HEALTHCARE & LIFE SCIENCES - SWEDEN

Named patient permission for unauthorised medicinal products – financial considerations

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Introduction

The Stockholm Administrative Court of Appeal recently considered whether financial aspects can be assessed when determining whether there are special requirements for granting a named patient permission. The court dismissed arguments that high prices and limited availability of an authorised medicinal product constituted special requirements for a named patient permission for an unauthorised medicinal product. The assessment of the need for a named patient permission must be based on an assessment of available medicinal care. The court's reasoning prevents the marketing authorisation system from being put out of balance by medical prescriptions and reduced prices of unauthorised products.

In Sweden, a physician can prescribe an unauthorised medicinal product to an individual patient if a medical condition cannot be treated with medicinal products that have already been approved in Sweden or if these drugs have been shown to be ineffective. However, the medicinal product must be authorised in the European Union.

The process for obtaining special permission on a named patient basis is initiated by the individual physician and local pharmacy. The Medical Products Agency makes an individual assessment of the application based on whether there is a need for a named patient permission, or whether the patient's needs can be satisfied by a product that has already been authorised in Sweden or by other means. If the need for a certain medicinal product is considered to exist, the agency will grant the named patient permission for use by that individual patient only.

Named patient permission

On February 19 2014 the agency rejected a named patient permission application for a medicinal product that was not authorised in Sweden. The medicinal product was used to treat familial amyloidotic polyneuropathy syndrome (also called Corino Andrade's disease), which is a degenerative neurological condition. The agency stated that an authorised medicinal product was already available on the Swedish market to treat the disease. However, based on a recommendation by the Association of Local Authorities and Regions, due to the product's high price and the fact that it was not included in the reimbursement scheme, the approved product should be prescribed to a limited number of patients only where treatment was deemed indispensable for each patient.

The pharmacy and the individual patient appealed to the Uppsala Administrative Court, arguing that the product authorised in Sweden was effectively unavailable to the patient due to the association's recommendation and the product's high price. Thus, there was a special requirement for a named patient permission.

The Uppsala Administrative Court held that it was unclear whether the patient's medicinal needs

could be satisfied by the product that has been approved in Sweden and referred the case back to the agency on the grounds that the patient would not receive adequate treatment if a named patient permission were not granted. This decision was also appealed, this time by the agency; the Stockholm Administrative Court of Appeal rendered its judgment on October 13 2015.

Decision

The Stockholm Administrative Court of Appeal granted the agency's appeal, declaring its initial decision correct on all accounts.

The question before the appeal court was whether there are special reasons to grant a named patient permission for an unauthorised medicinal product where an authorised medicinal product is available on the Swedish market that can satisfy the patient's medicinal needs, but the patient cannot be expected to be able to pay for it.

The appeal court began by mentioning that nothing in the Medicinal Products Act or its legal history states that the price of an authorised medicinal product should be considered when assessing whether a named patient permission should be granted. Instead, the court referred to the principle of interpretation of national legislation in conformity with EU law. The EU Medicinal Products Directive (2001/83/EC) states that an exception from the requirement that a medicinal product be authorised before it is placed on the market in a member state may be made only if there are special requirements for such an exception.

The European Court of Justice (ECJ) interpreted the term 'special requirements' under the Medicinal Products Directive in Case C-185/10, in which it held that an exception should be granted only if no equivalent authorised medicinal product is available and if it is motivated based on individual medicinal grounds. Financial considerations cannot in themselves lead to recognition of the existence of special requirements which can justify an exception to the requirement for authorisation.

In light of the ECJ judgment and Medicinal Products Directive, the appeal court held that the possibility to grant a named patient permission and thereby make an exception from the requirement for market authorisation for a medicinal product must be interpreted restrictively. An exception may be granted based only on medicinal grounds in the individual situation. Financial considerations should not form part of the assessment of whether a special requirement exists. Thus, the appeal court granted the agency's appeal and found that the agency was correct in rejecting the application.

Comment

The decision confirms that it is not possible to assess financial considerations when determining whether there are special requirements for granting a named patient permission. The appeal court's reasoning is in line with ECJ case law and establishes that only the individual patient's need for a certain medicinal product should form basis of the assessment.

Should the appeal court have made another assessment and decided to include financial considerations (eg, the price of the authorised product), it would have risked putting the marketing authorisation system out of balance. It would then be possible to circumvent the requirement that a medicinal product be authorised before it is placed on the market simply by giving it a lower price than a product which has passed the requirements for authorisation and then getting a physician to prescribe the product on a named patient basis. Instead, the court confirmed that a named patient permission for unauthorised products is an exception to the main rule intended only for situations where no authorised medicinal product is available that would fulfil the patient's need for medicinal care.

At the time of writing, it was unclear whether the judgment had been appealed.

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