

***Response to the European Commission public  
consultation on the pharmaceutical sector enquiry  
preliminary report of 28 November 2008***

***Joint Position Paper  
of the European Social Insurance Platform  
and  
the Medicine Evaluation Committee (MEDEV)  
of the European Social Health Insurance Forum***

***Submitted by MEDEV on 31 January 2009  
Resubmitted as a joint paper with ESIP on 11 February 2009***

### **About the *European Social Insurance Platform (ESIP)***

The *European Social Insurance Platform (ESIP)* represents Europe's social insurers in 16 EU Member States and Switzerland, active in the field of health insurance, pensions, family benefits, occupational safety and accident insurance and unemployment insurance. The aims of ESIP and its members are to preserve high-profile social security for Europe; to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP builds strategic alliances for developing common positions to influence the European decision-making process and is a consultation forum for the European institutions and other multinational bodies active in the field of social security.

### **About the *Medicine Evaluation Committee (MEDEV)***

The *Medicine Evaluation Committee (MEDEV)* was established in 1998 as a standing working group of the European Social Health Insurance Forum – a network of national liaison agencies, associations and institutions for social health insurance in the EU and Switzerland. Today, MEDEV represents the drug experts and pharmacologists of the national social health insurance organisations and other competent bodies in 14 EU Member States. The principal purpose of MEDEV is to provide the national health insurance organisations and other competent bodies with timely analyses about drug related trends and innovations at both national and European level. Further, with the overall objective of providing a necessary counterweight to the pharmaceutical industry, especially at EU level, MEDEV aims to support the EU's activities in formulating drug policies by giving input from the point of view of the statutory health insurers' and other competent authorities. MEDEV can offer expert advice to all EU bodies from the earliest stage of the pharmaceutical decision-making process and help them analyse the possible impact of drug-related policies on national health schemes.

For more information please visit the ESIP website at: [www.esip.org](http://www.esip.org)

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Firstly, ESIP and MEDEV congratulate the European Commission DG Competition services for taking the initiative to launch a sector enquiry in January 2008 into the EU pharmaceuticals markets under the EC competition rules (Articles 81 and 82 of the EC Treaty) and welcomes this opportunity to comment on the Commission's preliminary report on the results of that enquiry published on 28 November 2008.

**Introduction**

From the view point of the payer organisations and those responsible for pharmaceutical pricing and reimbursement decisions in the Member States represented in ESIP and MEDEV, the report succeeds in highlighting many of the practices and issues that can restrict or distort competition in the pharmaceuticals markets in the EU. ESIP and MEDEV recall however, that pharmaceutical products cannot be viewed as ordinary consumer products and that a strict regulatory framework is essential to ensure public safety.

As the report points out, the described practices (whether legal or illegal with regard to Articles 81 and 82 of the EC Treaty) and unresolved regulatory issues can lead to significant delays in patient access to both generic and innovative medicines and increased costs to already stretched healthcare budgets. They therefore should be addressed.

Below ESIP and MEDEV offer their remarks on the findings and comments referred to in the three areas described in the preliminary report of 28 November 2008 but in particular to the issues raised under "the regulatory framework".

### **Competition between Originator Companies and Generic Companies**

The report describes a “tool-box” of instruments used by some originator companies to extend revenue streams by delaying or blocking the entry of competitive generic products to the market. As the report clearly demonstrates, delaying the entry of generics to the market results in **additional costs to public health budgets** and ultimately to consumers. The “tool-box” lists the use of complicated and costly litigation strategies, the creation of “patent clusters” around a product or products, intervening in national procedures for the approval of competitive generic products, and settlement agreements with generic companies (to delay market entry of their product). The latter may be considered to contravene Article 81, while the former exploit weaknesses or loopholes in the existing regulatory framework which need to be addressed (see remarks under “the regulatory framework”).

### **Competition between Originator Companies**

Here the report describes the use of defensive patenting strategies by originator companies to block the development of new competing products from other originator companies. Such strategies lead to higher costs for competitors through royalty payments or delays in development. The result once again is likely to be **higher costs for health care budgets** through the creation of monopoly markets but in addition **delayed access to new/alternative innovative products for patients and healthcare systems**. A review of the system of issuing patents in the EU should consider tightening the criteria that need to be fulfilled for a successful application and ensuring the independence of the decision-making procedure (see remarks on “patents” below).

### **The Regulatory Framework**

#### **1. Patents<sup>1</sup>:**

As the report points out, the current system of issuing patents in the EU via the European Patent Office (EPO) and national patent offices is costly to the pharmaceutical industry as regards obtaining, maintaining and challenging patents. The fragmented system and the associated costs are considered a major impediment to innovation in EU and to Europe’s competitiveness in the global pharmaceutical market. The report indicates that the introduction of a Community patent, at once valid in all MS, accompanied by an EU unified and specialised patent judiciary would benefit all sectors of the pharmaceutical industry (small and large innovative companies and generic companies alike). The benefits to patients and healthcare systems are not so clearly expressed but it can be hoped that a unified system will lead to increased transparency and faster access to innovative medicines for patients and that the savings to industry will be translated into lower costs for healthcare systems. In this case, **ESIP and MEDEV would encourage the Commission to renew its efforts to establish a Community patent system** with the provision that safeguards are put in place to ensure the independence of the decision-making process and that decision makers are not vulnerable to lobbying by the industry. ESIP and MEDEV further **support the establishment of a**

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<sup>1</sup> The Norwegian Medicines Agency notes that it has no competency in the field of patents and therefore cannot support the MEDEV position as regards point 1

**unified and specialised patent judiciary** with the proviso that the procedures put in place are rapid and efficient and do not lead to long delays in litigation decisions and extended periods of uncertainty.

Further, the report highlights the issue of “evergreening” – the practice of obtaining secondary patents particularly on blockbuster medicines that serve to extend the market position of the originator product and delay the entry of generics to the market. ESIP and MEDEV support the criticisms that the European Patent Office - EPO (and national patent agencies) may grant secondary patents rather too lightly. **ESIP and MEDEV call on the EPO to review its criteria and procedures to ensure the high quality of the patents it grants and to act to counter patent strategies** that cause unnecessary delays to market of competitor and generic products.

## **2. Marketing Authorisation**

Various criticisms are made in the report by the industry (originator and generic) of delays to the market caused by bottle-necks in marketing authorisation procedures including delays and administrative burdens due to lack of resources in some agencies, discrepancies in assessment criteria and patent linkage - linking marketing authorisation of a generic to the patent of the originator reference product. ESIP and MEDEV remark that many of these issues have already been addressed by the introduction of the new legislative framework (Regulation (EC) No. 726/2004 and Directive (EC) No. 2001/83) in 2004 which provides for a centralised authorisation procedure through the European Medicines Agency (EMA), mutual recognition procedures and which as the report points out, makes patent linkage unlawful. However, outstanding issues related to secondary medical use patents vis à vis the Centralised Procedure need to be addressed particularly in view of biosimilars.

The report records that some originator companies are calling for further international harmonisation of marketing authorisation procedures e.g. harmonising requirements for paediatric trials in the USA and EU, saying that this would save money and reduce delays to market. **ESIP and MEDEV would support further international harmonisation of marketing authorisation procedures** as long as this does not lead to a lowering of existing standards in the EU and it improves data quality. Ideally the data should demonstrate the added therapeutic value of the product over and above that of existing therapies. Care needs to be taken however that external validity of clinical trials (e.g. using the same or similar comparators) is maintained for the different markets.

## **3. Pricing and Reimbursement**

First and foremost, as representing the national organisations responsible for pricing and reimbursement of pharmaceuticals, ESIP and MEDEV recall that **pricing and reimbursement policies are a Member State competence**. The different procedures applied and decisions taken necessarily reflect the different organisational structure, budget and priorities of each Member State. Nevertheless, as indicated in the report, the Member State authorities are governed at EU level by the **Transparency Directive** (89/105/EEC) which

requires transparency as regards procedures used and decisions made and sets the time-limits for pricing and reimbursement decisions at 90/180 days. The report refers to criticisms from originator companies that national pricing and reimbursement procedures can lead to delays (beyond those set out in the Transparency Directive) and uncertainties that reduce the expected reward for, as well as delay and / or create unequal access by patients to innovative drugs. These delays and uncertainties are considered (at least in part) to be due to different national data requirements, timelines and decision making criteria as well as the increasing use of HTA in the Member States. It is suggested that predictability (certainty) could be increased through more cross-border collaboration between national competent authorities to **develop common definitions** e.g. of expected “value” of innovation, **common datasets, common HTA methodologies and ultimately common assessments**. In this context, ESIP and MEDEV would refer to the important progress that has been made in this area by the Pharmaceutical Forum Working Group on Relative Effectiveness during 2005-2008 and the work of the EU network on HTA (EUnetHTA). This is work in progress, and while ESIP and MEDEV actively support initiatives towards these goals they stress that the decisions made on the basis of common analyses remain the competence of the Member State.

From the pricing and reimbursers’ point of view, delays in the decision making process are often the result of a lack of appropriate or poor quality data provided by the originator company. One of the major findings of the Pharmaceutical Forum Working Group on Relative Effectiveness was that there was a lack of suitable data to assess “added therapeutic value” at the time first reimbursement and pricing decisions are made. ESIP and MEDEV support the view that **early dialogue** between originator companies and pricing and reimbursement decision makers during the clinical development phase could help to clarify expected value and required proof of value with the aim of speeding up the decision-making process.

The report also refers to delays in pricing and reimbursement decisions in respect of generic medicines. The reasons for these delays are cited to be in part due to the deliberate strategies of originator companies and in part to **additional requirements for generics** in some local pricing and reimbursement regulations e.g. information on patent status or demonstration of “absolute” equivalence (for substitution) over and above the bioequivalence required for marketing authorisation. As the report points out these delays offer opportunities for originators to intervene and prolong the de-facto exclusivity of their own product (with lost savings for healthcare budgets). In this respect, ESIP and MEDEV would welcome actions by the Commission to: clarify outstanding issues as regards patent linkage at the point of pricing and reimbursement; ensure a harmonised and transparent application of EMEA's bioequivalence guidelines by agencies granting marketing authorisation to raise the confidence of authorities, patients and healthcare providers that generic drugs have been proved to be equivalent to the originator product at the point of authorisation; and implement rules which discourage originator companies from launching negative propaganda campaigns against generics.

Regarding **pricing mechanisms and specific practices to control expenditure**, the report contains criticisms particularly from originator companies about the **widespread use of cross-border reference pricing systems** that can result in too high prices in low GDP countries. Further criticism is made of **payback** mechanisms that are said to penalise a company for the success of its product. In response to the latter, ESIP and MEDEV would hasten to point out that payback mechanisms were proposed as part of the G10 recommendations to promote early access to and reward for innovation. In the face of ever more expensive new medicines and increased overall pharmaceutical expenditures Member States need to implement cost containment measures to ensure the widest access to the most cost-effective medicines. **Therapeutic reference pricing** helps to provide a level playing field and allows for competition between medicinal products (originator and generic) considered to be therapeutically equivalent. Contrary to the criticisms from some originator companies it discourages the development of me-too products while allowing for the exemption of new products proved to have an added therapeutic value. Further, as the report points out, it **facilitates market entry and extends the potential market for generics**.

Different pricing and cost controlling mechanisms have been the subject of intense discussions in the Pharmaceutical Forum Working Group on Pricing over the last three years up to October 2008. The discussions have laid the groundwork for **joint analyses of the impact of current practices** including newer models (e.g. risk-sharing models) on access for patients, reward for innovation and cost containment in the Member States. ESIP and MEDEV support further initiatives in this direction that lead to greater transparency of prices and pricing mechanisms and the exchange of experience between Member States particularly regarding the impact (including cross-border impact) of new cost-containment models.

Finally, in response to criticisms in the report about the application of reimbursement rules and conditions (including therapy guidelines and formularies) **restricting the use of some new medicines**, ESIP and MEDEV strongly defend this strategy. Rules restricting use are applied not only for economic reasons for new medicines that are expensive and whose place in therapy (added therapeutic value) is unclear, but also for safety reasons. Furthermore, it has been proposed that in some cases a phased-release program might improve access to drugs - limiting the use of a new medication until the population that would benefit from it is better defined might permit a drug that otherwise would have been withdrawn to be kept on the market<sup>2</sup>. Restrictions, which may even apply to antibiotics, are usually evidence-based and only for patients who can not be treated by drugs of choice. Further, we recall that decisions made by reimbursement authorities on restricted (conditional) use are already subject to the Transparency Directive.

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<sup>2</sup> Ray, Wayne A., Stein, C. Michael Reform of Drug Regulation -- Beyond an Independent Drug-Safety Board N Engl J Med 2006 354: 194-20

This position paper has the support of the member organisations of ESIP and MEDEV<sup>3</sup> in so far as the matter lies within their field of competence.

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<sup>3</sup>The Sociálna poisťovňa of the ESIP and the Swedish Dental and Pharmaceutical Benefits Agency (TLV) of the MEDEV are recorded as not being able to support this paper.