Transparency Directive 89/105/EEC: Transparency of measures relating to pricing and reimbursement of medicinal products

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European Commission
DG ENTR F.4
Food and Healthcare Industries, Biotechnology

Introduction

Decisions on prices of medicinal products and their reimbursement fall within the responsibility of Member States

However, national pricing and reimbursement measures may have an impact on market access & free movement of goods

Necessity to ensure that such measures do not hinder or distort intra-Community trade

➔ Harmonised legal instrument to guarantee the transparency of pricing and reimbursement measures

Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of national health insurance system (OJ N°40 of 11.2.1989, p. 8)

Objectives of the Directive

Obtain an overall view of pricing arrangements in each Member State

Ensure that all interested parties can verify that national pricing and reimbursement measures do not constitute quantitative restrictions on imports or exports, or measures having equivalent effect

➔ Procedural framework to facilitate the implementation of, and verification of compliance with the provisions of the Treaty on free movement of goods (Article 34 of the Treaty on the Functioning of the European Union (TFEU))

Scope of the Directive

Directive 89/105/EEC applies to any national measure (whether laid down by law, regulation or administrative provision)

- to control the prices of medicinal products for human use

  or

- to restrict the range of medicinal products covered by their national health insurance systems

The Directive does not affect national policies on pricing and reimbursement of medicinal products, except as far as it is necessary to guarantee the transparency of national systems

Key provisions (1)

Areas covered

Price decisions
(Articles 2 & 3)

- → Decisions on initial price
- → Decisions to increase price

Reimbursement decisions
(Articles 6 & 7)

- → Decisions on inclusion in / exclusion from the list of reimbursed products (positive list)
- → Decisions on inclusion in / exclusion from the list of non-reimbursed products (negative list)

Obligations

Strict timeframe

- → Rule = 90 days from receipt of application (90 for pricing / 90 days for reimbursement)

Transparent criteria

- → Objective and verifiable criteria must be defined and published
- → Individual decisions must be motivated in light of these criteria (statement of reasons)

Legal remedies

- → Applicants must be informed of the legal remedies available and timeframe to appeal (independent legal body)

Key provisions (2)

Areas covered

Price freeze
(Article 4)

→ If price freeze imposed on all medicinal products or on certain medicinal products

Profit control
(Article 5)

→ If systems of direct or indirect controls on the profitability of marketing authorisation holders

Obligations

Regular assessment

→ At least once a year: obligation to carry out a review to determine if economic conditions justify maintaining the price freeze

Derogations

→ Possibility to request a derogation from the price freeze

Specific information on the system

→ Must be published in relevant publication

→ Must be communicated to the Commission

Interpretation by the Court of Justice

Legal instrument linked to the free movement of goods (one of the fundamental freedoms of the EU)

Consequently, the European Court of Justice Directive considers that the Directive cannot be interpreted restrictively:

- The Transparency Directive must be interpreted in light of its objectives, so as to ensure its effectiveness
- Any national measure to control prices or reimbursement must comply with its provisions
- Otherwise, the obligations of the Directive could be easily circumvented and its objectives would be jeopardised

Implications

This broad legal interpretation has important consequences – for example:

- The Directive applies to measures of a general nature where they amount to a bundle of individual decisions

e.g. → *List of active substances*
Prescription vs. non-prescription medicines
Creation of therapeutic groups

- If different levels or categories of reimbursement are established, the transparency requirements of the Directive must be applied to each level or category

e.g. → *Criteria for each level/category of reimbursement*

See relevant case law:

- C-424/99, Commission v. Austria, 27 November 2001
- C-229/00, Commission v. Finland, 12 June 2003 12 June 2003

Conclusion

A key instrument for the functioning of the internal market in medicinal products

A short, but essential piece of the pharmaceutical *acquis*

Further information on DG Enterprise website:
http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/pricing-reimbursement/transparency/index_en.htm#h2-5

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Thank you