Marketing Auhorisations: Informed Consent

By

Dr Rosanna Cooper

Under the Informed Consent procedure, a pharmaceutical or biotech company ('Company A') is able to grant a another company ('Company B'), a 'piggy back' licence to obtain a second 'duplicate' Marketing Authorisation by relying on Company A's existing Marketing Authorisation documentation. The Informed Consent procedure applies to all national Marketing Authorisation applications under Article 10c of Directive 2001/83/EC (as amended). This article concentrates primarily on using the Informed Consent procedure in the United Kingdom ('UK') to obtain a Marketing Authorisation for an existing medicinal product.

1. Introduction

In order for any pharmaceutical or related company to market or sell a medicinal product in the UK, it requires a Marketing Authorisation. Current European legislation allows a company to obtain a Marketing Authorisation for an existing medicinal product via an abridged application. The Informed Consent procedure is a type of abridged application. In the UK, a company has to submit scientific data to the Medicines and Healthcare Products Regulatory Agency ('MHRA') in the form of a dossier to support the product application (Article 8 (3) of Directive 2001/83/EC as amended), before a Marketing Authorisation is granted for a medicinal product. The medicinal product has to meet the appropriate standards of safety, quality, performance and effectiveness as laid down by the MHRA.

2. Centralised Procedure

Under European legislation (Regulation (EC) No 726/2004 of the European Parliament and of the Council) there is a centralised European Community procedure for the authorisation of medicinal products. A company can make a single application and evaluation request to the European Medicines Agency ('EMEA') for a Marketing Authorisation of a medicinal product. If this application is successful, the EMEA will grant a Marketing Authorisation under the centralised procedure for this product. The Marketing Authorisation granted under the centralised procedure would cover the entire European Community market, meaning that the medicinal product may be marketed or sold in all Member States. Different categories of products may fall within this system such as medicinal products and/or medicinal products developed by means of biotechnological processes such as recombinant DNA technology, controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes, including transformed mammalian cells or monoclonal antibody methods. It also covers similar biological ('biosimilar') medicinal products developed by such biotechnological processes.

It is important to note that an Informed Consent application for a Marketing Authorisation by Company B which is already authorised by the centralised procedure has automatic access to the centralised procedure.

3 Informed Consent Application

When Company B makes an Informed Consent application to the MHRA for Marketing Authorisation in relation to a medicinal product, it has to show that the medicinal product possesses the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form of the authorised medicinal product and that **consent** has been granted by Company A to use its pre-clinical and clinical data ('Data') in support of the application. Company B is not required to undertake any tests or clinical trials required to support the appropriate standards of safety, quality, performance and effectiveness required to be met for this product. Company B simply has to apply for a 'duplicate' licence which would be an independent Marketing Authorisation to that of Company A.

There are a number of constraints on Company B as follows:

- There is an obligation on Company B to provide ongoing Periodic Safety Update Reports ('PSUR') ;
- For Company B to appoint a qualified person who would be responsible for producing the PSUR's, preferably a medically qualified person or a person that would be able to report or have access to a medically qualified person;
- During the lifetime of the said medicinal product, Company B would be required to have permanent access to the references in the documentation for such product or to be in possession of this information; and
- Under Article 104 of Directive 2001/83/EC, once the Marketing Authorisation is granted, Company B would be under a strict obligation to report all suspected adverse reactions to the MHRA relating to the said medicinal product.

4. Agreement

Company A and B will typically enter into an agreement and the terms of the agreement, including the cost for granting the 'piggy back' licence would be expressly set out. This last obligation in the list above can usually cause protracted discussions as Company A would typically wish to cut all ties with Company B once the agreement has been signed. It is crucial for companies granting the 'piggy back' licence to be aware of this obligation on them.

5. Current Legislations

The two main legislations governing Marketing Authorisations in the UK are Directive 2001/83/EC as amended on the Community Code relating to medicinal products for human relevance and Directive 2004/27/EC on the Community Code relating to medicinal products for human relevance (amending Directive 2001/83/EC).

Article 10c of Directive 2001/83/EC (as amended) gives Company B the authority to make an Informed Consent application to obtain a duplicate Marketing Application for an existing medicinal product owned by Company A:

"*…Following the granting of a marketing authorisation, the authorisation holder may allow use to be made of the pharmaceutical, pre-clinical and clinical documentation contained in the file on the medicinal product, with a view to examining subsequent applications relating to other medical products possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form".*

6. Renewal and Variation to a Marketing Authorisation

Marketing Authorisations are granted for up to a period of five years and are renewable at the end of this time. On renewal, each Marketing Authorisation must reflect all the up to date knowledge/information about the product including any necessary action from the most recent Periodic PSUR submitted (Article 24 of Directive 2001/83/EC).

After the first renewal of the Marketing Authorisation, the licence would be valid for an unlimited period unless there are issues such as pharmacovigilance then the MHRA may decide that a further renewal is required.

With regard to Periodic Safety Update Reports, under Article 26 of Directive 2001/83/EC, PSUR's have to be submitted every three years to the MHRA.

7. Conclusion

Company B must pay particular attention to its obligations under the legislation, in particular, the obligation to provide PSUR reports and to agree wherever possible that Company A agrees to provide all documents/data relating to changes/variations to the Marketing Authorisation for the medicinal product. This is a cost effective way of obtaining a Marketing Authorisation for a medicinal product.

RT Coopers

Dr Rosanna Cooper is the global head of RT Coopers. She is a leading pharmaceutical and regulatory lawyer and intellectual property specialist. She can be contacted on +44(0) 20 7488 9947 or by email: enquiries@rtcooperssolicitors.com. Website: www.rtcoopers.com