Healthcare & Life Sciences - Sweden

Medicinal products' approved indications irrelevant to substitutability

Contributed by **Advokatfirman Lindahl**

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Introduction

A pharmaceutical company applied to the Medical Products Agency for a decision on the substitutability of its generic inhaler. The active substance and formulation were identical to the original product. The inhalers themselves were almost identical but with certain minor differences. The original inhaler was approved for both adult and paediatric indications, while the generic inhaler was approved for adult indication only.

Under the Medicinal Products Act, medicinal products are considered substitutable if the products are equivalent to each other. Grounds for denying substitutability include important differences in how the products are handled (eg, inhalation medicines which require a certain breathing technique or injection pens or other products which are accompanied by aids essential to the administration of the medicinal product).

The agency denied the generic inhaler substitutability based on differences in the product's compatibility with spacers as compared to the original inhaler. Inhalers are used with spacers, for example, when administering to children or the elderly. The agency referred to differences in the dimensions of the generic inhaler's mouthpiece compared with that of the original inhaler. The agency argued that differences in compatibility with spacers meant that there was a risk that patients would handle inhalers with spacers incorrectly, posing safety and efficacy risks.

The spacer mentioned in the original product's summary of product characteristics was used for babies and small children. The spacer mentioned in the generic product's summary of product characteristics was for adults.

The generic company argued that the differences between the inhalers did not constitute incompatibility with the spacer mentioned in the original product's summary of product characteristics. It also argued that incompatibility with a spacer for children was irrelevant, considering that the generic inhaler was not approved for paediatric indication.

Decision

The Uppsala Administrative Court upheld the agency's decision that the generic inhaler was not considered substitutable within the substitutability groups that the company had applied for.

The court denied substitutability based on the generic inhaler's incompatibility with the spacer mentioned in the original inhaler's summary of product characteristics (ie, the spacer used for babies and small children). The court found that while it was probable that the generic inhaler would be compatible with the child spacer, there was no scientific evidence available to support such a position. There was therefore a risk that medicine could be dosed incorrectly for certain patient groups (one to four-year-olds).

The court stated that even though the generic inhaler was not approved for paediatric indication, the inhaler could be substituted for paediatric indication in a substitutability situation. When assessing whether substitutability can be granted, all patient groups must be considered. This meant that the generic inhaler could be administered to small children together with a spacer considered to be incompatible with it, creating a risk that product dosing could be incorrect. Substitutability was therefore denied.

Comment

This appears to be the first time that the courts have considered the substitutability of inhalers. The court's reasoning regarding whether it has been shown that the inhaler is compatible with the spacer is non-controversial.

However, the court's reasoning regarding the relevance of the products' approved indications is interesting. There is limited case law on assessments of substitutability in relation to differences in approved indications, making this judgment important, even though it was issued by a first-instance court.

The Swedish regulatory framework on substitution is product based and does not take into account a product's approved indications. The regulatory framework for pricing and reimbursement for medicinal products is based on the substitutability decisions made by the Medical Products Agency. Consequently, the government benefits financially from a product-based system which allows for substitutability despite differences in approved indications, as, due to mandatory substitution, it must reimburse only the cheaper generic products which are considered equivalent to the original products. This has certain questionable effects – for example, it has been an issue in the enforcement of second medical use patents in relation to products with 'skinny labelling'.

However, in this particular case the financial consequences of the regulatory framework for substitution, pricing and reimbursement are negative for the government, since the decision on non-substitution between the original and generic product will prevent the usual reduction of prices after a generic entry. This was noted by the court, which considered the patient-safety aspect of the assessment to be most important.

Regarding the issue of skinny labelling, the judgment confirms that the agency's case law in this respect is acceptable, at least from a regulatory perspective. The issue of infringement of second medical use patents by skinny labelled generics due to the mandatory substitution has yet to be tried by Swedish courts.

The judgment has been appealed by the pharmaceutical company.

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