European Diagnostic Manufacturers Association

COMMUNITY ACTION ON HEALTH SERVICES

Consultation from the European Commission

EDMA, the European Diagnostic Manufacturers Association welcomes the invitation by the European Commission to comment on the future Health Strategy for the European Union on Health issues.

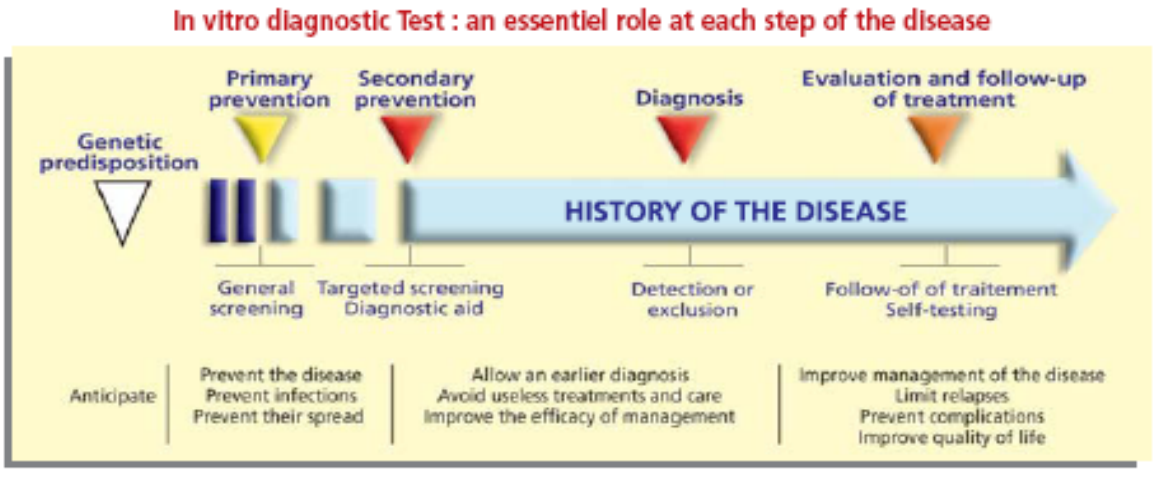
EDMA represents National Associations and major companies engaged in the research, development, manufacture or distribution of *In Vitro* Diagnostic (IVD) medical devices in Europe. Through its affiliated National Associations, EDMA represents in total more than 550 companies (or over 1000 legal entities) across Europe.

EDMA mission is to promote the value of *in vitro* testing and to raise awareness of the importance, usefulness and added-value that diagnostic information provides to healthcare. For this purpose, EDMA cooperates with European institutions, patients groups, trade associations, health professionals and academia to support an appropriate regulatory system, to work towards a realistic economic environment for health care in Europe and to be an effective voice in globalisation.

***In Vitro* Diagnostic** (IVD) testing provides objective information as a basis for better decisions in healthcare. Laboratory testing has indeed an essential part to play from the prevention and diagnosis, in the broad sense, which takes into account the predisposition and the precise determination of the disease and its severity; to monitoring of treatment, allowing assessment of its efficacy and its adjustment; disease management in the case of chronic pathologies; and confirmation of therapy efficacy to rule out any risk for persistence of disease.

For example, it is foreseeable, that new, more specific and much more expensive methods of treatment – such as in the case of patients with cancer and other severe diseases – will require highly specific diagnosis, in order to guarantee successful and affordable treatment.

An appropriate and rational use of *In Vitro* Diagnostics would allow European health and the national systems to improve the quality and the economics of the service they offer to the citizens.



(1) The value of diagnostic : innovation, adoption and diffusion into health care .2005. The Lewin Group.

According to the EDMA 2005 European Market Estimates, the average IVD industry sales represent less than 2% of the Total Healthcare Expenditure (*i.e.* around €20 *per capita* and *per annum*), although clinical diagnostics influence about 64% of the medical decisions, as stated by J. D. Kruse-Jarres(Lab. med. 18:213/1994). Moreover, disparities between European countries is considerable. While most EU-15 countries' invested in clinical diagnostics around 20€ *per capita* – with Sweden 26.7€ *per capita,* Italy 26.0€ *per capita*, and France 25.7€ *per capita*, although UK just 10.9€ *per capita* –, the investment in IVDs in Poland and Hungary only reached 5.2€ *per capita* and in Slovakia, 4.6€ *per capita*.

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?

The cross-border healthcare phenomenon is today in an incipient stage, but is expected to grow because of the increased mobility of patients and healthcare providers. It is true that the cases of cross-border health as per the four types described in the consultation document are today closely linked to the private initiative, with the exception of the provision of public health services organised jointly by public authorities in cross-border regions. Anyhow, patients without private insurances also have the right to seek for best treatment abroad, and they will indeed claim for this right once they get access to better information about availability of healthcare services and their quality. In order to ensure that this choice is possible, public health systems need to put in place mechanisms to guarantee adequate medical quality and legal certainty when seeking/providing care services abroad.

From the point of view of the Diagnostics Industry, the impact of this development can be positive in terms of facilitating the spread of ***best practices for the prevention, screening and monitoring of conditions***, as well as in relation to ***equal access*** to care, new technologies and innovation.

Healthcare is a fast growing sector with exigent needs of investment to meet its challenge of providing the best care for European citizens. However, budget constraints block innovation and the effective functioning of healthcare systems. The ***coordination of health systems*** could identify synergies and commonalities to reduce costs and allow further research, as well as ensuring access to innovation to all European citizens. Specialisation and ***Centres of Reference*** can be an answer in this sense, namely to deal with some conditions such as rare diseases.

As regards cross-border provision of health services and technologies, some cases are already taking place in Europe. Some international hospital chains and private laboratories offer their services in different Member States. ***Legal certainty is necessary*** to clarify liability in cases such as this one.

Current market concerns related to ***late payment issues, public tenders or taxes*** can distort the functioning of the European internal market for health services. As an example, the Days of Outstanding Sales (DOS) in 2005 go from 30-60 days in UK, to 60-73 days in France or 97-103 days in Hungary. Delays that differ considerably from the DOS experienced in Greece (320 days), Czech Republic (a full year), Portugal (229-354 days varying from month to month), Italy (305-337 days) and Spain (45-675 days, depending on the region. Best performance = Ceuta and Melilla; worse DOS = Valencia). As regards the amounts of debt, in the latest case for example, the Spanish total debt in 2005 represented €54,073.35 Mio. (Source EDMA).

Question 2:
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?

As described earlier, there is certainly a need to improve the current data monitoring efforts performed at European level, to ensure a better overview of the national health systems in the different countries and the identification of best practices. These should include a wider concept of Prevention that includes health monitoring, early prediction and diagnosis. The final goal must be to develop common guidelines on screening, diagnosis and treatment for Europe to ensure best healthcare and equal access for all EU citizens.

Moreover, a careful analysis should be done on the ***information to be addressed to the patient***: type of information on available services, format, ranking of services quality, and credibility of the source of information. In this sense, Europe, as per the initiative of the European Commission should discuss the possibility to recognise, apply and promote trustmarks for health information. With the primordial role that the Internet is acquiring, it may anyhow be a better option to hold this debate in the international sphere and promote the international recognition of any adopted solution.

Question 4:
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?

In the case of the Diagnostic Industry, the European Directive 98/79/EC on In Vitro Diagnostics Medical Devices already includes provisions to ensure that liability is clarified and problems solved.

Question 5:
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)?

In general terms, the coordination of national health systems across Europe, both from the clinical and economic points of view, would improve equal access for all European citizens to best care, medical technology and innovation.

From the clinical perspective, the agreement on common care guidelines and screening/prevention programmes would benefit all citizens at the same time. In this way, citizens from specific countries without access to concrete therapies or screening campaigns will not have to ask themselves: "Why not Us?", why do we not have the same rights as our neighbours?

From the economic point of view, it is necessary to ensure better communication amongst the national care systems (for example, to avoid the leak of public funds the Health Tourism phenomenon is causing in Spain), and to guarantee that offering quality service will not have negative repercussions on the overall functioning of the system.

Moreover, information and coordination processes should also reduce the risk for patients, providers and public systems to suffer from late payment and other related problems when offering cross-border services. In addition, the reduction of red tape would only have

positive repercussions as regards investment in research and new products, better and more effective performance of technologies available, and economic growth and employment.

Current obstacles to foster research in Europe are 1) the complexity to get funding; 2) high taxes and lack of fiscal incentives linked to research initiatives; 3) the labour costs, which difficult preventing the brain drain phenomenon; and 4) the difficulty to get the approval for introduction of new products into reimbursement schemes. Private investment on innovation will be diminished as far as there are no assurances of return on investment.

Question 6:
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?

The current rules guaranteeing the mutual recognition of professional qualifications between Member States, which provide in particular for automatic recognition of professional qualifications, are an important step in facilitating ***movement of health professionals.*** Moreover, EDMA considers that this mechanism of mutual recognition should be reinforced by the development of common clinical guidelines.

Educational programmes for healthcare professionals should be compared and best practices adopted, including an increased attention to *In Vitro* Diagnostics, prevention, nutrition, screening or current and future IVD technologies. No specific course is dedicated to those disciplines in the medical studies (DNA chips, theranostics, etc.). In parallel, mechanisms must be defined to ensure the availability of clear and reliable ***information to citizens***/patients that they can understand (due to the complex picture of diverse languages).

As mentioned above, defined ***medical and diagnostic standards and procedures*** should also be developed starting by a common and global concept of Health from prevention and diagnosis to treatment and recovery of healthy status. These measures should be accompanied by the necessary ***legal certainty on liability*** at European level.

Another issue to be addressed when defining the rules of the future internal market for healthcare is the ***difference existing amongst the VAT rates applied throughout Europe to Health products***, and in particular IVDs. Analysing the current VAT rates applied in Europe, we come the conclusion that the Member States do not share a common concept of the value of Health.

While some countries like Hungary, Poland, Spain or the Czech Republic apply reduced VAT rates to IVDs as well as medicinal products; others like, Belgium, Finland, France Italy, the Netherlands or Romania only admit reduced rates for pharmaceutical products under prescription. In this case, Over the Counter (OTC) drugs and medical devices, including IVDs are not considered essential to healthcare in the same way, thus they do not benefit from a reduced VAT rate. There are as well countries such as Austria, Denmark, Germany, Ireland, Sweden and UK where no reduced tax is applied to healthcare products. This policy, namely in the case of self-testing such as coagulation testing or glucose meters, penalises directly the patient.

In conclusion, EDMA proposes that the European Union agrees to introduce the necessary legal amendments to ensure that all health-related products (not only medicines but also medical devices and *In Vitro* Diagnostics) benefit from reduced vat rates in all Member States, being thus considered as essential goods.

Data as of 1 January 2007, based on EDMA national associations data

	VAT Standard Rates	*VAT Rates for Pharma-prescription*	*VAT Rates for OTC*	*VAT Rates for IVDs*
Austria	20%	20% 0% on reimbursable medicines	20%	20%
Belgium	21%	6%	6%	21% 6% for glucose self-tests
Bulgaria	20%	20%	20%	20%
Czech Rep	19%	5%	5%	5%
Denmark	25%	25%	25%	25%
Finland	22%	8%	8%	22%
France	19,6%	2,1% - 5,5%	2,1% - 5,5%	19,6%
Germany	19%	19%	19%	19%
Greece	19%	9%	9%	19% (9% for some intensive care MDs)
Hungary	20%	5%	5%	5%
Ireland	21%	0% (oral medication) – 21% (other)	0% (oral medication) – 21% (other)	21%
Italy	20%	10%	10%	20% 4% for glucose self-tests
Netherlands	19%	6%	6%	19%
Norway	25%	25%	25%	25%
Poland	22%	7%	7%	7%
Portugal	21%	5%	5%	21% 5% for glucose self-tests
Romania	19%	9%	9%	19%
Spain	16%	4%	4% on OTC pharmaceuticals 7% on OTC medical devices	- 7% for products sold for clinical diagnosis in a sanitary centre - 16% for rent, maintenance or products used in other fields (for example gloves in a University or test not for human diagnosis)
Sweden	25%		25%	25%
Switzerland	7.6%			7.6%
UK	17.5%	0% for medicines administered personally by Doctors 17.5% on self-administered medicines *(HMRC source)*	17.5%	17.5%

Question 7:
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?

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?

EDMA consider that the proposals included in the consultation by the European Commission services are the keys for the success of the future European Health. Developing shared evidence for policy making, to agree on clinical guidelines and facilitate specialisation and foster the development of networks of centres of excellence. Approximating national health systems through the open method of coordination and creating joint structures to guarantee equal access to the best quality healthcare. And finally, defining monitoring and evaluating systems such as impact assessments, for the appraisal not only of purely health policies but also all other policies with a possible impact in health.

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?

The ***Open Method of Coordination (OCM)*** should be a useful tool to start introducing certainty and clarity in the concepts (Prevention, Healthcare) and practical organisation (guidelines, protocols, screening programmes, access to healthcare and innovation) across the EU, to ensure that all citizens benefit from the best quality of life and healthcare.

An effective implementation of the OMC should ensure that current efforts to collect comparative information about healthcare in Europe result in productive and concrete actions. The process should allow setting up common policy goals or guidelines to be transposed into national and regional policies; specific benchmarks and indicators should measure best practice; and results should be monitored, evaluated and made public. Impact assessments, both for dealing with health topics and for all other fields (Health in All Policies) must be implemented.

In particular, the full commitment to the OMC should help identify specific problems experienced by the national health systems (including issues related to Late Payments or Tenders). The exchange of information about the different performance of the systems and the solutions each of them applies should result in the definition of best practices to be implemented in Member States with problems to overcome their weaknesses.

A commitment from Member States is indispensable to discuss and analyse commonalities amongst the various health systems, and the possibility to adopt joint solutions to coordinate the procedures and reduce costs.

As a result of the coordination efforts, a ***European body*** should perform Health Technology Assessments and decide upon the cost-benefit of new IVD tests and their “Added-value” for the quality of patient care, in order to recommend them or not for inclusion on the national reimbursement schemes.

This new agency should be independent and autonomous. In particular, the involvement of citizens and patients representatives, together with health professionals and industry, in such an agency would be essential.

Such a European body would ensure that national or regional budgetary circumstances do not determine when patients will benefit from a new technology already available in other countries, thus ensuring equal access. At the same time, this neutral European approach to evaluate new technologies would provide fair conditions to players in all countries, avoiding the current situation in certain Member States where manufacturers do not have clear procedures to submit their new CE-marked tests and apply for reimbursement. The responsibility for the amount of reimbursement would remain with the national healthcare systems.