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NABARRO
CLARITY MATTERS

ECJ rules that generics cannot rely on a pre-EU accession marketing authorisation

Summary and implications

The European Court of Justice has ruled on an important aspect of EU marketing authorisation procedures for generic medicines.

An application for marketing authorisation cannot rely on the marketing authorisation of an earlier drug with the same active ingredient if that earlier marketing authorisation does not meet EU standards, even if the original marketing authorisation was granted before EU procedures applied in that member state.

Whilst the Court's conclusion is not altogether surprising, the decision has significant implications for research and for generics firms:

- Products cannot be valid reference products until the original pre-EU marketing authorisation has been fully updated to comply with the EU rules (especially the data in the underlying dossier).
- Drugs companies that compile their own full and free-standing dossiers to support product approvals will be able to generate a new period of data exclusivity, even if a product not authorised under EU law had previously been on the EU market.

Background of Case – Case C-527/07

This case concerned the use of galantamine for the treatment of Alzheimer's disease and the difficulties caused by the choice of reference product for the marketing authorisation.

Nivalin, a galantamine product for the treatment of poliomyelitis, had been authorised by the Austrian regulator in 1963. Its indications had later been extended to Alzheimer's, but the dossier contained almost no relevant supporting data. This product had been on the market in Austria before and after Austria's accession to the EU.

Shire Pharmaceuticals and Janssen-Cilag had co-developed a galantamine for the treatment of Alzheimer's (Reminyl). This had been approved in Sweden in 2000, and subsequently across Europe.

Ask a question

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Later, Generics (UK) applied for a UK marketing authorisation for a generic galantamine product also for the treatment of Alzheimer's. In its application Generics (UK) specified Nivalin as the reference product.

The UK regulator, the MHRA, refused the application in early 2007. Generics (UK) challenged this decision in the UK High Court. Shire and Janssen-Cilag intervened in this litigation to support the MHRA refusal. They argued that Reminyl was the only valid reference product and that its data exclusivity period did not expire until March 2010.

A reference to the ECJ for clarification

The reference sought clarification on

- whether or not a local marketing authorisation granted before that member state had joined the EU could be used as a valid reference product for a generic drug under EU marketing authorisation rules, and
- whether Generics (UK) should be entitled to damages if the MHRA had incorrectly applied EU law.

Article 10(1) of Directive 2001/83

The applicant shall not be required to provide the results of pre-clinical tests and clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community

Generics (UK) argued that its MHRA application was proper – and Nivalin was a valid reference product - because Austria had implemented the EU pharmaceutical laws before it had joined the EU. Moreover, Nivalin had remained on the EU market without objection after this. This therefore constituted an authorisation in accordance with EU law.

Generics (UK) also argued that interpretation of EU laws on marketing applications must be consistent with EU laws on supplementary protection certificates. The SPC Regulation provides that some pre-accession authorisations in Austria and certain other member states should be treated as authorisations granted in accordance with EU laws.

ECJ Judgment paragraph 25

In order to be able to grant a marketing authorisation for a generic medicinal product on the basis of the abridged procedure, what matters is that all the particulars and documents relating to the reference medicinal product remain available to the competent authority concerned.

The ECJ rejected these arguments. It held that the MHRA was correct to reject Generics (UK)'s application. Nivalin had not been the subject of a marketing application procedure compliant with EU rules (such as the appropriate pharmaceutical, pre-clinical and clinical trial data), nor had Nivalin's original Austrian dossier been updated to reflect the harmonised EU marketing authorisation rules which became applicable after Austria joined the EU in 1995.

The ECJ judgment did not discuss the arguments based on the SPC Regulation. These had, however, been dismissed in the earlier opinion of Advocate General Mazák.

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