



**AIM**

ASSOCIATION INTERNATIONALE DE LA MUTUALITE



**AIM and ESIP joint position on  
Pharmaceutical Forum priority topics**

**29 September 2006**

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### ***Association Internationale de la Mutualité (AIM)***

The '*Association Internationale de la Mutualité*' (International Association of Mutual benefit societies) (AIM), brings together 41 national federations of autonomous health insurance and social protection bodies in 29 countries. All these organizations are operating according to the principles of solidarity and not-for-profit orientation.

In Europe, they provide coverage against sickness and other social welfare risks to more than 150 million people, either by participating directly in the management of compulsory health insurance, by providing voluntary health insurance or by delivering directly health care and social services through own facilities.

AIM's goal is to defend and promote, at international and European level, the social values and basic principles shared by its members: access to health care as a fundamental right, solidarity and non-exclusion as essential means to ensure this access to quality health care for all, irrespective of health status or financial capacity to pay; and non profit orientation as guiding principles for health insurance based upon the needs of citizens.

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

The *European Social Insurance Platform* (ESIP) represents the social insurers of over thirty organisations from twelve Members States, Romania 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.

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## **AIM and ESIP joint position on Pharmaceutical Forum priority topics 29 September 2006**

AIM and ESIP together represents 38 social health insurance organisations in 17 EU Member States<sup>1</sup>, Romania and Switzerland. Our organisations provide coverage against sickness and other social welfare risks to around 300 million people, either by participating directly in the management of compulsory health insurance, by providing voluntary health insurance or by delivering directly health care and social services through own facilities. Social health insurance organizations are not just payer organizations; they are at the same time spokespersons for their 300 million insured members/patients. Based on not-for-profit principles, our member organisations have a duty to their insured persons to allocate their limited financial means to the most effective and cost efficient drugs at the most competitive prices. AIM and ESIP claim value for money in the interest of its members.

### **Information to patients**

#### ***Steps towards an informed and empowered patient***

The challenge is to encourage responsible health behaviour. This goal can only be reached by helping the citizens through the labyrinth of available information to identify trustworthy, reliable and independent information and to enable them, to take a knowledge-based decision.

#### ***EU added value: learning from experience***

Today's information society provides a multitude of sources and channels of information. In order to become able to manage them, there is a great need to provide tools and guidance to citizens and patients to identify objective information, independent from commercial interests. A knowledge-based, rational decision is not a question of quantity of information but rather a factor of quality.

Within the European Member States, a lot of sources of independent high quality information exist already in different languages. Making better known these sources at European level would constitute an added value for European citizens.

#### ***Each actor has to play its specific role***

Different actors in the health care field play a role regarding information to patients: health professionals (doctors, pharmacists,...), health authorities, social health insurers, patient and consumer organisations, families and friends, etc.

**AIM and ESIP members** play a leading role in providing access to high quality health care to patients at affordable prices. In most European Member States, social health insurers participate in the pricing and reimbursement decision process. They have to inform their members of the results of the evaluation process and the

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<sup>1</sup> Belgium, Germany, France, Spain, Italy, Austria, Greece, Ireland, UK, Luxembourg, Portugal, The Netherlands, Poland, Czech Republic, Slovakia, Slovenia, Hungary.

consequent decisions relating to price and reimbursement. Social health insurers furthermore actively promote the importance of prevention and non medical treatments. They offer information to members as regards treatments, services, etc. They have call centres where members can address any question they have concerning services or health questions.

The **pharmaceutical companies** have a legal obligation in drug packaging and the patient information leaflets. Well conceived leaflets contribute to a better use of drugs and the prevention of medication errors. Communication on clinical trials and pharmacovigilance data to medicines agencies and competent authorities will highly contribute to improve information for patients. Pharmaceutical industry should focus on and be limited to that task. Patient leaflets have to become more readable and understandable. Uncertainty on the extent of risks actually leads to non-compliance and waste. Concerning information, patients want information in the first place from health professionals, health agencies and sickness funds and consumer organisation. Only a small proportion of patients want information from pharmaceutical industry<sup>2</sup>.

The source of information plays an essential role. This was rightly taken into account by the EP and the Council who rejected in 2004 the proposal to allow pharmaceutical industry to provide directly information to patients regarding prescription medicines. More and more voices strongly call for independent centres for testing medicines and to assess them, and also for the provision of independent information.

AIM and ESIP call on all concerned parties not to create confusion between public health and commercial interests. Such confusion would have a negative impact on public health. AIM and ESIP pledge to maintain the current ban on DTCA. Experience in the USA and New Zealand proves that DTCA leads to increasing consumption, costs and biased information that can lead to problems of safety by underestimating risks.

**AIM and ESIP want to boost the access of citizens to patient-centred evidence-based, independent and evaluated information.** A specific EU-logo<sup>3</sup> as trust mark for the citizens could visualise accredited, independent information.

## Pricing and reimbursement

### ***National cost containment practises are necessary and effective***

Pharmaceuticals are no ordinary consumer goods. Normal market mechanisms based on the principle of supply and demand can not be applied.

In the EU, pricing and reimbursement decisions are the competence of Member States who have to respect EU rules, the Transparency Directive in particular. Practically this means that national pricing and reimbursement decisions must be transparent and must be taken within a period of 180 days. Thanks to these national price control and reimbursement decisions, European patients benefit from timely access and affordable prices for newly authorised medicines.

<sup>2</sup> Delphi study: Benefits, costs, preferences-knowing what citizens want Iges/University of Duisburg-Essen/Janssen-Cilag 2006

<sup>3</sup> Such a logo would need to be designed.

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**Value for money**

AIM and ESIP are of the opinion that the price must be related to the therapeutic benefit of the medicine, identified through the assessment of therapeutic value (efficacy – effectiveness – safety – compliance – convenience) and cost-effectiveness. Clinical reassessment studies are therefore absolutely necessary. In other words, payer organisations want value for money. The top priority for sickness funds is access to quality pharmaceutical treatments for all insured persons at affordable and correct prices.

AIM and ESIP also call for a reflection process to find pioneer ideas for **rewarding added therapeutic value of medicines. This would also foster R&D in Europe.** During the last decades, patent and intellectual property rights as a reward for new authorised products have been considerably extended. Currently, with the pharmaceutical revision in 2004, the EU adopted one of the highest incentive and reward systems for R&D of new pharmaceuticals worldwide. Nevertheless, these major incentives and rewards do not seem to encourage the European pharmaceutical industry to provide new “patient driven innovative” products. The current patent situation hinders the distribution of knowledge and substantial developments in research. Today, 10 to 15% of all new patented products can be considered as “patient driven innovative”. Nevertheless, profits in the pharmaceutical sector are amongst the highest worldwide. The financial risks for R&D are more and more taken over by the public contribution to research, while the profits remain in private hands.

Furthermore, the protection of intellectual property rights is detrimental to competition. AIM and ESIP therefore support measures which favour price competition. In the view of AIM and ESIP, only new medicines providing an added therapeutic benefit should be eligible to claim a higher price than already available treatments.

**Rational cost-decisions need transparency**

The dialogue on “fair prices” and future concepts for rewarding added therapeutic value and new pricing concepts has no rational basis as long as the relevant cost components and allocation between R&D costs, production costs and cost of marketing are a black box.

AIM and ESIP call for more transparency on the relevant price components of pharmaceuticals (transfer price, R&D, marketing, etc.). AIM and ESIP are in favour of an EU-wide databank that contains prices especially of new pharmaceuticals on a comparative level, e.g. ex-factory prices.

Within the future work of the Pharmaceutical Forum, it will be an important topic for social health insurers and Member states to bring forward mutual access to information on prices and products and to make data comparable.

## Relative effectiveness

The development of patient driven innovative treatments and medicines is in the common interest of the patients, governments, health authorities, sickness funds, citizens and industry.

The objective of relative effectiveness assessment is to evaluate the value of the product for patients compared to other possible treatments. Assessment of the relative effectiveness makes sure that patients get value for money. These assessments are also of great benefit to doctors.

In order to be in a position to assess the relative effectiveness of a medicine AIM and ESIP deem that controlled non-inferiority trials with the best standard therapy as reference should be mandatory. Such non-inferiority trials can best indicate the true innovative character of new medicines.

## Conclusion

The pharmaceutical forum creates an environment for exchange of positions and – on a voluntary level - progress on important questions relating to pharmaceutical provision e.g. value/benefit, access, price of medicines as well as on the capacity to establish a strong competitive innovative pharmaceutical industry in Europe. AIM and ESIP welcome the opportunity to be involved in that process.

For AIM and ESIP the following key aspects are vital:

- No confusion of public health missions and commercial interest. The ban on DTCA has to be maintained. Future discussions in the Forum must address the important issue of information provided via the internet.
- A "fair price" for a new pharmaceutical is based on transparency of data and on the assessment of therapeutic value (efficacy – effectiveness – safety – compliance – convenience) and cost-effectiveness.
- AIM and ESIP support collaboration and exchange among Member States on relative effectiveness assessment.

*Adopted by the AIM Board of Governors and the member organisations of ESIP in September 2006*