EU member states and the Transparency Directive

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Since 1989, pricing and reimbursement policies of EU member states have been regulated by Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products (Transparency Directive). It provides the member states with a common framework to set up their pricing and reimbursement systems. Every now and then a new ruling of the European Court of Justice (ECJ) is made, in procedures in which a pharmaceutical company challenges compliance of national pricing and reimbursement authorities with the Transparency Directive. The case law on the implementation of the Transparency Directive does not give much cause for optimism. This article analyses the:

- Relevant EC principles and national healthcare policies.
- Main principles of the Transparency Directive.
- ECJ case law on the Transparency Directive.
- National application of the Transparency Directive.
- Adequacy of national legal remedy systems.

EC PRINCIPLES AND NATIONAL HEALTHCARE POLICIES

Medicinal products are important economic commodities: highly valued and priced products, marketed in a competitive environment and with extremely high development costs. From the patient’s perspective, medicinal products represent an important part of medical treatment. For governments of EU member states, the costs of medicinal products are an important concern, as well as their contribution to healthcare and to the promotion of public health. The pharmaceutical industry contributes substantially to the EU economy in terms of income and employment.

The development and marketing of medicinal products takes place in an economic, European, environment. The use of medicinal products is within the remit of nationally organised healthcare systems, mainly financed from collective funds. Medicinal products therefore are at the crossroads of European and national legislative systems and policies.

EU principles

The main reason for European integration is to promote welfare by completion of the single market and promotion of the competitiveness of European industry. The pharmaceutical industry is historically a very important economic operator. Since the development of the Lisbon agenda, an innovative industry like the pharmaceutical industry is even more at the centre of economic policies, because EU member states acknowledge that innovation should remain one of the most important drivers of economic development.

The main EU principles with respect to the development and marketing of medicinal products are:

- Free movement of goods.
- Promotion of innovation and industrial activity.
- Guaranteeing a high level of protection of public health.

Articles 28 and 30 of the EC Treaty (Articles 28 and 30) are key provisions of the EC Treaty. Article 28 prohibits national measures that create barriers for the free movement of goods. An exception to this is when allowing free movement of goods would create risks to public health or the environment (Article 30). Article 152 of the EC Treaty (Article 152) provides that all Community and national policies will ensure a high level of human health protection.

National healthcare policies

All EU member states have constitutional obligations to protect and promote public health and to provide adequate healthcare to their citizens. With respect to medicinal products this obligation leads to at least two governmental interests in the activities of the pharmaceutical industry:

- The pharmaceutical industry should deliver the medicinal products necessary to enable the national healthcare systems to provide adequate pharmaceutical care.
- Member states need to comply with general and European rules with respect to balancing their budgets. Pharmaceutical spending needs to be in line with the country’s GDP and needs to offer an optimal contribution to the promotion of public health. Therefore, all member state national pharmaceutical policies include cost containment elements, like maximum prices, positive or negatives lists for reimbursement and combinations of these.

National policies and EU principles

In early case law, the ECJ held that member states are free to organise their own social security systems and to adopt provisions intended to govern the consumption of medicinal products, in order to promote the financial stability of their health insurance schemes (Case 238/82 Duphar and Others [1984] ECR 523). The room to manoeuvre for EU member states is set out by Articles 28 and 30 in conjunction with Article 152. The EC Treaty sets out that a single market for medicinal products should exist, in which no member state is allowed to take measures which would disturb the free movement of goods in the Community, except if this free movement of goods would be detrimental to the...
secondary EU objective to protect public health. All national cost containment policies deal with this inherent conflict of interest, allowing on the one hand the principle of free entrepreneurship and free marketing of medicinal products, and on the other hand the burden that pharmaceutical industry sales lay on collective funds. The Transparency Directive tries to clarify how member states have to deal with this conflict of interests.

**NATURE OF THE TRANSPARENCY DIRECTIVE**

The Transparency Directive is of a special kind. Although directives are always directed at member states of the EU, they have to be transposed into national legislation. This transposition occurs by copying or paraphrasing the text of the directive into national law and adding national specifics, for example references to national administrative law. The Transparency Directive is not transposed into national legislation: it provides a legal framework for national legislation relating to pricing and reimbursement of medicinal products.

**Purpose of the Transparency Directive**

The preamble states that it is therefore urgently necessary to lay down a series of requirements intended to ensure that all concerned can verify that the national measures do not constitute quantitative restrictions on imports or exports having equivalent effect. On the other hand, it is intended that the Transparency Directive does not affect national policies on price setting and the determination of social security schemes, except as far as is necessary to attain transparency within the meaning of the Transparency Directive.

The Transparency Directive provides for different means to stimulate transparency. Member states need to notify changes in the legal framework for pricing and reimbursement to the European Commission (Commission). If the national authorities make decisions on pricing and reimbursement, they have to provide a statement of reasons based on objective and verifiable criteria. The decisions on pricing and reimbursements have to be published in an appropriate publication. Expert opinions or recommendations on which the decision is based. In addition, the applicant or the responsible person must be informed of the remedies available to him under the laws in force, and the time limits allowed for applying such remedies.

**The provisions of the Transparency Directive**

The Transparency Directive contains six provisions that deal with specific systems used by member states in cost containment policies:

- **Article 2 maximum prices.** This deals with systems in member states which provide maximum prices for medicinal products. These systems could either establish a maximum price as such, or set a maximum price as a condition for allowing a product on the market. Systems to calculate maximum prices are usually based on calculations using prices in other, reference, member states. As a result, maximum prices in many member states interact.

- **Article 3 prior approval of price increases.** The second system used by member states involves procedures necessary to be allowed to increase the price of a medicinal product. Pharmaceutical companies considering an increase in the price of their medicinal product need to apply for authorisation first. These systems are regulated in Article 3.

- **Article 4 price freezes.** This deals with price freezes for all medicinal products to be adopted by government measures. These price freezes intend to maintain the prices of all medicinal products at the same level, until the price freeze is revoked.

- **Article 5 profit control.** This deals with systems of profit control such as those applied in the UK. Primarily, pricing of medicinal products is free, but if a pharmaceutical company’s profit passes a ceiling value of profit, a specified part of the profit is levied by the state.

- **Article 6 positive lists for reimbursement and Article 7 negative lists for reimbursement.** These do not deal with prices, but concern reimbursement systems applied by member states, using positive lists for reimbursement or negative lists for reimbursement.

Each article, to be applied to a specific cost containment mechanism, provides for transparency and legal protection.

The Transparency Directive requires that if an authority makes a decision to include or exclude a product from the list of products covered by the health insurance system, or accepts or refuses a proposed price, it has to provide a statement of reasons based on objective and verifiable criteria, including, if appropriate, any expert opinions or recommendations on which the decision is based. In addition, the applicant or the responsible person must be informed of the remedies available to him under the laws in force, and the time limits allowed for applying such remedies.

**Pharmaceutical Forum on pricing and reimbursement**

The recent (October 2008) recommendations of the Pharmaceutical Forum established by the Commission (Forum), in which a broad range of pricing and reimbursement stakeholders are represented, support the conclusion that the transparency of pricing and reimbursement decisions by governmental authorities needs to be improved.

In the Forum, the stakeholders expressed their shared understanding that pricing and reimbursement policies need to balance:

- Timely and equitable access to pharmaceuticals for patients all in the EU.

- Control of pharmaceutical expenditure for member states.

- Reward for valuable innovation within a competitive and dynamic market that also encourages Research & Development.

The Forum stresses that although it is clear that reimbursement is a national responsibility, something needs to be done to improve the way that value assessments are translated into pricing and reimbursement decisions. The Forum sets out that to achieve the above mentioned balances:

- Member states are to set clear expectations on what innovation they will reward.

- Member states must give clear direction on what evidence is required.

- Timely access must be ensured.
The Forum considers that clear and common expectations, together with consistent pricing and reimbursement decisions, can motivate the development of highly needed medicines, and that it is necessary that pricing and reimbursement policies and practices are based on good quality knowledge, including data, facts and experiences exchanged between different member states and stakeholders.

The report presented by the Forum describes the characterisation of the value of innovative medicines. A number of potential benefits can be expected from new innovative medicines. The results of a survey show that therapeutic and clinical benefits are the main benefits member states are looking for, in particular benefits related to recovery, survival, disease progress and management of symptoms. In short, member states are seeking to establish the effectiveness of the medicinal products. Benefits related to side effects and interactions of a medicine are considered as a second important category. Benefits related to improved compliance are only considered when this translates into an overall clinical benefit.

The Forum states that if the member states set clear and common expectations, this will give companies a clear direction on healthcare priorities and indications on the evidence needed by authorities, while bringing authorities clarity on the mid- to long-term budget needs. Companies are called on to deliver the innovative medicines that society needs. National pricing and reimbursement policies should reflect and recognise these expectations and give a consistent reward to benefits considered valuable.

**Effectiveness of the Transparency Directive**

The Transparency Directive has remained unchanged since its adoption. This could mean that member states and the Commission consider it to be functioning well. The pharmaceutical industry, though, is struggling with the different pricing and reimbursement systems in each member state, and the weak position the holders of a marketing authorisation have in relation to negotiating fair prices and reimbursement of their products. Further, the Forum, (see above, *Pharmaceutical Forum on pricing and reimbursement*), focused anew on national pricing and reimbursement policies.

Obviously, the recommendations of the Forum extend far beyond the minimum interpretation of the Transparency Directive, which suggests that the level of reasoning required under the Transparency Directive is only such as is needed to see that a company is not being prejudiced by a scheme that favours home grown products over imports, and that the driver for restricting the price or reimbursement status of the product is judicial and not an anti-competitive initiative focused on products imported from outside the member state.

However, even under such a minimum scheme, to assess the Transparency Directive's effectiveness, the most important aspect is, from the industry's point of view, the legal structure in which an effective legal remedy is available when decisions do not comply with the Transparency Directive. If an individual member state decision relating to pricing or reimbursement of a medicinal product cannot be challenged adequately, this renders the Transparency Directive ineffective.

**CASE LAW**

ECJ case law about implementation of the Transparency Directive is relatively limited. The main issues brought before the ECJ concern the scope of the Transparency Directive, effective legal remedies and what happens if member states do not adhere to time limits in the Transparency Directive.

**Scope of the Transparency Directive**

In Case C-242/99 (Commission v Austria), the Commission challenged Austria because it had introduced a system in which the cost of a medicinal product prescribed by an approved doctor can be borne by the insurance scheme, if the product appears on the register of medicinal products published by the competent authority in Austria. The Commission considered that the national legislation did not comply with the Transparency Directive, because Austria did not respect the 90-day time limit (see below, *Time limits*), lacked a statement of reasons for refusal to include a medicinal product in this register and did not provide legal remedies against such a refusal.

Austria argued that Article 6 of the Transparency Directive did not apply to their system, because any medicinal product could be reimbursed under the legislation. The ECJ stated that the purpose of the Transparency Directive is to ensure that any national measure 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, complies with the Transparency Directive. It found that inclusion of a medicinal product on the register normally means that its costs will automatically be borne by the scheme, that the register enables the competent authorities to reduce the expenditure of the Austrian social security system, and that the inclusion of a medicinal product in that register is therefore a measure intended to control prices, so that the register can be regarded as a positive list within the meaning of Article 6 of the Transparency Directive.

**Effective legal remedy**

Another aspect of Case C-242/99 addressed the question of whether the Austrian system provided sufficient legal protection. If an application to include a medicinal product in the register was refused, the manufacturer could only launch a complaint at the competent administrative authority, and this would only come before a scientific advisory board. The ECJ stated that, since the scientific advisory boards can only issue recommendations, they have no decision-making power and are not genuine judicial bodies, so therefore Austria did not offer the judicial protection intended in the Transparency Directive.

**Time limits**

In cases C-296/03 (*GSK vs Belgium*) and C-245/03 (*MSD vs Belgium*), the issue brought before the ECJ involved the time limits of decisions about reimbursement of medicinal products. The first question raised in both cases was whether the time limits of the Transparency Directive are mandatory. The ECJ ruled in both cases that the time limits are mandatory.

In Case C-296/03, the additional question concerned the consequences of exceeding the time limit by the Belgian authorities where a previous decision adopted in good time has been annulled. The Belgium administration held that when a refusal to
reimburse a medicinal product had been adopted, the time limits the Transparency Directive provide start all over again. GSK was of the opinion that there should be only one time limit to take the decision. The ECJ held:

“that it is for the member states to determine whether the fact that the time limit laid down in the first subparagraph of Article 6(1) of the Directive is exceeded precludes the competent authorities from formally adopting a new decision when the previous decision has been annulled in Court proceedings, although such a possibility can be exercised only within a reasonable time which may not in any event exceed the time limit laid down in that article.”

The time limit of Article 6(1) is 90 days. This means that the authorities have to make the new decision in 90 days.

Sanctions for non-compliant member states

In Case C-245/03, the additional question was whether exceeding the time limit is deemed to have established inclusion in the positive list of medicinal products covered by the reimbursement system.

The ECJ held that the Transparency Directive does not impose the automatic entry of a medicinal product on the list of proprietary medicinal products covered by the healthcare insurance system, if the time limit laid down in Article 6(1) is exceeded.

In his Combined Opinion to C-245/03 and C-296/03, Advocate-General Tizzano states that exceeding the time limits of the Transparency Directive can be seen as unlawful conduct. He repeatedly states that the wording and structure of Article 6 is clear and that this places the member states under a clear and precise obligation to ensure that a decision is adopted within the time limit of 90 days, which may in certain circumstances be extended for a further 90 days.

He takes the view that expiry of the time limit without a decision having been made constitutes unlawful conduct, since the member states must take all appropriate measures to ensure fulfilment of their obligations under Community law and Community rules have full effect:

“States are to grant individuals the opportunity to obtain redress when their rights are infringed by a breach of Community law for which a Member State can be held responsible; failure by national authorities to comply with the time limit laid down under Article 6 of the Directive is just such a breach.”

Unfortunately, the ECJ does not elaborate on the consequences of a member state’s breach of their legal obligations. The ECJ just states that in the absence of a specific provision in the Transparency Directive, it is for the member states to determine the effects of exceeding the time limit, on condition that the rules it adopts are no less favourable than those in similar situations (principle of equivalence), and that they do not render the rights conferred by the Community legal order impossible or difficult in practice to exercise. This means that it is up to the member states (within their legislation) to enforce their own obligations under the Transparency Directive.

NATIONAL APPLICATION OF THE TRANSPARENCY DIRECTIVE

The following section focuses on the effectiveness of the Transparency Directive in relation to judicial protection of pharmaceutical companies against pricing and reimbursement decisions. Four issues have been chosen and are discussed in relation to Czech Republic, Germany, The Netherlands, Portugal, Slovak Republic, Spain, Sweden and the UK. The source of this section is a short questionnaire about legal remedies answered by experts in pharmaceutical law. The questions are as follows:

- Is there a sanction if reimbursement authorities do not keep to the Transparency Directive time limits?
- Does the company have a specific legal remedy at its disposal, or must it rely on government tort action?
- Is the legal remedy an administrative revision or an appeal procedure?
- Is it possible to bring scientific arguments before the court? Are expert opinions taken into consideration?

Sanctions

Since the ECJ has ruled that it is up to member states to decide what the consequences of failure to adhere to the Transparency Directive time limits are, the legal protection the directive offers to applicants is as strong as a nationally provided legal remedy.

European countries have a different approach in dealing with authorities that do not keep the Transparency Directive time limits. Of the member states covered in this article, not one has specific sanctioning methods if the authorities do not keep to the Transparency Directive time limits. However, some countries are forthcoming to manufacturers in these cases.

In Sweden, the Ordinance on Pharmaceutical Benefits stipulates that a request for a price increase will come into effect automatically if not dealt with by the Price and Benefits Board within 90 days. In Portugal and the Czech Republic, the applicant is entitled to market the product at the price he proposed, if the authorities do not take a decision within the defined time limits. In contrast, the applicant cannot consider reimbursement as being granted if the authority did not make a decision within the defined time limits. The same applies in Spain, where it has already been decided that marketing authorisation holders could market a medicinal product at the proposed price, because of administrative silence. In The Netherlands and the Slovak Republic, no legal remedy is available, except for government tort.

In the UK, it may be argued that the requirements to obtain pricing agreement under the Pharmaceutical Price Regulation Scheme (PPRS) on certain new products are ones that engage the Transparency Directive, but the language of the Transparency Directive is open to interpretation. The application of the Transparency Directive is complicated by the fact that the UK does not stop a product being marketed until the price is approved, unless it is for use in the National Health Service (NHS). In practice, as NHS use covers over 90% of prescribing, for most products the private market is de minimis. Judicial review is available if the National Institute for Clinical Excellence (NICE) does not comply
with rules relating to procedural fairness in making its recommendations. However, NICE maintains that it is not subject to the Transparency Directive because it is not making a decision, but only giving a recommendation.

When reviewing cases about exceeding the time limits of the Transparency Directive, some member states’ courts test in full and others just marginally. A relevant question is if the marginal test is sufficient. It is generally accepted in European law that the ECJ tests the conduct of an administrative body marginally if the body has a broad discretionary margin. However, referring to the opinion of AG Tizzano (see above, Case law: Sanctions for non-compliant member states), Article 6 leaves no discretionary margin about deciding within the time limit. If Community law leaves no or little discretion, a mere infringement may lead to liability. This principle should be applied by national courts as well, in cases where member states do not comply with the Transparency Directive time limits.

Specific legal remedy or government tort

The nature of the procedure is relevant to assess legal remedies for pharmaceutical companies, because there may be differences in relation to the nature of the test of the decision against legal requirements, the level of scientific discussion in court and the involvement of independent experts.

In The Netherlands, pharmaceutical companies do not have a specific legal remedy against reimbursement decisions. The only available procedure is to claim reimbursement or damages as a result of government tort. In Spain, an administrative legal procedure is available: the court will test the decision against the legal criteria. In the Slovak Republic, a request to review a decision can be made to the Minister of Health. In Portugal, the applicant can challenge the decision in an administrative court and seek annulment or damages as a result of a government tort. In Germany, the courts will consider scientific arguments and professional evidence. In The Netherlands, the situation is similar, in that the courts will decide scientific issues that are crucial to the decision of the governmental body. Dutch courts however will in such a case engage the advice of independent court appointed experts, rather than rely on experts brought forward by the manufacturer.

In other member states, scientific arguments are valued less by the courts, because they will test the conduct of the administrative bodies only marginally.

The English courts will not involve themselves in scientific assessment and argument in matters of pricing and reimbursement. It is unlikely that an English court will take into account an expert opinion, except to the extent that it may be used to support a case of absence of adequate reasoning in the ultimate decision. Before an English court will intervene, the decision has to be to manifestly wrong on its facts (scientific or otherwise), that no reasonable tribunal addressing the evidence in front of it could have come to the decision under review.

ADEQUACY OF NATIONAL LEGAL REMEDY SYSTEMS

Providing adequate legal remedy for pharmaceutical companies against pricing or reimbursement decisions is one of the key objectives of the Transparency Directive. In practice, the procedures in member states show a large variety of procedures and the scope of the legal test performed by the competent court. In The Netherlands, the company has to rely on a government tort procedure. In other member states, administrative revisions and/or judicial review proceedings are available. The appropriateness of the legal remedy depends on the details of the national legislation.

Procedural complaints

If a member state does not adhere to the time limits of the Transparency Directive, it is clear from ECJ case law that the authorities act unlawfully. Although it is up to member states to decide on the consequences of this breach, in every EU member state a legal remedy should be available. The effectiveness of the national legal remedies varies from member state to member state.

Complaints on the merits

Marginal test or full appeal? The most important aspect relating to the adequacy of legal protection is the remit of the court deciding on the matter. Must the court apply a marginal test of the lawfulness of the decision, or can it also take scientific arguments and pricing and reimbursement policies into account?

The system of the Transparency Directive links transparency immediately to the availability of legal remedies. The transparency aspect provides that decisions on pricing and reimbursement of medicinal products must be based on objective and verifiable
criteria. The appropriateness of the available legal remedy relies on the quality of the motivation of the decisions. Theoretically, if, as foreseen in the Transparency Directive, the arguments of the administration can only lead to the decision that has been taken, courts can provide adequate legal remedy applying a marginal test.

In practice, decisions about pricing and reimbursement cannot be based on objective and verifiable criteria, because the assessment of the effectiveness of a medicinal product, and the cost-benefit ratio of a new medicinal product, cannot be calculated in an absolute manner, but will always have a subjective element to it, due to the lack of legal definitions of the criteria involved.

**Scientific arguments and the need for experts and expert opinion.** Decisions on pricing and reimbursement of medicinal products rely on the assessment of scientists advising the governmental authorities on the effectiveness of the medicinal product and in many member states on the cost-benefit ratio. Unlike the criteria for determining safety and efficacy and the risk/benefit ratio in EU marketing authorisation law, the criteria for determining effectiveness and cost-benefit are usually subjective and not or ill defined. Nor are they expanded in scientific guidelines that are developed in a transparent process.

If the court is required to verify if the decision is based on objective and verifiable criteria, it has to assess scientific arguments. For the assessment of scientific aspects of the medicinal product to be useful, governmental authorities need to develop their assessment criteria allowing the court to consider this, with the help of court appointed or party experts. This would contribute considerably to the effectiveness of the legal remedy.

**A single market for medicinal products?**

Even though the procedures authorising access to the EU market for medicinal products to the market have been harmonised, each member state runs its own system for pharmaceutical pricing and reimbursement. As a result, in practice all EU member states have their own specific pricing and reimbursement systems, regulating practical access to their national market. The pharmaceutical industry has to deal with 27 member states individually to gain access to the EU market place. The single market for medicinal products does not exist, because of differences in the national healthcare systems, especially with respect to pricing and reimbursement.

The large variety in legal remedies available in the member states does not contribute to the completion of the single market for medicinal products. In this respect the Transparency Directive failed to reach its objectives.

**CONCLUSIONS**

The purpose of the Transparency Directive is to create transparency to be able to verify if impediments to the free movement of goods can be justified.

To test the effectiveness of the Transparency Directive, analysis of the efficacy of legal remedy mechanisms is key. If a pharmaceutical company does not have standing in a court, or cannot combat negative decisions by pricing and reimbursement authorities based on a scientific debate about the medicinal product and pharmaco-economic aspects of it, governmental policies can take a dangerous direction. Adequate legal remedy is essential to create a well-functioning single market for medicinal products, and therefore to stimulate pharmaceutical innovation and entrepreneurship.

As far as ECJ case law is concerned, it is clear that the Commission does not take an active approach to guarantee adequate transparency and legal protection for pharmaceutical companies. Only when cases of obvious breaches of the Transparency Directive are reported will the Commission take action. The ECJ also does not involve itself too much in national systems for pricing and reimbursement. In those cases where the ECJ points out that a member state steps out of line, it concludes that the member state is responsible for taking corrective actions itself.

From the results of our small study, the conclusion can be drawn that a serious evaluation of the national systems for pricing and reimbursement, and strict supervision of the relevant competent authorities, should be considered. Only real transparency about pricing and reimbursement decisions, combined with independent procedures to challenge flawed decisions, can lead to a better functioning single market for medicinal products and a flourishing industry, able to create true innovation and the best possible treatment of patients in Europe.

At this time, judicial protection in some member states is very limited. A variety of administrative and non-administrative procedures is available, but they are local in nature. There is a large amount of disharmony with respect to the pharmaceutical industry’s legal status to defend a price and a place in the reimbursement system for their products. This in itself is already a considerable disadvantage for investment in new medicinal products and innovation.

The conclusion can be drawn that implementation of the Transparency Directive has not led to the desired result. In practice a single market for medicinal products has not been accomplished. Different decisions with respect to pricing and reimbursement of the same medicinal product prove that national and political policies play an important role in pricing and reimbursement policies.

An official evaluation of the Transparency Directive might prove to be a valuable tool in improving the commitment to a healthy European pharmaceutical industry.

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