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But finishing was never part of the (paediatric investigation) plan…

The UK's High Court recently decided upon Dr Reddy's application to revoke the 6 month paediatric extension of Warner-Lambert's SPC for atorvastatin (Lipitor), which is used for lowering blood cholesterol.

Background

SPCs are granted to compensate patent holders for the time taken to obtain marketing authorisation for a medicine covered by a patent. An SPC comes into effect at the end of the patent's term. It extends the protection for the authorised medicine for a period equal to that between the filing date of the patent and the date of the first marketing authorisation, to a maximum of 5 years.

Provision for the extension of SPCs was introduced by Regulation 1901/2006 ("the paediatric regulation") which took effect in January 2007. The regulation's purpose is to encourage research into the use of medicines in children. This research is considered to be important, because, as noted in Recital 3 of the regulation, a lack of information in this area leads to increased risks of adverse reactions, ineffective treatment through under-dosage, and the non-availability to the paediatric population of therapeutic advances, suitable formulations and routes of administration. In this regard, however, there is no requirement that a medicine be authorised for paediatric use for an extension to the SPC to be granted following the research.
The discovery that the medicine is not effective in the paediatric population is also considered valuable information.

Briefly, in order to obtain a paediatric extension, the applicant must complete a number of steps, including the following:

1. Draw up a draft paediatric investigation plan (PIP) and submit it to the European Medicines Agency (EMA), through the Paediatric Committee (PDCO), for agreement. The PIP should specify the timing and measures proposed to assess the quality, safety and efficacy of the medicine in the paediatric population. In addition, it should describe any measures to adapt the formulation of the medicinal product to make its use more acceptable, easier, safer or more effective. The proposed PIP is assessed by the PDCO, which may request modifications to the plan. The PDCO then adopts an opinion as to whether or not the proposed studies will generate the necessary data, and if they are justified by the envisaged benefits. The EMA issues a decision, annexing the PDCO's opinion.

2. Apply for a marketing authorisation including the decision agreeing to the PIP, the results of all studies performed and details of all information collected in compliance with the agreed PIP. The competent authority (i.e. the body that grants marketing authorisations) which has received the application verifies that the PIP has been complied with.

3. Apply to the national patent offices for a paediatric extension to its SPCs, if the applicant has been issued a marketing authorisation indicating compliance with the PIP.

The paediatric extension for atorvastatin

Pfizer had proposed new pharmaceutical forms for oral atorvastatin, which were more appropriate for children aged 6 years and above than the previously authorised film-coated tablet.

The agreed PIP required three clinical studies. The first was a bioequivalence study to check the bioavailability and effectiveness of the new form in comparison to the existing formulation in healthy adult volunteers. The second was a pharmacokinetic study to determine dosing. The third was a 3-year study of safety and efficacy.

The PIP specified that the first study was to be completed by 30th September 2009 and the second study by 30th December 2009. The third study, however, was only required in the PIP to be commenced by 31st March 2009. In due course an extension to the SPC was granted, on the basis of a decision that the studies conducted by Pfizer were in accordance with the PIP, as the first and second studies had been completed and the third study had been started.

The Court's judgment

Three grounds for revocation were advanced by Dr Reddy's, but all were dismissed by the Court.

First, Dr Reddy's argued that the EMA had acted incorrectly by approving a PIP that required Pfizer merely to commence the third study, and as such the PIP was not lawfully approved and Pfizer was not entitled to the extension. However, the Court instead assessed that the relevant question was whether or not the requirements of the PIP had been fulfilled. It judged that Pfizer had indeed complied by completing the first and second studies, and initiating the third study.

Second, Dr Reddy's argued that, pursuant to Article 45(3) of the regulation, a paediatric extension should be granted only when 'significant studies' contained in the PIP have been completed. It alleged that at no stage had any assessment been performed as to whether either of the two completed studies was significant; it further alleged that they were not significant. The Court decided, however, that Article 45(3) was a transitional provision which related to research performed before the regulation came into effect. Accordingly, it did not apply in this case.

Finally, Dr Reddy's argued that even if it was legitimate for the EMA to approve a PIP that required the initiation but not completion of the third study, Pfizer was not entitled to an extension unless it included the results of the completed third study within its marketing authorisation application. Here, the Court considered that this argument also failed once it had been decided that Pfizer had complied with the PIP.

A further issue in this case related to the interpretation of Article 16 of the SPC regulation (Regulation 469/2009), which sets out that the paediatric extension may be revoked if granted contrary to the requirements of Article 36 of the paediatric regulation. Dr Reddy's argued that this would oblige the Court to revoke the extension of the SPC if it had been granted when this article of the paediatric regulation had not been complied with, but Pfizer argued that it merely gave the Court discretion to do so. On this point, the Court also agreed with Pfizer.

Comment

This decision is of interest in clarifying the interpretation that the UK courts will take with regard to whether or not a PIP has been completed. As SPCs are dealt with on a national basis, however, there is significant potential for contradictory judgments to be issued in different countries, meaning that it is only when questions of this type have been referred to the Court of Justice for the European Union that the issues raised in this case will be definitively addressed. Indeed, bearing in mind that this legislation is relatively new, it is likely that many further issues of interpretation will be raised in due course. This is even more likely because the paediatric extension extends the SPC and so coverage for the authorised medicine, irrespective of the indication, at the tail-end and hence most valuable part of an SPC's life.

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