

***Response to the European Commission public
consultation on the future of pharmaceuticals for
human use in Europe***

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

submitted 12 October 2007

About the *European Social Insurance Platform (ESIP)*

The *European Social Insurance Platform (ESIP)* represents Europe's social insurers in fourteen 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, which comprises 16 national liaison agencies, associations and institutions for social health insurance in the EU Member States 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.

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The role of the European pharmaceutical industry is to make safe and effective medicines available to people in Europe who need them. In the past, it has done a good job and has done well by it. However, there are signs that this may change. In the past few years, the rate of new drugs being brought to market has shown a decline, and events such as those cited in the call for contribution (particularly removal of newly approved drugs from the market) have shown that the present system for developing new drugs is far from perfect. As for making new drugs available, the case of drugs against AIDS was only the most egregious example of drugs being unaffordable and therefore unavailable in developing countries such as Africa where they need them most. New drugs can have prices which make them unaffordable even in EU countries where average earnings are lower.

Considering the above, the European Commission's consultation process is a welcome opportunity to address the challenge of making safe, effective and innovative medicines available in a sustainable way. ESIP and MEDEV therefore contribute the following answers to the questions raised by the call for contributions:

1. Do you agree with the analysis of the main challenges outlined above? Do you see other challenges?

The main challenges' outlined in the consultation paper are:

- Globalization of the sector
- Smooth functioning of the internal market
- Safety of medicines
- Proactive role of patients
- New technologies

Regarding **globalization**: while it is certainly important to ensure fair international competition and remove barriers which impede access to foreign markets, **a comprehensive**

reflection should be undertaken before measures are implemented to pinpoint which specific parts of the European pharmaceutical industry need strengthening. Measures taken at the cost of European taxpayers should be to the benefit of European patients and - in the global context – people suffering in the Third World. If we look to the experience of the USA, the American Jobs Creation Act of 2004 has allowed US pharmaceutical companies to repatriate large amounts of foreign earnings at a low tax rate with the aim of creating jobs in the sector but according to some reports this money has instead fuelled a spate of acquisitions and mergers¹.

Under globalization, it is also necessary to reconsider the place of medicines in a more global approach which includes mainly the curative aspects but also the aspect of prevention i.e. vaccination, and to develop the diagnostic sector for a more rational and more targeted use of drugs which will become more personalized.

Further it is important not only to think in terms of the pharmaceutical industry but also of the place of medicines in the global economy of health-related goods, including aspects related to their distribution, in order to optimize their access to consumers and the socially insured.

ESIP and MEDEV do not consider that the **shortcomings of the internal market** are responsible for the lack of access to medicines for some patients. While there is always scope for better regulation, we consider the measures outlined in our answer to question 4 to be more important for improving competitiveness. Further, as explained in our answer to question 5, since different national pricing and reimbursement schemes reflect the different levels of welfare in the European countries ESIP and MEDEV doubt whether harmonization with regard to reimbursement would noticeably decrease market fragmentation. Such fragmentation exists even within countries (e.g. between the hospital and the outpatient sectors) and even in the USA, where different payers pay different prices. Finally, whether parallel trade or price harmonization is really desirable seems to be a matter of controversy even within the pharmaceutical sector and among the reimbursers. ESIP and MEDEV concur, however, that the **lack of transparency** in these areas is a challenge that needs to be addressed.

ESIP and MEDEV agree with the analysis of the paper that the **safety of medicines** can be improved by improving the efficiency of regulatory requirements. The requirement for industry to provide clinical trials data **comparing a new medicinal product against alternative medicines or therapies** where they exist rather than only against placebo at the marketing authorisation stage would save time later at the point of the reimbursement decision. It is also important not to forget the **environmental aspects** and to take into account all the public health issues in the long-term development and integrated management of waste.

Proactive role of patients: ESIP and MEDEV agree that patients require better access to high quality information. We are not in agreement with the statement that pharmaceutical companies cannot, for legal reasons, make (important) information they possess available to patients. While informing patients directly (on prescription only medicines) may be banned, this information can (and should) be made available via existing legal channels. There are quite sound reasons for the legal framework which precludes the makers of prescription medicines from direct to consumer advertising (DTCA). In addition, examination of the research and international experience reveals no reliable evidence that DTCA improves

¹ BusinessWeek January 29, 2007

http://www.businessweek.com/magazine/content/07_05/b4019077.htm?chan=search

public health or patient well-being². ESIP and MEDEV **strongly contest any weakening of the current ban on advertising** and ESIP along with the *Association Internationale de la mutualité* (AIM) has explained its position at length on this issue at the Pharmaceutical Forum and in response to the public consultations on patient information and on the draft report on current practice with regards to provision of information to patients on medical products (Article 88a of Dir 2001/81/EC) in May and June this year^{3,4,5}. Furthermore, one needs to consider that DTCA of prescription drugs needs to be regulated (one must be extremely naïve to believe that the information provided by the manufacturer of a product can be unbiased, and that a layperson can detect this bias). This would increase the regulatory burden on the competent authorities and may well lead to a more cautious approach to marketing authorization and important time-to-market delays for innovative drugs.

ESIP and MEDEV agree with the analysis of the Commission in that **emerging technologies** in the field of medicinal products do represent a regulatory challenge (see answer to question 6). However, we should also consider here the development of the Internet with regard to the distribution of medicines and access to information. The Internet offers the possibility to optimize the distribution of medicines to the greatest number of citizens, but this must be accompanied by a rigorous legal framework so that the consumer is protected from purchasing unsafe products.

A further important challenge is how to incentivize the pharmaceutical industry to develop innovations that are really needed at prices which ensure the sustainability of reimbursement for all necessary pharmaceuticals. This was already referred to in the project "**Priority Medicines** for the Citizens of Europe and the World" under The Netherlands' EU presidency.

Finally, ESIP and MEDEV consider that the one-stop-shop policy established by the Commission for marketing authorization was a powerful means of rationalizing procedures and has made it possible to avoid redundant national studies. Following this logic it is perhaps time to consider a **co-operative network structure responsible for comparing the relative improvements of new products** compared to existing products and to other available therapies.

2. Do you see other areas than those already targeted by the Commission where regulatory action should be taken?

At present, the approach of the Commission to pharmaceuticals is traditional in the sense that the European Union was primarily an economic entity. However, this primarily economic approach to pharmaceuticals (which is reflected in the responsibility of the DG Enterprise for market authorization) needs to be reflected upon. It might be worthwhile to consider whether the agency which has to determine whether a new pharmaceutical product is safe and effective might not better reside in the DG responsible for health (in the USA the FDA is part of the Department of Health and Human Services).

One might also consider whether the present system of providing market exclusivity as an incentive for developing new drugs is adequate. As mentioned in the introduction, the present system has led to fewer new substances being developed recently – and some applications (such as bevacizumab for intraocular use to treat macular degeneration) are not available at all. It would be in the interest of public health to install a mechanism for

² Health Council of Canada report, January 2006

http://www.healthcouncilcanada.ca/docs/papers/2006/hcc_dtc-advertising_200601_e_v6.pdf

³ Joint ESIP and AIM position statement on information to patients on diseases and treatment options addressed to the 2nd Pharmaceutical Forum on 26 June 2007

⁴ <http://www.esip.org/publications/pb126.pdf>

⁵ <http://www.esip.org/publications/pb127.pdf>

licensing pharmaceuticals which are needed but for which the MAH (marketing authorization holder) has a purely economic disincentive. It would be worthwhile to look for other economic models for MAH to develop new drugs than the present one, which grants a monopoly to innovators. Alternative ways of stimulating innovation have been proposed in the Working Group on Pricing of the Pharmaceutical Forum⁶⁷.

The European Commission should intervene to strictly regulate the amounts of money that companies are allowed to spend on the promotion of drugs to health professionals. The money saved should be redirected towards research and development. Alternatively, a tax could be levied on marketing budgets which could be used to finance publicly funded research - the Italian experience.

The Commission should prohibit compliance programmes managed directly or solely by pharmaceutical companies.

3. What would you suggest as concrete measures to ensure the safety of medicines supplied in the EU, addressing in particular counterfeit medicines, and provision of high quality and affordable medicines also to third countries?

Ensuring the safety of medicine supplies through anti-counterfeiting measures is a problem for which technical solutions have been proposed (e.g. holograms, RFID chips). Anything that has a high price is a target for counterfeiting, and high-price pharmaceuticals can be very tempting indeed. If pharmaceutical companies were offered **reward for innovation by other mechanisms than price**, these might be more affordable for low-income countries on the one hand and provide less incentive for counterfeiting on the other.

Recent attempts by industry to ban parallel trade by linking it to counterfeit medicines are unjustified. Parallel imports are well regulated and controls are done to make them safe. To avoid the selling of counterfeit medicines in the EU, it is essential to develop clear public health messages about the risks of buying medicines from sources outside the regular channels and about the role of health professionals in advising patients.

Publication of pharmacovigilance data would be an important contribution to increasing patient access to information and improving safety. In this context, it should be considered if **patient reporting** of adverse effects and the publication of this information might not also contribute to patient empowerment as well as improve the quality of pharmacovigilance.

Further, publication of all clinical trial data related to an authorized medicine should be obligatory. This data should be made publicly available through the EMEA clinical trials database.

4. What can be done to improve Europe's international competitiveness?

ESIP and MEDEV consider that **improving Europe's science base** is the most important measure for improving competitiveness. The economies of scale provided by the European Union as a whole should be taken advantage of to create research institutions which are attractive as centres of excellence at a European level in order to prevent even more scientists from leaving Europe. Further, measures which increase competition (such as allowing the **development of generics** before market exclusivity expires) are preferred to

⁶ ESIP working paper on pricing presented to the Working Group on pricing of the Pharmaceutical Forum on 10 February 2006

⁷ ESIP working paper on budget control/financing and affordability and access to medicines presented to the Working Group on pricing of the Pharmaceutical Forum on 23 May 2006

measures which provide added protection from competition (such as extending market exclusivity). Competitiveness within Europe will improve competitiveness globally, as demonstrated in the USA following the introduction of the Roche-Bolar provision.

5. What can be done to foster convergence and transparency as regards pricing and reimbursement in the EU?

ESIP and MEDEV consider that the public availability of clinical trials data in a consolidated and easy to access EU database is an important contribution to transparency. Another would be the availability of a comprehensive EU **drug price database** that should include prices net of rebates and discounts. The success of the Euro-Med-Stat project shows that such EU level databases are possible and operational and that the criteria can be agreed even considering the different situations and conditions in the different Member States. Transparency would be further improved through increased harmonization of package sizes for authorized medicines.

Convergence regarding pricing and reimbursement is controversial (is there consensus even within the pharmaceutical industry?), because these reflect the values and socioeconomic environment of an individual country. The policy of a single European price with negotiation of rebates at the national level does not go in the direction of greater transparency and works to disadvantage the smallest economic entities which have little power in negotiations.

An interesting alternative would be to negotiate prices for specific targeted populations defined at Community level with the establishment of appropriate registers or guidelines. The approach would be primarily based on the molecule, with the indication valued at a secondary level.

ESIP and MEDEV consider that the best way to achieve convergence is to implement **measures to increase the economic welfare of poorer countries**. Convergence in the shorter term could lead to inequitable access to certain extremely highly priced pharmaceuticals due to their unaffordability in some countries.

6. Do you think the current EU regulatory framework can accommodate emerging technologies like regenerative and personalised medicines as well as nanobiotechnology?

ESIP and MEDEV consider that **the present EU regulatory framework needs adjustment** (see answer to question 2), also to accommodate the emerging technologies. In particular, it should provide for new rules as regards clinical safety and ethical considerations and should take into account the environmental aspects, which will need an interdisciplinary approach. The prescription and mode of administration of these products should also be covered by the legislation.

Further, the EU needs to learn from the lessons of the orphan drug regulation – this was highly successful in providing new pharmaceuticals; however, the prices of some orphan drugs are prohibitive in some cases and a **correction mechanism** should be established to correct the unintended or unforeseen consequences of creating monopolies.

Summary

ESIP and MEDEV propose:

- **a comprehensive reflection process** to identify those parts of the European pharmaceutical industry that need strengthening in order to ensure the sustainable supply of safe and affordable medicines to patients in Europe and worldwide
- **increased transparency** in all areas related to the supply of safe medicines in Europe through the establishment of publicly accessible databases e.g. on prices, pharmacovigilance and clinical trials data
- **patient reporting of adverse effects** to improve the safety of medicines and increase patient involvement
- **no weakening on the current ban on DTCA** of prescription medicines
- **establishing a programme of priority medicines and licensing pharmaceuticals** of public health interest to improve access to needed medicines
- **improving Europe's science base** by establishing centres of excellence for research
- **implementing measures to increase the economic welfare of poorer countries** to improve access to medicines
- **establishing a correction mechanism to counter monopoly markets** as part of adjustments to the current EU regulatory framework

This position paper has the support of the following ESIP member organisations in so far as the matter lies within their field of competence:

AUSTRIA	HVSVT	Hauptverband der österreichischen Sozialversicherungsträger, Vienna
BELGIUM	ONP/RVP	Office National des Pensions/Rijksdienst voor Pensioenen, Brussels
CZECH REPUBLIC	CSSZ	Czech Social Security Administration, Prague
FINLAND	ETK	The Central Pension Security Institute of Finland, Helsinki
	FAII	Federation of Accident Insurance Institutions, Helsinki
	TVR	Finish Unemployment Insurance Fund, Helsinki
FRANCE	FNMF	Fédération Nationale de la Mutualité Française, Paris
	CNAF	Caisse Nationale d'Allocations Familiales, Paris
	CNAM	Caisse Nationale d'Assurance Maladie, Paris
	CNAV	Caisse Nationale d'Assurance Vieillesse, Paris
	CCMSA	Caisse Centrale de la Mutualité Sociale Agricole, Paris
GERMANY	AOK-BV	AOK-Bundesverband, Bonn
	BKK-BV	Bundesverband der Betriebskrankenkassen, Essen
	IKK-BV	Bundesverband der Innungskrankenkassen, Bergisch Gladbach
	LKK-BV	Bundesverband der landwirtschaftlichen Krankenkassen, Kassel
	VdAK	Verband der Angestellten-Krankenkassen, Siegburg
	AEV	Arbeiter-Ersatzkassen-Verband, Siegburg
	Kn	Knappschaft, Bochum
	See-KK	See-Krankenkasse, Hamburg
	DGUV	Deutsche gesetzliche Unfallversicherung, Berlin
	BLB	Bundesverband der landwirtschaftlichen Berufsgenossenschaften, Kassel
	DRV	Deutsche Rentenversicherung Bund, Berlin
	GLA	Gesamtverband der landwirtschaftlichen Alterskassen, Kassel
ITALY	INPDAP	Istituto Nazionale di Previdenza per i Dipendenti Dell'Amministrazione, Rome
	INPS	Istituto Nazionale della Previdenza Sociale, Rome
LUXEMBOURG	ALOSS	Association Luxembourgeoise des Organismes de Securite Sociale, Luxembourg
THE NETHERLANDS	SVB	Sociale Verzekeringsbank, Amstelveen
	CVZ	College voor Zorgverzekeringen, Amstelveen
POLAND	ZUS	The Social Insurance Institution of Poland, Warsaw
ROMANIA	CNAS	Casa Națională De Asigurări De Sănătate, Bucharest
SLOVAKIA	SOCPOIST	Sociálna poisťovňa, Bratislava
SWITZERLAND	SUVA	Schweizerische Unfallversicherungsanstalt, Lucerne

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BELGIUM	INAMI/RIZIV	Institut National d'Assurance Maladie Invalidité - INAMI / Rijksinstituut voor ziekte- en Invaliditeitsverzekering - RIZIV, Brussels
FINLAND	PPB	Pharmaceuticals Pricing Board, Helsinki
FRANCE	HAS	Haute Autorité de santé, Paris
	CNAM	Caisse Nationale d'Assurance Maladie, Paris
GERMANY	AOK-BV	AOK-Bundesverband, Bonn
	BKK-BV	Bundesverband der Betriebskrankenkassen, Essen
	IKK-BV	Bundesverband der Innungskrankenkassen, Bergisch Gladbach
	VdAK	Verband der Angestellten-Krankenkassen, Siegburg
HUNGARY	ESKI	National Institute for Strategic Health Research, Budapest
	OEP	Ország Egészségbiztosítási Pénztár, Budapest
LATVIA	ZCVA	Medicines Pricing and Reimbursement State Agency, Riga
LUXEMBOURG	UCM	Union des Caisses de Maladie, Luxembourg
THE NETHERLANDS	CVZ	College voor Zorgverzekeringen, Amstelveen
PORTUGAL	INFARMED	National Authority of Medicines and Health Products, Lisbon
SLOVENIA	ZZZS	Zavod za Zdravstveno Zavarovanje Slovenije, Ljubljana