



**AIM**

**ASSOCIATION INTERNATIONALE DE LA MUTUALITE**

## **AIM MEMORANDUM TO THE SWEDISH EU PRESIDENCY**

Brussels, 16 June 2009

### **CONTENT:**

#### **COMPETITIVENESS: BETTER REGULATION**

- Need for a European Mutual Society Statute
- Solvency II

#### **SOCIAL AND HEALTH POLICY**

- Proposal for a Directive on the application of patients' rights in cross-border healthcare
- Social Security Coordination: patient mobility rulings
- Social Services of General Interest – SSGI
- Quality and safety for patients
- E-health and telemedicine
- Intergenerational solidarity and long term care

#### **PHARMACEUTICAL POLICY**

- Legal proposal on information to patients on prescription-only medicines provided by the pharmaceutical industry
- European pharmacovigilance system
- Combat counterfeit medicines for human use
- Pharmaceutical sector inquiry

#### **EXTERNAL RELATIONS: DEVELOPMENT COOPERATION POLICY**

- Social protection and development policy

### ***ABOUT AIM***

The '*Association Internationale de la Mutualité*' (International Association of Mutual benefit societies) (AIM), brings together 42 national federations of autonomous health insurance and social protection bodies in 27 countries. All these organizations operate 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 140 million people, either by participating directly in the management of compulsory health insurance, by providing voluntary health insurance or by delivering health care and social services directly through their 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. All these values are guiding principles for health insurance based upon the needs of citizens.

# PRIORITY ISSUES

## ***Competitiveness: Better Regulation***

### ***STATUTE FOR A EUROPEAN MUTUAL SOCIETY***

In September 2005, under the “better regulation” initiative, the European Commission took the decision to withdraw the 1993 draft Regulation and Directive for a statute of a European Mutual society. That decision came into effect in March 2006.

We assert that this legislative proposal remains important for recognizing formally at EU level the specific role that mutual benefit societies play in the delivery and management of ‘services of general interest’, especially in the health sector. Such a European statute for a ‘European Mutual Society’ will enable societies to operate outside their national borders in a well-adapted and secure legal framework, putting solidarity and non exclusion at the forefront of their organization. It will also enable such mutual societies and European citizens to create European mutual societies and mutual groups through consolidation, transformation, conversion or merger. Today, only joint-stock companies and cooperative societies can do so thanks to the European statutes for these corporate structures. Most importantly, such a European statute would enable mutual societies to benefit fully from the EU Single Market, continue to contribute to the Lisbon Agenda and to compete with other forms of entrepreneurship on a level-playing field.

AIM and AMICE<sup>1</sup> have developed a joint proposal for an EU Regulation on a European mutual society statute and sent it to the President of the European Commission.

The mutual sector, the EP<sup>2</sup> and the EESC have repeatedly called for a statute for all social economy actors, including mutuals.

**AIM asks the Swedish EU Presidency to begin discussions with the other Member States with a view to agreeing a Commission action for a proposal on a statute for a European Mutual Society.**

### ***SOLVENCY II – TOO LITTLE TIME TO IMPLEMENT!***

Health mutuals consider the time limits to fulfil Solvency II requirements too short. Especially in this time of financial and economical downturn, more time is needed for most health mutuals.

## ***Social and health policy***

### ***PROPOSAL FOR A DIRECTIVE ON THE APPLICATION OF PATIENTS’ RIGHTS IN CROSS-BORDER HEALTHCARE***<sup>3</sup>

On 2 July 2008, the Commission adopted a draft Directive on the application of patients' rights in cross-border healthcare. On 23 April 2009, the EP adopted its resolution on first reading. As a follow-up of the EU rulings on patient mobility during the last decade, this new legal instrument constitutes additionally and in parallel to the Regulation 1408/71 a second procedure for reimbursement. The proposed Directive is based on the Internal Market rules and the principles of free movement. According to AIM it goes beyond a simple codification of the underlying EU-rulings and it neither adds to legal and financial security, nor clarity, for patients and payer organisations. The proposal makes today's practice even more complex.

AIM welcomes the progress made so far by the French and the Czech Republic's EU Presidency. AIM asks the Swedish EU Presidency in collaboration with the other Member States to take into account the following considerations when amending the proposed Directive:

- European health systems are built on common values and principles: universality, access, equity and solidarity. AIM strongly recommends that these ‘general interest’ principles should remain the cornerstones of EU health systems, otherwise there is a danger of opening this sector to a completely profit-driven market characterised by risk-selection leading to exclusion.

<sup>1</sup> AMICE, the Association of Mutual Insurers and Insurance Cooperatives in Europe, was created in 2007 by the two Europe based mutual and cooperative insurance associations, AISAM, with around 120 direct members in 21 countries, and ACME, with 57 members in 19 countries.

<sup>2</sup> Most recently, in an EP resolution on Social economy adopted on 19 February 2009, P6\_TA(2009)0062.

<sup>3</sup> Adopted by the Commission on 2 July 2008, COM(2008) 414 final 2008/0142 (COD), in the framework of the Renewed Social Agenda.

- Member states are responsible for the organisation, planning and financing of their health systems, including quality and safety standards.
- For legal clarity, for simplification of the whole process and to avoid red tape at all levels, Regulation 1408/71 (adapted to integrate ECJ rulings) should be applied. Member states should maintain full competence on the definition of hospital care as well as on their own prior authorisation system for hospital care.

#### **SOCIAL SECURITY COORDINATION: PATIENT MOBILITY RULINGS**

AIM reiterates its suggestion that the case law of the European Court of Justice (on the matter of reimbursement of the costs of healthcare provided in another Member State) should be integrated into the new social security coordination Regulation 883/04, or into the proposed successor to EC Regulation 574/72, as was adopted by the Commission on 31 January 2006. A unified legal framework for cross-border healthcare cover could thus avoid the confusing duality of procedures that has existed since the rulings in the cases of *Kohl* and *Decker*.

#### **SOCIAL SERVICES OF GENERAL INTEREST – ‘SSGI’**

Social services of general interest (SSGI) are defined as being based on specific characteristics, typically as set out by the European Commission in its Communication of 26 April 2006:

- they operate on the basis of the solidarity principle,
- they are comprehensive and personalised, integrating their response to differing needs in order to guarantee fundamental human rights,
- they are not-for-profit,
- they include the participation of voluntary workers, being an expression of citizenship capacity,
- they are strongly rooted in (local) cultural traditions.
- they reflect an asymmetric relationship between providers and beneficiaries that cannot be compared with a ‘normal’ supplier/consumer relationship and which requires the participation of a financing third party.

In the current situation, actors and providers of SSGI are faced with legal uncertainties in the Community’s approach to SSGI and in the application of European competition and internal market rules.

The Lisbon Treaty, signed in December 2007, included three major innovations as regards SSGI:

- **Article 14** provides a legal basis for the European legislator to lay down, by means of regulations, the principles and conditions for services of general economic interest (SGEI).
- An **appended Protocol**, recognising the discretion of Member States, and the diversity of their applications, when interpreting in primary law references to Services of General Economic Interest (Protocol Article 1), and also acknowledging the competence of Member States in defining ‘non-economic’ services of ‘general interest’ (Protocol Article 2) .
- The European Union’s **Charter of Fundamental Rights**, annexed to the Treaty, acquires mandatory legal status. It refers in its Article 36 to a right of access to SGEIs.

The **implementation of the Services Directive** before the end of 2009 also constitutes a major challenge to the otherwise-permitted ‘general interest’ protection of social services, which could instead be faced with obstacles resulting from competition and internal market rules. Evidently it is up to the Member States to provide an explicit ‘entrustment<sup>4</sup>’ mission to providers of social services of general interest, in order that these may thus benefit from the provisions of the Treaty - in particular articles 16 and 86.2.

**On the basis of the “road map” adopted under the French Presidency and the EPSCO Council conclusions adopted on 8 June 2009, AIM calls on the Swedish EU Presidency to consider ‘Health and Social Services of General Interest’ as an important issue for the implementation of the Lisbon strategy, taking into account its contribution to the creation of employment and the improvement of social cohesion in the EU. Therefore, AIM calls for the continuity of the process initiated by the European Commission and Presidencies, pointing out the specificities of these services in order to bring the best answer for legal certainty, and also calls for continued discussion on the need for a legislative proposal on the SSGI. AIM also invites the Swedish EU Presidency to encourage each Member State to establish explicit ‘entrustment’ measures for SSGI providers in national law.**

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<sup>4</sup> ‘Entrustment’ is the process by which a State formally delegates a sovereign activity to a non-State actor in explicit, usually legal, terms.

## ***E-HEALTH AND TELEMEDICINE***

The AIM members are involved at national level in this topic and are monitoring closely the evolution in this sector. AIM supports the communication on "Telemedicine and chronic diseases" and its three levels of actions (national, EU, Commission). AIM was pleased that the Communication covered the vast majority of points to which its own memorandum on telemedicine (footnote reference) had drawn attention.

**AIM calls on the Swedish EU Presidency to consider the different proposals and initiatives launched by the European Commission as regards e-health in the field of health care. AIM would like to stress that before taking any decision on the use and reimbursement of these services on a large-scale it is paramount to assess the need, priorities, efficiency and costs of these new technologies, in particular on the basis of effectiveness and cost-effectiveness studies.**

## ***INTERGENERATIONAL SOLIDARITY AND LONG TERM CARE***

AIM supports the importance of intergenerational solidarity as a common value for all European societies and agrees that intergenerational solidarity and Long Term Care should be an integral part of the EU social protection systems. AIM fully supports the joint report on social protection and social inclusion 2009 by the European Commission, in the framework of the 'Open Method of Coordination'. AIM calls for a paradigm shift with regard to Intergenerational Solidarity and Long Term Care. Thus, Long Term Care would be a responsibility of the community as a whole and ensuring access for all to high quality and affordable Long Term Care in a sustainable way should remain a priority of all actors.

AIM, as an active stakeholder in the field of Long Term Care, has been asked by the Swedish Ministry of Social Affairs, in the framework of the Swedish EU Presidency, to help in preparing the future conference on "Healthy, active and dignified ageing", to be organised for 15-16 September 2009 in Solna, Sweden.

**AIM asks the Swedish EU Presidency to support the need for the development, with the NGOs active in the field of Long Term Care, of a European framework or guidelines for delivering qualitative Long Term Care, respecting the principles of subsidiarity and diversity and including a European Charter of fundamental rights for people in need of Long Term Care.**

## ***Pharmaceutical policy***

The role of AIM and its member organisations in pharmaceutical policy is clearly recognised at European level. AIM was invited to participate in the former G10 high level group on pharmaceuticals. In 2006 AIM was further invited to participate in the Pharmaceutical Forum whose mandate ended in October 2008.

After the organisation of several public consultations in Spring 2008, the European Commission adopted on 10 December 2008 a legislative package regarding pharmaceutical policy encompassing:

- information to patients,
- combat against 'counterfeit' medicines for human use,
- an EU pharmacovigilance system.

## ***LEGAL PROPOSAL ON INFORMATION TO PATIENTS ON PRESCRIPTION-ONLY MEDICINES PROVIDED BY THE PHARMACEUTICAL INDUSTRY***

AIM asks the Swedish EU Presidency in collaboration with the other Member States to take into account the following considerations:

- AIM is very much concerned by the Commission's legal proposal. The proposal authorises pharmaceutical industry to provide information to the general public on their prescription-only medicines through internet websites as well as health-related publications. The Commission does not provide any definition or distinction between advertising and information in its proposal. AIM is of the opinion that such a Commission proposal will lead to the established abuses of 'Direct-to-Consumer-Advertising' (DTCA) with known adverse effects on public health, especially on perceptions, requests for specific drugs, medication prescribing and compliance - as well as on healthcare expenditure and drug prices. Considering these aspects, in AIM's opinion, shared by many others, this proposal clearly gives priority to industrial and commercial interests rather than to public health concerns and consumer protection interests.

- AIM instead invites the Commission and other European Institutions as well as the Member States to support the empowerment of EU-citizens and patients through better access to comparative, unbiased high-quality information generated by official independent bodies within a validated process. Many examples of such information and good practice exist already and should be benchmarked throughout the Member States. AIM is convinced that high added value for all Member States, EU citizens and patients is best achieved by developing synergies at EU-level and reinforcing collaboration among existing national bodies involved in issuing independent patient information.
- AIM strongly rejects any direct or indirect processes aimed at relaxing the existing ban on information provided to patients/consumers by pharmaceutical companies about prescription drugs (equivalent to DTCA). **AIM is therefore committed to opposing any changes to the current EU-legislation on advertising.**
- **To refocus pharmaceutical policy primarily on public health instead of industrial interests, AIM requests that the responsibility for pharmaceutical policy in the European Commission should be switched from DG ENTR to DG SANCO.**

### **EUROPEAN PHARMACOVIGILANCE SYSTEM**

AIM presents the following views for the Swedish EU Presidency to consider in collaboration with the other Member States:

- Pharmacovigilance is clearly a key public health function. AIM agrees that the current pharmacovigilance systems include major weaknesses which should urgently be addressed and improved through the establishment of clear roles and responsibilities, strengthened requirements for the monitoring and assessment of the safety of medicines as well as effective reaction measures.
- AIM calls on the European Commission and legislators and all Member States:
  - to reinforce marketing authorisation criteria so that new medicines being approved offer genuine therapeutic benefit; AIM strongly opposes a generalising of the conditional marketing authorisation procedure;
  - to organise public, Europe-wide collection of high-quality 'adverse effect' reports;
  - to guarantee that all data, information and decisions in the field of pharmacovigilance are open to public scrutiny;
  - to guarantee public funding for the European pharmacovigilance Committee and the national and regional pharmacovigilance systems so that they can be financially and morally independent of pharmaceutical companies;
  - to provide resources for effective pharmacovigilance systems, notably by encouraging 'adverse effect' reporting by patients directly to health authorities, and by promoting exchanges between the authorities and networks specialised in medication error management and adverse event reporting.
- AIM calls for the submission of actively-controlled comparative clinical trials data with all applications for marketing authorisation approvals.
- AIM calls for compulsory post-marketing surveillance studies.

### **COMBAT COUNTERFEIT MEDICINES FOR HUMAN USE**

AIM asks the Swedish EU Presidency in collaboration with the other Member States to take account of the following:

- According to recent studies, 'counterfeit' medicines have become an increasing threat to public health. These **studies unfortunately often do not focus on and explain the origin and main sources of counterfeit products**. However such data are extremely important in tackling and remedying these problems.
- AIM agrees with the Commission's proposal to strengthen the controls on active substances and in the distribution chain and inspections.
- AIM would however like to highlight that the ultimate proposal must not incur disproportionate costs compared with expected benefits.
- AIM also recommends that patients themselves should be made better aware of the problem of 'counterfeiting';

- AIM calls on the European Commission and legislators and all Member States:
  - To focus on more reliable data to measure the real extent of the problem;
  - To add a clear definition of a 'counterfeit' medical product;
  - To increase the liability of all actors involved throughout the legal distribution chain;
  - To tackle the aspect of Internet trade
  - To focus on public awareness-raising campaigns.

### ***PHARMACEUTICAL SECTOR INQUIRY***

On 28 November 2008, the European Commission issued a preliminary report on competition problems in the pharmaceutical sector. The report provided an impressive set of data and figures providing a detailed overview of the competition problems and strategies involved in abuse of the current patent system. This report is a very valuable tool for understanding the strategy underlying the pharmaceutical industry's behaviour during the whole life-cycle process of a medicine.

AIM asks the Swedish EU Presidency in collaboration with the other Member States to encourage and to support the European Commission in taking urgent initiatives and measures to put an end to the abuse of the current patent system. AIM also invites all Member states to encourage a strong 'generics' policy allowing financial savings in order to fund new innovative medicines and increasing patients' access and affordability to pharmaceuticals.

**AIM further asks the Swedish EU Presidency to continue discussions on the legislative proposals with the other Member States with the primary objective of giving prior attention to respect for public health and 'general interests' aspects. AIM also invites the Swedish EU Presidency to consider with the other Member States the switch of the 'lead' on pharmaceuticals policy from DG ENTR to DG SANCO, as medicines should be primarily looked at from a public health perspective as they are not ordinary consummation goods.**

<b><i>External relations: Development cooperation policy</i></b>
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### ***SOCIAL PROTECTION AND DEVELOPMENT POLICY***

AIM welcomes the EU policy for better aid delivery, the EU thematic policy for tackling the critical shortage of health workers in developing countries and the future Communication on policy on financing of health systems and social protection in health. AIM strongly supports a deeper EU involvement at political, financial and technical level in the issue of universal health protection. This is of particular importance in the current context of economic crisis.

Furthermore, AIM welcomes and supports the draft document on "Health and social protection in EU development policy" submitted during the EU French Presidency, as well as the summary report of the Commission's consultation workshop on financing of health systems and social protection in health in developing countries (23/24 March 2009). AIM is looking forward to the expected EU Communication on "financing of health systems and social protection in health".

Nevertheless, AIM deeply regrets the lack of a formal platform at EU level, where "civil society" could promote exchanges on social protection issues in the EU development policy.

**AIM asks the Swedish EU Presidency to begin discussions with the other Member States with a view to agreeing a Commission action for DG Development, to create a platform involving all the civil society stakeholders who can contribute to the extension of social and health protection.**

The Association Internationale de la Mutualité (AIM) represents national federations of private, but not-for profit healthcare funders.



ANMC - Belgium  
▶ 4,5 million EU citizens



UMP - Portugal  
▶ 0,850 million EU citizens



UNMN - Belgium  
▶ 0,450 million EU citizens



BKK - Germany  
▶ 10 million EU citizens



IKK e.V. - Germany  
▶ 3 million EU citizens



Benenden - UK  
▶ 0,950 million EU citizens



LSV - Germany  
▶ 0,850 million EU citizens



Zorgverzekeraars Nederland  
The Netherlands  
▶ 16 million EU citizens



MLOZ - Belgium  
▶ 1.9 million EU citizens



FIMIV - Italy  
▶ 0,6 million EU citizens



OATYE - Greece  
▶ 0,1 million EU citizens



Knappschaft - Germany  
▶ 1,7 million EU citizens



FNMF - France  
▶ 38 million EU citizens



Santésuisse  
Switzerland  
▶ 7,2 million citizens



**VZAJEMNA**  
zdravstvena zavarovalnica, d.v.z.

Vzajemna - Slovenia  
▶ 0,9 million EU citizens



SZP - Czech Republic  
▶ 3,8 million EU citizens



VZP - Czech Republic  
▶ 6,2 million EU citizens



UNML - Belgium  
▶ 0,580 million EU citizens



VHI - Ireland  
▶ 1,55 million EU citizens



VZP - Slovak Republic  
▶ 2,9 million EU citizens



vdek - Germany  
▶ 24 million EU citizens



BUPA - UK  
▶ 4,1 EU citizens



UNMS - Belgium  
▶ 3 million EU citizens



MSA - France  
▶ 4 million EU citizens