Dear Ms/Mr,

Hospitals, pharmaceutical and medical device companies, organisations of health care professionals, etc., are increasingly merging together even on a cross-border level. In view of this kind of globalisation in the health care sector, our three law firms specialised in health care have decided to create a European network specialised in medical law and health law, named EuMedLex.

With our law firms we aim to build a highly specialised network to meet the demands of customers in this European and globalised market. We are pleased to send you a newsletter that deals with some recent developments at the European level that are of importance for health care actors. They relate to medical devices, e-health and ….

EuMedLex will inform you regularly through publications, lectures, brochures etc. of future developments that may be of interest of our customers in the health care sector.

On behalf of EuMedLex,

Callens Advocatenkantoor	Dierks + Bohle	Lucas-Baloup
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THE EUROPEAN COMMISSION AND ISSUES RELATING TO E-HEALTH AND TELEMEDICINE

1. The importance of e-health

Electronic health records

The European single market in health care is developing and cross-border activities in health care are increasing. Patients tend to be treated more in other Member States than in the past, especially if waiting lists exist in the country where they live. Moreover, doctors ask for more, and more varied, telematic information from their colleagues. Hospitals are creating hospital networks that store a great deal of medical data on patients. Patients often order medicinal products through the Internet from pharmacies that are located in other countries. All these developments are related to e-Health. E-health refers to information and communication technologies for health.

The European Commission has invested in the past in several research programmes related to e-Health. Moreover, the European Commission established an action plan for a European E-Health area in 2004. However, the Commission observed a low implementation of telemedicine applications in real-life medicine and is now identifying the barriers and triggering factors. The Commission plans to issue a Communication on Telemedicine and innovative ICT tools for chronic disease management in October 2008.

2. Towards more European rules

The involvement of the Commission on e-Health is important. The organisation of health care is up to the Member States but e-Health (including telemedicine services) has the potential to be used in cross-border settings. The Commission has a specific mandate to address cross-border care issues which cannot be addressed on a national basis alone (see also EUROPEAN COMMISSION, "Questionnaire. Telemedicine. I2010 eHealth sub group Members", 2007, p. 2.). This is why it is desirable that e-Health gets much more attention at the EU-level. Several issues need to find a more European answer. We describe some of them below.

- Electronic health records in hospitals and DNA banks

Member States are working on the introduction of electronic health records, i.e. comprehensive medical records providing ready availability of health data for medical treatment and allied purposes.

The Data Protection Directive provides several measures to be taken by the controller of a file in order to guarantee the right to privacy of the data subject. However, article 8 of the Directive is too vague to provide for good legislation at the EU-level with regard to the further use of data and the creation of electronic health records nation-wide or in big hospital chains.
The Article 29 Working Party is not convinced that relying only on the obligation to professional confidentiality provides sufficient protection. If more persons may have access to the record because the records are kept by hospital chains, more specific safety measures must be taken and the patient must be asked for consent as to which categories of persons may have access to the record.

University centres also often store blood and human tissue samples that can be used for research purposes. Since DNA sequences of samples can be analysed via and stored on computers, it is obvious that the distinction between the processing of human tissue and the processing of health data becomes small. Several European documents already refer to the use of human tissue, such as Directive 2004/23/EC and the Regulation on Advanced Therapy Medicinal Products. However, these documents remain too vague to provide Member States with guidance on further use of tissue, blood and DNA sequences for treatment and other purposes.

Reimburse-ment and liability

- Reimbursement and telemedicine

The E-Commerce Directive does not regulate the reimbursement of telemedicine services, which

falls under the competence of the Member States. European and international telemedicine projects have often failed because they were too expensive for the patients and reimbursement by their health insurance funds was not possible. An essential condition for reimbursement was never fulfilled, i.e. the physical presence of the (tele)-physician with the patient at the moment of performing the medical treatment. The refusal to reimburse medical costs if there was no physical presence might have been reasonable in a period without ICT. It could be argued that a physician who only listens to a patient on the phone cannot make a good diagnosis and that therefore reimbursement would not be possible. The revolution in the ICT sector makes it perfectly possible nowadays to collect the required medical information for a diagnosis at a distance without being physically present. The question is then whether it is still reasonable under EU law to refuse reimbursement just because the physician did not see the patient physically.

- Liability and telemedicine

We believe that the EU may play an important role even with regard to the liability issue. It is not good for the free movement of patients and health care services in Europe if patients are subject to different liability schemes. Some countries like France and Belgium have recently enacted so called no-fault legislation related to health care. The no-fault issue is already considered in the EU Directive on products liability but is being increasingly expanded to other domains like health care delivery. Good compensation for patients if something goes wrong during a medical intervention might indeed be considered an important right for patients. It is not good for patients or health care professionals if this right is regulated all over Europe in a different way. This will not promote the use of telemedicine. Therefore, EU legislation should require Member States to provide similar rules for compensation; this would enhance the free movement of patients and health care services and ultimately the use of e-Health tools.

3. Medicinal products and the Internet

The EU has enacted several directives and regulations on medicinal products and medical devices.

However, it is important to verify how ICT and in particular the Internet is playing an important role in the selling of medicinal products. The Community Code of medicinal products regulates marketing authorisations for medicinal products, manufacture and distribution of medicinal products, publicity issues, etc. but does not have specific rules on the internet and medicinal products.

It is legal, at least for OTC products, to buy medicinal products without being physically in the pharmacy. However, Member States will enact different rules for prescription medicinal products. Some Member States may argue that online selling should not be legal while other Member States may accept ordering prescription products through the internet. To ensure that medicinal products are sold safely over the internet it might be desirable for new rules to be enacted at the EU level.

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MEDICAL DEVICES

Directive 93/42/EEC

Directive 2007/47/EC

AFSSAPS

COMPATIBILITY BETWEEN MEDICAL DEVICES AND INCURRED RESPONSIBILITIES

1. Introduction

(In) compatibility between medical devices:

- brings into conflict manufacturers, some of them being selling accessories they affirm to be compatible with those of other manufacturers, who in turn denounce the quality and performance of the combination,
- may compromise the clinical condition or the safety of patients or users or, where applicable, other persons, medical practitioners or private/public hospital personnel, and make them responsible for non-observance of the instructions for use supplied by the manufacturer.

2. Directive 2007/47/EC of 5 September 2007

on medical devices did not modify either the provisions of Article 12 of previous Council Directive 93/42/EEC of 14 June 1993 about particular procedures for systems and procedure packs, or the definition of "accessory" referred to in Article 1.-2.(b) as "an article which while not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device". As Article 1.-1 provides that "accessories shall be treated as medical devices in their own right", for the purposes of the Directive accessories are not themselves medical devices but are "treated as" medical devices.

But Article 12 only concerns elements a manufacturer puts together in order to place them on the market as a system or procedure pack on his own responsibility as to the result.

The difficulty appears, in practice, when two or several producers' medical devices are put together by the users while a producer of at least one of the elements of the combination does not approve this assembly and mention it in the instructions for use.

3. Directive 93/42/EEC of 14 June 1993

in Annex I concerning Essential Requirements deals with compatibility between medical devices in:

- Point 9.1: "If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use."
- Point 13.6: "Where appropriate, the instructions for use must contain the following particulars: […] (c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;"

Therefore, an obligation as to security and performance of the assembly, as well as an obligation to communicate restrictions on use in the notice and in labelling, is clearly imposed in the Essential Requirements.

4. French Health Products Safety Agency (AFSSAPS)'s clarification of 14 February 2007

AFSSAPS published a Clarification to users in which it is particularly recommended:

"It is essential to verify the assertions of the manufacturer of the medical device announced as compatible in its instructions for use. Indeed, they are the fundamental element which allows explicit determination of the claims which engage the manufacturer's responsibility.
"When a manufacturer of a medical device announced as compatible with another does not mention in the instructions for use the list of

medical devices considered as compatible, the user may ask the manufacturer for confirmation of compatibility.
"The user's responsibility is engaged for using medical devices outside the scope of the manufacturers' instructions."

5. Conclusion:

Any actor in the market should be aware of the responsibility incurred by:

- a distributor in declaring "compatible" an association of an accessory (that he sells) with the medical device of another manufacturer who rejects the assertion of compatibility and limits his guarantee to associations of medical devices which he enumerates,
- a user in assembling elements the various manufacturers of which did not unanimously declare that they harmonised safely to constitute a high-performance medical device.

Instructions for use and certificates of compatibility engage the responsibility of the manufacturers and the distributors who establish them. If requirements are void, updated, exceeded by the technical or technological evolution of one of the elements of the combination, and the relevant material is not revised at the appropriate time, the author of a deceitful assertion engages his civil and penal liability if the medical device concerned becomes dysfunctional and causes damage.

Numerous declarations of incidents are registered within the framework for oversight of medical devices and users, hospital pharmacists, doctors, bursars of public and private health establishments, and patients at home have to exercise caution and rigour in dealing with such risks, as they often rush to take advantage of promotional prices on accessories when the qualities claimed by the distributors do not equal those of the original medical devices of proven performance.

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GERMAN PHARMACEUTICAL MARKET AND COST-BENEFIT ASSESSMENT

IQWiG new method paper encounters heavy criticism

Pharma-ceuticals

The German pharmaceutical market and its significant role in international pricing is confronted with a potential new barrier to market entrance. In recent years reimbursement restrictions have already been imposed by the Joint Committee (GBA) some of which are based on benefit assessment reports issued by the newly founded Institute for Quality and Efficiency in Health Care (IQWiG). Germany has followed the UK (NICE) and France (HAS) in Health Technology Assessment with a different model. IQWiG merely lays the grounds for reimbursement decisions without own decisive power. On this basis, however, the vast majority of drugs assessed so far, e.g. short acting insulin analogues, atorvastatin and montelukast have been classified as "without additional benefit" and subject to restriction in reimbursement and pricing has followed or is expected. Latest legal reforms have introduced a new task for IQWiG's director, Professor Peter Sawicki. Since 1st April 2007 cost-benefit-assessment shall be undertaken for drugs with patented substances and other drugs 'that are of particular importance'.

Cost-benefit-assessment

On 24th January 2008 IQWiG presented a method proposal based on an 'Efficiency Frontier Analysis'. The innovative concept also includes an analysis of budget impact. The 'Efficiency Frontier' is a graphic presentation determined on the one hand by benefit units and cost units on the other. According to the IQWiG the cost axis illustrates the costs that are accrued in order to achieve the specific benefit previously determined. This graphic presentation will be used to 'make it clear at a glance which existing therapies are efficient and which are not.' (http://www.IQWIG.de/index.738.en.html).

This method has been presented to the public on several occasions and is subject to severe criticism. The pharmaceutical industry and many specialists in health economics agree that such a procedure does not at all suffice the legal requirement of taking into account international standards of health economics. Especially the cost structure of drugs from the past encounters scepticism, since pricing is influenced by development of generics and fixed pricing schemes. This gives way for the question at what cost innovation may enter the system.
An example: AChE-inhibitor's DDD cost was at 1.08 € in the 90s. They are down to 0.11 € by now. Substantial benefits from a new therapy will exceed this cost by far. What shall the basis of an efficiency frontier be?

The most recent statement of the highly reputed 'Verein für Socialpolitik' (the largest German speaking community of economists founded in 1837) focuses on five major points of criticism towards the IQWiG suggestion:

1. The suggested cost-benefit-assessment is confined to the perspective of the Statutory Health Insurance (SHI). Cost effects in other parts of the social security system need to be taken into account to be in line with the legal preconditions according to §35b SGB V.
2. The method paper neglects basic categories of relations between cost and benefit. Thus important questions of economic evaluation are not been dealt with in an international manner.
3. There is no precise definition of the term 'benefit' in the paper. The requirement for determining a clear and transparent procedure to determine different benefit components is not met.
4. The concept of determining an efficiency frontier is unrealistic since it is based on the assumption that all drugs included in the procedure can be assessed in the same manner. However, there is no scientific or normative reason that can support such a suggestion.
5. According to the paper economic evaluations are confined to the particular indication (disease). If reimbursement decisions are based on such a strategy the impact on the allocation of resources is being neglected.

Decisions based on such a system will inevitably become erratic. Therefore a parameter for benefit like QALY is required to raise reimbursement decisions of the Joint Committee to a transparent level.

All over all the 'Verein für Sozialpolitik' deems this proposal of cost-benefit-assessment as unsuited to comply with legal and practical requirements.

What are the next steps? According to recent experiences with IQWiG experts consider it improbable that the public discussion will bring about major changes to IQWiG's new methodology. The legal frame work does not foresee a specific accountability of IQWiG to the Joint Committee nor to the Ministry of Health concerning the methods. However, it can be expected that IQWiG's Board of Directors will have some influence on the further development. Since the board is dominated by funds and health care professionals (the industry is not represented) the cost containment potential of the method might be the decisive factor.

If the methodology will be accepted as suggested the impact on international pharmaceutical pricing might be noteworthy. Pharmaceutical innovations would be assessed on the basis of an efficiency frontier that is based on price development in particular indications and be subject to a somewhat arbitrary scale. Looking at the importance of the German market in terms of international pricing these effects will be more than national. Facing this predicament some within the pharmaceutical industry feel that producer-to-funds negotiations on pharmaceutical pricing might be favourable. However, the public dispute on these issues in the course of this year will be a most interesting one.

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