AIM
ASSOCIATION INTERNATIONALE DE LA MUTUALITE

Secretariat

AIM response to the Commission's "Consultation regarding Community action on health services"

Brussels, 2 February 2007

About AIM
The Association Internationale de la Mutualité (AIM) was founded in 1950 and has its secretariat in Brussels. AIM groups 41 national federations or associations of autonomous health and social mutual societies from 30 different countries worldwide. The members of AIM generally operate according to the principles of solidarity and not-for-profit orientation. They provide cover against health and social risks to more than 170 million people worldwide, and to more than 140 million within the European Union. In several EU countries AIM members actually manage the compulsory health schemes, and/or offer 'complementary cover too.
Today, AIM serves its members by representing their different interests in diverse committees and forums. The Association is seen as the members' link to governments, non-governmental organisations and stakeholders in the field of health and social services at multi-country level, and as the spokesman of the health and social mutual societies. The representativeness of AIM is broadly recognised and is built upon its expertise and consensual, constructive and pro-active attitude.
AIM takes care to organise a permanent exchange of information between members' organisations and to inform on evolutions in the field of social protection and healthcare at the European and international level. These exchanges are done through meetings, conferences, publications, and the website.
AIM also strives to voice members' concerns and opinions and to defend the common values shared by all members. AIM's goal is to preserve and to strengthen social protection systems and solidarity-based health care insurance.
The association is led by democratically elected members. They hold posts in the Praesidium, the Board of Governors or in the General Assembly. The secretariat, based in Brussels, assists the governing bodies in their daily business.

About this response

This response to the consultation on health services has been developed by the European Affairs Committee of AIM. This committee is a forum for all European members of AIM. Together they discussed and prepared this position paper which was endorsed by the AIM Board of Governors. In that respect, it is a joint position. Nevertheless, certain AIM member organisations have responded individually to the consultation as well and have expressed their individual opinions and views separately in ways which may differ in detail. The following AIM members responded individually to the consultation: CIN (B), DSV (D), FNMF (F), ZN (NL), Benenden (UK), BUPA (UK) and VZP ČR.

In general, all members of the AIM European Affairs Committee see this consultation as an excellent opportunity to express their interest and to contribute – in sharing their expertise and knowledge – to the important work the European Commission does in the field of health and social services.

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General remarks about health and social services in the European Union

AIM welcomes the growing attention of the instances of the European Union to health and social services. For a better understanding of the AIM response to the consultation, it is good to take a closer look at some elements of this discussion.

♦ **European health systems are based on general interest criteria**

AIM would like to highlight the common values and principles which underpin the European health systems: universality, access to good quality care, equity and solidarity. These common values and principles were highlighted in a Council Resolution of 1-2 June 2006. The European solidarity-based social and health systems make a major contribution to the social cohesion and social justice which the EU can be proud of. As social cohesion is a fundamental objective of the European Union it is of paramount importance to safeguard these common values and principles.

AIM would like to emphasize that health services cannot be compared with common consumer goods. Universal access to quality healthcare can only be secured by respecting the above mentioned values and principles. Complete deregulation in health care could make health systems less effective, more costly and less equitable. Fundamental and public objectives of solidarity-based access to care and of cost-effective management of care can be regarded as services of 'general interest', taking precedence over private commercial interests.

European health systems are built on common values and principles: universality, access, equity and solidarity. These 'general interest' principles should remain the cornerstones for EU health systems otherwise there is a danger of opening this sector to a completely profit-driven market based on risk-selection and exclusion.

♦ **Mutual benefit societies and health and social services**

Mutual benefit societies play an important role in the European health and social sector. They provide coverage and services in both sectors, to more than 140 million European citizens. Because the structure and organisation of health systems differ between the Member States, they do it in specific, distinctive ways. Mutual benefit societies provide services to their members on a solidarity, not-for-distributable-profit and non risk selection basis. The primary goal is to satisfy members' needs. They are persons-based societies: they have no shareholders. Therefore, their goal is not to maximize profits or to re-distribute externally any financial surpluses.
As such, and by way of internal democracy, mutual benefit societies can be seen as representatives of their members. This is important especially in the field of health and social services, as this implies a distinctive view of the organisation and realisation of accessibility, quality and financing of these services.

AIM stresses the fact that its members are representatives of their own members, i.e. the European citizen. As such, the members of AIM represent both healthy insureds as well as patients. The activities of the mutual benefit societies reflect the needs and wishes of their own members. That is why AIM member organisations call on European and national public authorities to respect the general interest criteria and regulated health market instead of pushing for a completely free market approach.

♦ **Health and social services as key elements of a Social Europe**

AIM represents mutual benefit societies which are essentially associations of people organising the provision of services to the benefit of the collectivity. Social cohesion is the starting point and the basis of mutual benefit societies. In that sense, they provide a counterbalance to all 'private', for-profit alternatives which may have other goals than satisfying the health and social needs of the European citizen.
This counterbalance is needed to build a Social Europe that provides a solid, solidarity and sustainable basis for further economic prosperity within the European Union.

AIM sees health and social services as a cornerstone of a Social Europe. Whereas the concept of the internal market may suit other sectors very well and may contribute to a strong European economy, health and social services form an integral part of the Lisbon Strategy as a vital contributing factor to social cohesion and should be treated accordingly.

♦ **Health and social services and the internal market**

AIM member organisations sometimes find a conflict of interest between the application of the 'subsidiarity principles' and the required application of competition and internal market rules. AIM members do apply the rules of the internal market in their activities. However, these rules do not always seem to be in favour of their members or in favour of the 'general interest'. And sometimes, the concept and the rules of the internal market hinder the proper activities of mutual benefit societies involved in the field of health and social services as demanded by their members.

Health care is a good example of a sector needing a specific approach instead of a purely market approach. It is AIM's strongest conviction that health care is not an ordinary good and that the health sector cannot be subjected to complete market deregulation as it embodies fundamental human and social constraints and can be subject to important market imperfections. Not only can the 'asymmetry in information' between provider and patient prevent normal price setting, in addition health care expenditure is highly concentrated among a minority of the population, revealing socio-economic inequalities as regards health risks.

For AIM it is not always clear and/or wanted if and whether the concept of the internal market and its rules do, should or could apply to health and social services for its members. In that respect, AIM sees a clear link between this consultation and the current official discussion about (non-economic) Health and Social Services of 'General Interest'.

General remarks about the consultation

Apart from these more general remarks, AIM wants to make some remarks about the consultation process.

- **The added value of the European Union in the field of health and social services**

Although AIM members may have different visions of the European Union due to the diversity of the healthcare systems and its interference with the organisation of national health and social services, they all recognize that there is an important role to play by the instances of the European Union. Nevertheless before any type of new action, it should be made clear if this would bring an added value for accessibility and quality of social and health services. The legal basis for this action may be somewhat unclear, but the need for co-ordination, steering and guidance on a European level is generally recognized.
AIM recognizes that the principle of subsidiarity is a key feature in discussions, making a distinction between what should be done on the level of the Union, and what could better be done at national level.

AIM sees a clear role for the European Union in the field of health and social services. This role should be seen more as a co-ordinator, a steersman, and as a guide. Concrete legal initiatives should be left to the Member States, as they are closer to the European citizen.

- **The added value of stakeholders' participation in the consultation process**

AIM welcomes the public consultation process initiated by the European Commission, as it gives the opportunity for all parties involved to express their interests and views. Public consultations enable the European Commission to gather specific expertise, new ideas, and concrete proposals. We would like to underline that the Open Method of Coordination is also a valuable tool for exchanging best practices. However in that process there seems so far to be a lack of participation involving all the various key actors and stakeholders.

AIM takes seriously its responsibilities as a representative European association of mutual benefit societies active in the field of health and social services and wants to contribute to the consultation in a constructive, positive and reliable way.

- **The field of health and social services: scope of the consultation**

AIM considers this consultation as very important for the future of health and social services in the European Union and has therefore been discussing this issue for a long time. During these discussions, AIM members have come to the conclusion that the scope of the consultation is overly broad, or at least unclear.
AIM has the impression that the initiative of the European Commission intends primarily to focus on patient mobility, 'legal uncertainty' and a new legal framework, probably a Directive.

♦ **Regulation 1408/71 vs Non Life Insurance Directive**

At present patients' EU based rights for re-imbursement for healthcare services delivered whilst the patient is "temporarily" in another EU member state are confined to services financed by "mandatory social security schemes" and fall under the Regulation 1408/71. At present private medical insurances in EU member states are regulated by the provisions of the Third Non Life Insurance Directive. This Directive gives insurers the rights to define the price, content and geographic scope of such insurances which do not fall within the scope of the Regulation 1408/71.

Patient mobility

Patient mobility is an important aspect, but marginal in volume within the European healthcare sector. From AIM's perspective, a distinction has to be made between:

1. Patients living in border regions: these citizens look for care in their region, which is crossed by national borders. For this type of patient mobility, AIM members do have much experience and specific cross-border (legal) arrangements are available.
2. Patients who cross borders according to contractual arrangements between healthcare providers, mutual healthcare funds and national health services. These arrangements are specific and tailored to the needs of the patient, the provider and the payer. AIM members stress the importance of these arrangements and the need for a (legal) 'free zone' or experimental status for these arrangements.
3. Patients who have chosen their own provider abroad for all kind of reasons. This type of patient is generally well informed, physically and economically able to move and therefore not stereotyped. AIM members consider this type of patient mobility as interesting, but foresee problems if the volume of this type of patient mobility increases too fast. Such a system where individual choice, irrespective of necessary cost-containment measures, becomes the decisive element would put under pressure national healthcare systems, solidarity and equity. There is even a risk that a 'two-speed' Europe for health care could evolve, with better informed and better-financed patients more easily able to travel abroad for treatment, thus damaging the 'solidarity' of their home schemes.

Legal uncertainty

Legal uncertainty is a problem which justifies appropriate corrective action. It should be clear to all parties involved 'who is responsible for what', 'what are their rights and duties' and 'who is in charge of what'. Codification, modification or adaptation of existing EU legislation to improve legal clarity and 'certainty' is in the interest of all.

'Legal uncertainty' however, seems however often to be confused with lack of complete and reliable information. It is important to identify the true nature of the problem, before legislative action is considered. It is possible that legislative action may be necessary to improve the (provision of) information, but nevertheless, the two distinctive features of the same problem should be considered. The European Commission has already various possibilities to support better communication. Therefore, and in the light of the 'better regulation strategy' the introduction of additional legislative procedures in this area seems unnecessary.

New legal framework

According to AIM and as in light of the above, the current discussions are too much focussed on the introduction of a new Directive. AIM stresses the fact that a Directive is no more than an instrument, and not a goal. The problems identified in this answer, will not be solved merely by a Directive. Solutions should be sought in co-ordination and co-operation between Member States and stakeholders and by using or modifying existing (legislative) instruments.

AIM defines the scope of this consultation as broad as possible. Nevertheless, its response focuses on some key elements of health and social services: patient mobility, existing social security coordination rules, bilateral agreements and access to reliable information.

Answers to the questions of the consultation document

These answers should be read in the context of the general introduction above.

***Question 1:* what is the current impact (local, regional, national) of cross-border healthcare on accessibility, quality and financial sustainability of healthcare systems, and how might this evolve**?

Social health insurance organisations represented within AIM confirm that, so far, patient mobility is marginal. Cross-border patient mobility does not, so far, affect the accessibility of health services nor the financial sustainability of healthcare systems.

However, for the future, due to the enormous differences in the standards of living and access to health care and quality of services between the 27 Member States, cross-border care might come to have a financial impact especially for the 10+2 new Member States applying Regulation 1408/71. This could lead to accessibility problems.

There is a real lack of reliable and accurate data. The official 'Administrative Committee', in charge of the implementation of Regulation 1408/71, composed of delegates from the different Member States, would be the best placed to design an adequate and well functioning reporting system based on a standardised set of data. In general, it would be of great importance to make the data more available and in particular more valid. Cooperation will only lead to an added value when the framework for surveys is comparable. It would remain the responsibility of the different Member States to collect and process the data and to make them available to the European Commission. Such data should also be made available to relevant health insurance organisations (i.e. mutual benefit societies).

Today, patient mobility in the EU is marginal. However, if patient mobility increases in the future, this could lead to financial and access problems in Member States which are not so wealthy. Therefore it has to be examined carefully how these problems could be solved within the existing legal framework. More reliable and accurate statistics on patient mobility are needed. The 'Administrative Committee' in charge of Regulation 1408/71 should refine a standardised data set.

<u>Question 2</u>: what specific legal clarification and what practical information is required by whom (e.g. authorities, purchasers, providers, patients) to enable safe, high-quality and efficient cross-border healthcare?

The 30 years experience with the Regulations 1408/71 and 574/72 have illustrated that the system works reasonably well. It would seem an advantage however in the newly enlarged EU if, on suitable issues, the Administrative Committee or its working groups could make decisions by qualified majority.

<u>1408/71 Regulation: case study: E112 form only based on medical and geographical criteria</u>

Some AIM member organisations managing the compulsory system are faced to problems especially with the E112. The E112 is allocated on the basis of medical criteria. However, in reality patients do request authorisation for treatment abroad for additional reasons, for example presence of family, knowledge of language, etc. The refusal of the allocation of the E112 form 'because no medical reasons are present', leads sometimes to frustration or even more to the Court of Justice.

In some cases, cross-border check-ups and analyses require no mobility on the part of the patient (genetic tests, analyses made abroad). In such cases, a patient can not be reimbursed under the E112 because he did not himself move. Currently the E112 involves a geographical element where the patient must have gone across the border. It is recommended that the 1408/71 Regulation takes into account new techniques by which it is not necessary the patient to have crossed the border.

<u>Identification of health professionals (public or private) and acceptation of European documents</u>

From patient reporting it appears that in several Member States the European Health Insurance Card (EHIC) is not accepted by some healthcare providers who should have an obligation to accept it. This has already been a persistent problem with the old E-forms, which the new EHIC was in part intended to remedy. This problem could be solved by requesting healthcare providers and medical institutions who accept the card to make this known through a common EU logo or label to be made visible at the entrance of the medical cabinet or health institution (in the same way as shops make known which credit card they accept). Member States should also be invited to set up a database of health professionals and health institutions indicating who is / is not accepting the EHIC. The general rule should be followed, that all health care providers offering services covered by social security systems have to accept the EHIC. AIM invites the European Commission to call on all EU Member States to discharge their obligation to ensure internally that all local health care providers under the Council Regulations (EEC) No 1404/71 and No 574/72 will accept insureds and will act in accordance with the above mentioned regulations.

<u>European case-law</u>

Some Member States have implemented patient mobility rulings into national law (Germany, France, Belgium, Luxembourg, the Netherlands,…) others have not. This is a first source of legal uncertainty. Furthermore EU case-law has laid down other rules - in particular for non hospital treatment - than what were foreseen in the Regulation

1408/71. Patients who benefit from one or the other set of rules can thus be confronted with different procedures. This is a source of uncertainty.
In the Watts case, the ECJ stated that the delay in providing hospital care is one element to take into account when authorising or declining authorisation of cross-border care. It would be useful to have a concise codification of ECJ interpretations of what is meant by "undue delay".

AIM is in favour of harmonising the 1408/71 and later Regulations in particular No 883/04 with the ECJ rulings on patient mobility.

Access to reliable information and clarification of applicable rules, rights and obligations

'Legal uncertainty' is mostly due to a lack of information on rights and duties as regards access and conditions for cross-border healthcare.
An interpretative Communication about the different existing tools and instruments would create more clarity and visibility not only for public authorities and experts but also for the general public. Member States should each be encouraged to provide this information in an understandable and easily accessible way to their citizens.

The focus should be on accessible, understandable and reliable information for the general public. The European Commission could propose through a Communication a "**European Patients' Rights Charter**" laying down what rights and duties of the patients are provided by European tools and instruments. The individual Member States could be invited to make this information available to their citizens.

Some Member States already have a patients' rights charter or a charter for the social health insured person.

In Belgium such a charter already exists and the social security institution has a duty to inform the social-insured population on their rights, entitlements, duties and procedures. This was set up by a law of 11 April 1995. The law focuses on the obligations of the social security institutions (obligation of information on the insured's' rights and duties). These institutions have also a duty to advise the insureds how to get their rights. The law furthermore lays down the procedure for introducing a request for information or the procedure to complain.

The Netherlands has also a specific patient law called "*Wet op de Geneeskundige Behandelovereenkomst*" (WWGBO). This law regulates the duty for doctors to inform their patients (in order for them to give 'informed consent') and to assure privacy.

From experience with the European coordination rules of social security and patient mobility rulings, AIM is convinced that most problems could be solved by the modification of the Regulation 883/04 (successor of 1408/71) and the inclusion of former art. 23 of the draft Service Directive in this Regulation. AIM sees a real role for the Commission in providing support to improve access to reliable information to the patients. Certain other problems could be solved by changes of national legislation, resulting from Open Coordination rather than necessarily a Directive in this area.

<u>Question 3:</u> which issues (eg: clinical oversight, financial responsibility) should be the responsibility of the authorities of which country? Are these different for the different kinds of cross-border healthcare described in section 2.2 above?

In principle the competent authorities and facilities of the country in which the service is provided, should be considered as fully competent for assuring safety and for supervising service providers who provide services within that country.

<u>Question 4:</u> who should be responsible for ensuring safety in the case of cross-border healthcare? If patients suffer harm, how should redress for patients be ensured?

The authorities and facilities of the country in which the service is provided should be competent for safety and for supervising service providers. Redress for patients should be ensured by national administrative and social law, as well as by International private law.
However, there is a general need for clarification and the Commission should take the initiative to provide an explanation of the common rules and how this is applied in reality for example through the method of "frequently asked questions". The Commission could also provide information on dispute settlement rules and information on national compensation rights should be made available to citizens.

<u>Question 5</u>: what action is needed to ensure that treating patients from other Member States is compatible with the provision of a balanced medical and hospital services accessible to all (for example, by means of financial compensation for their treatment in 'receiving' countries)?

AIM is of the opinion that these questions must be treated between the individual Member states as the needs and offers are completely different from one country to another as well as from region to region.

<u>Question 6</u>: are there further issues to be addressed in the specific context of health services regarding movement of health professionals or establishment of healthcare providers not already addressed by Community legislation?

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<u>Question 7</u>: are there other issues where legal certainty should also be improved in the context of each specific health or social protection system? In particular, what improvements do stakeholders directly involved in receiving patients from other Member States – such as healthcare providers and social security institutions – suggest in order to facilitate cross-border healthcare?

- There is a need for clarification of rules applied to telemedicine and e-health (liability, reimbursement, etc.) especially when cross-border.
- Explanation of "undue delay" in terms of applicable criteria.
- Clarification of 'in/out patient' care and the logic underlying established ECJ definitions of 'Hospital care'.

***Question 8*: in what ways should European action help support the health systems of the Member States and the different actors within them? Are there areas not identified above**?

Health technology assessment and shared therapeutic evidence-based medicine

In order to maintain high-quality and effective care, AIM members are in favour of **health technology assessment and evidence based medicine**. AIM is in favour of greater encouragement for sharing good practice across the EU in terms of both health systems and clinical practice e.g. through the EU-netHTA. These assessments, at European or international level, should however exclusively focus on the therapeutic medical effectiveness of the treatments/care. As priorities and the economic and financial situation of the different Member States diverge greatly, common cost-effectiveness studies would be without value.

It should be noted that several Member States have already established organisations to analyse the therapeutic effectiveness of the treatments and care e.g. NICE (UK), HAS (F), IQWIQ (D), KCE (B). A suitable 'best practice' forum at EU-level could support these institutions in comparing evidence leading to shared and documented experience on which locally-appropriate decisions about relative effectiveness can be made. Since these bodies make rulings on what is deemed to be preferred clinical practice locally – and what is not – they are part of the regulatory effort.

Several issues like rare diseases or transplantation should of course benefit from the widest European experience. Sharing of knowledge about practice among the different Member states is of major importance. In those fields where the benefit of European collaboration is evident, the Commission should seek ways of using **centres of reference** in an optimal way. Stakeholders themselves should be invited to contribute to this subject: for example some AIM member organisations own and manage health care services such as medical centres or clinics.

Cross-border cooperation: bilateral agreements and contracting

In border regions, experiences with bilateral agreements and cross-border contracting have shown that these practices are good examples in responding to local and/or regional needs. These bilateral agreements improve access to health infrastructures physically by reducing distances but also economically by reducing possible waiting lists. They take into account the insufficiencies of the national systems and enable better cross-border planning of health infrastructures.

Shortages in health care professionals and new technologies

All Member States are (or will be) confronted with a shortage of healthcare professionals. This can have varied reasons locally (numerus clausus, demography, shifting M/F balance of the healthcare profession, mobility of health professionals).

A possible assistance could be the coordination of databases of health professionals, and also perhaps of major equipment in specific healthcare fields. The purpose would be to enable organisation of efficient "collaboration" between medical staff and in the use of new technology in order to ensure comparable accessibility to medical care for all EU citizens. The networks needed to do this could evolve and be tested in cross-border cooperation projects.

Further to exchange of good practices, collaboration in the evaluation of relative effectiveness of treatments and healthcare would provide an added-value for all member States. EU (financial) support for cross-border agreements organising tailor made solutions would also be of great benefit. Linking databases on the availability of health care professionals as well as expensive equipment and technologies could be of help in several Member States.

***Question 9:* what tools would be appropriate to tackle the different issues related to health services at EU level? What issues should be addressed through Community legislation and what through non-legislative means**?

So far, AIM member organisations do not see any need to propose new European legal instruments in the area of cross-border health and patient mobility. Member States which may not have implemented the patient mobility rulings should be invited to do so as soon as possible. Most identified problems could be solved through the adaptation of the Regulation 883/04. The priority should be to optimise these existing legal tools. However there is a lack of understandable and reliable information for the general public regarding their rights and duties in case of cross-border healthcare. European action could help to improve transparency and reliability of these elements.

AIM would furthermore like to highlight the real danger and risk allowing two-speed health systems to develop in Europe by encouraging maximum the use of the principles of free movement. For sustainability, solidarity and access reasons, such mobility would be most available to those who could pay for it and who are well informed. AIM would encourage European institutions instead to support the Member States in constantly improving their own systems to provide high-quality care based on solidarity principles to those who need them, without the need to travel far for treatment.

To conclude, AIM would like once again emphasise – as said already earlier - that European health systems are built on common values and principles: universality, access, equity and solidarity. These 'general interest principles' should remain the cornerstones for EU health systems. In case where Member States national initiatives and measures aiming at the realisation of these measures may be in possible conflict with European internal market or competition rules than the 'general interest' rules should prevail. This has already been affirmed by President Barroso to the Members of the European Parliament. AIM would therefore be grateful if the Commission could make the functioning of this principle a reality.

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