UK Medicines Legislation Assists Generic Competition

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On October 30, 2005, the UK Medicines Amendment Regulations 2005 (the 2005 Legislation) entered into force.

The 2005 Legislation implements provisions of European Directive 2004/27/EC (the 2004 Medicines Directive) relating to the granting, suspension and revocation of drug marketing authorizations and obligations of authorization holders, and introduces an exemption to patent infringement for preparatory acts undertaken prior to seeking marketing authorization for generic medicinal products.

Background

The 2004 Medicines Directive was part of a package of European legislation designed to standardize national law and administrative provisions across the European Community. The legislative package constitutes a major revision to the existing European medicines legislation and could have a significant impact on the approval of drug products in Europe.

Key Provisions

Some of the key effects of the 2005 Legislation are:

Patent Infringement Exemption

The 2005 Legislation amends the infringement provision of the 1977 Patents Act so that an act committed while "conducting a study, test or trial which is necessary for" and which "is conducted with a view to" applying for drug marketing authorization for a generic version of a drug will not infringe a patent covering that drug.

This means that pre-patent-expiration testing may now be done in the United Kingdom, putting generic drug manufacturers on a more equal footing with their competitors in the United States, Canada and Asia.

Data Exclusivity Period

Under the abridged application procedure for marketing authorization, a generic drug

applicant can rely on clinical data submitted by an innovative drug manufacturer once the data exclusivity period relating to a particular drug (the reference medicinal product) has expired.

The 2005 Legislation now standardizes the data exclusivity period across the European Community to eight years from the date of initial authorization in the Community, for all innovative drug products granted authorization after October 30, 2005. Previously, periods of between six and ten years (and in some cases even zero years beyond patent expiration) were in force across European Community Member States. The 2005 Legislation supersedes earlier legislation authorizing these other periods.

Marketing Exclusivity

Although data exclusivity expires after eight years, a generic product cannot be placed on the market until ten years after initial authorization of the reference medicinal product.

Definition of a Generic Medicinal Product

In addition, the 2005 Legislation introduces a new, broader definition of a "generic" medicinal product, replacing the previous "essentially similar" language.

A generic medicinal product is now one "which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product and whose bioequivalence...has been demonstrated."

The language "active substances" is defined as "different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance," provided that such substances do not "differ significantly in properties" affecting "safety and/or efficacy."

These definitions are intended to expedite assessment of abridged applications for generic drug marketing authorizations.

Line Extension

Where a medicinal product has been granted an initial marketing authorization, "any additional strengths, pharmaceutical forms, administration routes, presentations as well as variations and extensions shall be granted an authorization," but "shall be considered as belonging to the same global marketing authorization." There is, therefore, no separate data exclusivity period for line extensions as such. The data exclusivity period for the reference medicinal product (including any line extensions), however, may be extended by a maximum of one year, if during the eight years following the initial marketing authorization of the reference medicinal product, the marketing authorization holder obtains an authorization for one or more new therapeutic indications that provide a significant clinical benefit.

Definition of a Medicine

Finally, the definition of a medicine has been amended to require it to exert "a pharmacological, immunological or metabolic action."

This amendment is intended to more closely regulate "borderline" medicines--in particular, medical devices, food supplements and cosmetics.

Comment

The reduction of the United Kingdom's data exclusivity period from ten to eight years, together with the clarified definition of a "generic" medicinal product, now permits competition from generic drug manufacturers to occur up to two years earlier in the life cycle of drug products.

Under the new infringement exemption, generic drug manufacturers will have a safe harbor allowing preparatory testing in the United Kingdom.

The 2005 Legislation applies to drug marketing authorizations granted only after October 30, 2005. In practice, therefore, generic drug marketing authorizations under this new scheme are unlikely to be granted before 2014.

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