. Once published, trade associations and pharmaceutical companies will in principle have four weeks to comment on the text.

Veterinary Medicines

As from January 2022, veterinary medicines will no longer be subject to Regulation 726/2004 but will be governed by the new veterinary medicines Regulation 2019/6. There are equivalent financial penalties provisions in that Regulation. The list of regulatory obligations that can be enforced through EU penalties builds on the corresponding list in Regulation 658/2007 but is a bit broader and also reflects substantive changes in the new rules on veterinary medicines.

The European Commission must adopt similar delegated acts as for medicines for human use, but the specific penalties rules for veterinary medicines will only apply as from January 2022.

Conclusion

The EU penalties regime for the pharmaceutical industry exists since almost twelve years but was defective. The European Commission was very aware of the various legal problems, which effectively clipped the wings of regime as any fine would likely be annulled by the EU Court. Key corrections have now been made and we expect that the new EU penalties rules will likely be used more often.

Practical recommendations for pharmaceutical companies are available upon request.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drugs, and Devices practice:

Peter Bogaert

+32 2 549 52 43

pbogaert@cov.com

Grant Castle

+44 20 7067 2006

gcastle@cov.com

Robin Blaney

+32 2 549 52 60

rblaney@cov.com

Bart Van Vooren

+32 2 549 52 50

bvanvooren@cov.com

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