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EARLY BENEFIT ASSESSMENT OF INNOVATIVE PHARMACEUTICALS

On 1 January 2011, the Federal Drug Market Reorganization Act (AMNOG) came into effect which introduced mechanisms for the pricing of pharmaceuticals that recently accessed the German market by reference to other therapeutic equivalents. Therefore, AMNOG instituted a process of early benefit assessment for pharmaceuticals with new active ingredients.

Early benefit assessment

Within a period of three months the Federal Joint Committee (G-BA) will assess whether the new pharmaceutical provides an additional benefit in comparison to an appropriate comparator set forth by the G-BA. For this purpose, the pharmaceutical entrepreneur shall submit a dossier to the G-BA that contains information regarding the licensed area of application, the medicinal benefits, additional medicinal benefits in respect to appropriate comparable therapies, the number of patients in a group of patients for whom medical benefits exist and last not least the therapy costs which will arise for the statutory health insurance funds. The manufacturer shall submit this information together with clinical studies. These studies must be implemented in compliance with international standards of evidence-based medicine and, in particular, in the form of direct comparative studies. During the approval time, the G-BA will carry out an own assessment procedure on basis of the information provided by the pharmaceutical entrepreneur, or refer the matter to the Institute for Quality and Efficiency in Health Care (IQWiG) for evaluation. The review will be published via Internet and the pharmaceutical entrepreneurs, their associations and experts are then given the opportunity to make verbal or written statements at hearings. After another three months the G-BA will pass a resolution based on the benefit assessment and the hearings.

Price Negotiations

If the G-BA decides that the pharmaceutical is truly innovative and provides a previously unrealized advantage or benefit, a rebate granted by the pharmaceutical entrepreneur (*Erstattungsbetrag*) will be negotiated between the manufacturer and the umbrella organization of German sick funds (National Association of Statutory Health Insurance Funds - *GKV-Spitzenverband*).
If no agreement is reached, the matter will be referred to a central arbitral body that will set a price on the basis of European reference pricing.

Reference Price Group

If the resolution finds that the pharmaceutical provides no or insufficient therapeutic improvement, the medicine will be classified as a fixed-price drug and will be clustered in a reference price group together with a limited number of pharmaceuticals which are considered to be therapeutic equivalents. A maximum reimbursement amount is computed for each group using an econometric model that takes into account the prices of existing products and ensures that a determined number of the clustered pharmaceuticals will be available to patients with no additional payment. The pharmaceutical entrepreneurs may set their price above the maximum reimbursement amount. However, the patient will be required to pay the difference between the costs of the prescribed pharmaceutical and the maximum reimbursement amount in addition to any applicable co-pay.

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If the pharmaceutical is not suitable for fixed pricing, a rebate to be granted by the pharmaceutical entrepreneur will be negotiated.

Outlook

On 4 October 2011 the first pharmaceutical Brilique® (Ticagrelor) has passed the assessment successfully. The IQWiG has come to the conclusion that Ticagrelor provides considerable added benefit to patients with myocardial infarction without changes in the ECG (NSTEMI), as well as to patients with unstable angina pectoris (UA). It remains to be seen whether this will lead to successful negotiations, too.

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EU AND GERMANY: DATA PROTECTION AND E-HEALTH

Living in Berlin, business meetings in Paris combined with a French radiologist's appointment and a second medical opinion from Rome? Are we truly European yet? And how is our sensible health data protected when we use E-Health services throughout the European Union? Is sensible personal health data at risk?

The European Union provides an internal market which is mainly based on free movement of goods and services. It also ensures free movement of union citizens. The new Directive 2011/24/EU defines common standards on the application of patients' rights in cross-border healthcare.

Personal Health data is well protected throughout the European Union: The European Data Protection Directive (Directive/1995/46/EC) defines common privacy standards which generally enable the transfer of personal data between European member states as long as prior informed consent or a legal provision justify the collection, processing or use of personal data. As soon as sensible health data is affected, high standards of data protection have to be obeyed and special provisions apply. Contractual data processing agreements open secure pathways for successful outsourcing projects. As soon as medical professionals are involved in the handling of personal data, professional disclosure rules have to be kept in mind in order to avoid unjustified disclosures.

Practical challenges, for example the need for mutually respected eIDs and sufficient cross border eAuthentication procedures, have been identified on European level and governmental panels are working on possible solutions.

As a conclusion the European Union already offers a broad variety of possible transborder (E-) Health services and additional opportunities arise at the horizon. (E-) Health is already becoming truly European.

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TELEMEDICINE – RECENT DEVELOPMENTS AND FUTURE CHALLENGES

Within the "Commission Staff Working Paper" Sec (2009) 943 final, June 2009 titled: "Telemedicine for the benefit of patients, healthcare systems and society" the European Union certified telemedical services a positive potential to meet future societal challenges in Europe´s healthcare systems. Hence telemedicine was intended to be promoted also on a European level. To date no further steps with impact on the development of telemedicine on the European level have been undertaken. Directive 2011/24/EU of the European Parliament and of the Council as of 9th of March 2011 include support of eHealth in articles 14 and 15.

At this stage it remains questionable whether these statements of intent will have any impact on the further development of telemedicine. In particular cross-border services that are rendered without personal contact between patient and physician (such as teleradiology, telemonitoring, online-counseling e.g.) may need not only further review but also European regulation, as many believe. Other issues are the reimbursement, authorization or registration of service providers, the applicable law as well as the determination of quality standards and guarantees regarding patients´ rights may have to be put on the agenda on a European level.

In Germany a discussion has sparked on the scope of feasibility of telemedicine-services under the aspect of professional law (sec. 7 para. 3 "Musterberufsordnung für Ärzte" – doctors´ professional law). The availability of medical online-counseling has currently increased and thus promoted the discussion in regard to professional law and liability rules as well as in regard to questions of data protection law and quality issues. Nonetheless German cabinet proposed a draft of the "Versorgungsstrukturgesetz" (*Act for the amendment of supply structures in German healthcare*) which includes the intent to promote telemedicine-services in order to secure a countrywide and well accessible medical supply. The further development of telemedicine services shall also help to maintain sufficient security levels for medical treatment and to ensure the medical supply in regions with less inhabitants.

As a matter of fact great chances and possibilities may collide with member state regulations and restrictions in health care law. Thus a European initiative for the standardization of telemedicine services might be helpful – since technical development will not stop at national borders.

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EUROPEAN COURT OF JUSTICE (CASE 34/10) – NO PATENT PROTECTION FOR HUMAN EMBRYO STEM CELLS

The European Court of Justice in Case 34/10 has decided with regards to the question whether human embryo stem cells may be subject to a patent or not. As a result European Court of Justice ruled that human embryo stem cells as a rule shall not be patentable. German Federal Court of Justice asked for a decision in the light of Directive 98/44/EC of the European Parliament and of the Council dated 6 July 1998 on the legal protection of biotechnological inventions. In detail the questions concerned the definition of human embryo in terms of Article 6 (2) (c) of the Directive as well as the definition of "use of human embryos for purposes of industrial or commercial purposes" set out in Article 6 (2) (c) of the Directive.

The decision

The court stated that any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted, and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a 'human embryo'. European Court of Justice states that the competent national court needs to

ascertain, in the light of scientific developments, whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a 'human embryo' within the meaning of Article 6(2) (c) of Directive 98/44.

In the court´s opinion the exclusion from patentability concerning the use of human embryos for industrial or commercial purposes set out in Article 6 (2) (c) covers the use of human embryos for purposes of scientific research, only use for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it being patentable.

As a third part of its ruling, the court states that an invention is excluded from patentability wherever the prior destruction of human embryos or their use as base material is required. This shall apply regardless to the stage of growth in which the destruction or use takes place.

Conclusion

The court´s ruling receives divergent feedback. On the one hand scientists fear a so-called "brain-drain" to countries outside of Europe and see a risk for the European scientific landscape. On the other hand

there are opinions who welcome this as a positive signal for protection of human life.

One will have to await the ruling´s influence on scientific research. Pharmaceutical industry until now remained relaxed. Stem cell research anyhow will not be fully impeded as scientific research will persist feasible in regard to adult stem cells as well as to stem cells which are derived from umbilical cord. In this respect the ruling could have positive and focusing effect on such research projects. It is after all a contribution to the German / European discussion in biotechnology law regarding protection of human life even though the question of a conduct towards blastocysts remains unsolved still.

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EU DIRECTIVE 2011/24/EU ON THE APPLICATION OF PATIENTS' RIGHTS IN CROSS BORDER HEALTH CARE

The Directive on patient rights in cross border health care as of 9th of March, 2011, was published in the Official Journal of the EU, 4.4.2011, L 88/45. It applies to individual patients who decided to receive treatment in a member state other than the member state of affiliation. The Directive includes general principles for reimbursement of cross border health care to ensure that the insured person will receive reimbursement for services rendered in member states other than the state of affiliation. Administrative procedures of cross border health care and regulations on the recognition of prescriptions issued in another member state are also considered in order to reach mutual assistance and cooperation in health care.

The Directive's regulations may have major impact on many administrative proceedings in the respective member states. In article 14 it promotes e-health designated by the member state such as cross-border health care via information and communication technology as well as other innovative health technology utilization (see article 15 of the Directive).

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FUTURE OF MEDICINE = "PERSONALIZED MEDICINE"? – EUROPEAN STATUS QUO

"Personalized Medicine", "Individualized Medicine" or "stratification in medicine" is on everyone´s lips these days. All terms aim at the same methods, namely the targeted utilization of a customized treatment for individuals which were classified in specific patient populations according to their molecular profile beforehand.

Based on the assumption that certain treatment methods and in particular drug applications have different effects on the individual patient (e.g. due to genetic constitution of the individual) scientists in this field hope for a revolution in effectiveness of medical treatment. By detecting certain parameters, such as existence of specific receptors, via genome sequencing or other analytical / diagnostic measures (biomarkers e.g.) it can be predicted whether a treatment will have positive effect or if it does not have effect at all or if it even leads to inadvertent negative events / side-effects. Trial and error may be avoided by these tests. As of May 12th/13th 2011, a conference on European perspectives on Personalized Medicine took place in Brussels which had been organized by the Health Directorate of the European Commission (DG Research and Innovation). John Dalli, Commissioner for Health and Consumer Policy and Máire Geoghegan-Quinn, Commissioner for Research, Innovation and Science supported the conference.

Aside from research and cooperation challenges the conference pointed out, that also regulatory challenges will have to be met in the coming future. Crucial aspects would be a rapid availability of personalized medicine products to patients whilst ensuring the health and safety of the patient. The conference report mentions required revisions of EU legislation such as the Clinical Trials Directive(2001/20/EC) and the three medical device Directives, including the Directive on in vitro diagnostic medical devices (98/79/EC).

In Germany meanwhile diagnostics producers struggle with reimbursement issues regarding their personalized medicine products which require a "two-step-approach", meaning a diagnostic test prior to the utilization of a medicinal product (drug). The vast majority of the personalized medicine products require a prior diagnostic test by authorization (wording in the SPC). As German system requires a medical treatment/diagnostic method to be explicitly mentioned in one of the respective reimbursement-acts or regulations in order to receive reimbursement, some of the diagnostic test methods are not yet "listed" and therefore not reimbursed even though the subsequent drugtreatment is subject to reimbursement since the date of its authorization on. Due to this fact personalized medicine cannot use its potential in these cases. The treatment will not be utilized or it will be utilized without the knowledge from the prior tests, - leaving it to luck whether the treatment has an effect or not. The proceeding for implementation of a (diagnostic testing-) method in the respective regulation may last about 1 to 4 years at this stage. Hence the use of the innovative method "personalized medicine" in these cases still meets many obstacles. European initiatives and eventually amendments in the set of current regulations would have the potential to reach the first step into a future "Personalized" Medicine.

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HEALTH MADE IN GERMANY - INITIATIVE FOR THE EXPORT OF GERMAN HEALTH CARE SERVICES

German health care providers being battle-tested by numerous and repetitive legal amendments regarding authorization requirements and reimbursement issues and other regulatory restrictions now gain Confederate support from the world of politics. The team consisting of German Minister of Health (Daniel Bahr) and German Minister of Economics (Dr. Philipp Rösler, former Minister of Health) is currently igniting and promoting an initiative for the export of health care services called "Health made in Germany"

(link in English language: **http://www.health-made-in-germany.de/EIG/Navigation/EN/root.html).**

The initiative is planned to encompass projects in regard to the export of goods and services as drugs, medical devices, biotechnology and telemedicine. The project is based on the assumption that German Health care providers will continue to open new markets and to cooperate abroad. "Marketing travels" of members of the German parliament and of business representatives are planned not only throughout Europe.

The numbers of German health care system - besides the U.S. and Japan, Germany is by far the largest health care market with EUR 408.66 billion total volume of health care industry in 2007 and with a 10.5 percent share of GDP in 2008 - and a strong experience and know-how in health care give basis for the contribution of knowledge and networking between health care providers and life sciences stakeholders, which shall cross national borders. "Health made in Germany" will roll out by offering expert information on the health care

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ADVERTISING OF MEDICINAL PRODUCTS – SPECIFIC GUIDANCE BY THE EUROPEAN COURT OF JUSTICE

Questions concerning advertising of medicinal products are more and more coming in front of the Court of Justice. Two new cases of 5th of May 2011 illustrate this assessment.

In a first case of 5 May 2011 (C-316/09), a pharmaceutical company presented a choice of prescription-only medicinal products on its website. The website was accessible by using a link which was not password-protected. The website was accordingly freely accessible, reproducing the packaging of the product, the therapeutic indication and the leaflet containing the instructions for use of the product. A competing firm took the view that such conduct must be prohibited.

The Court decided the following: The dissemination of information about prescription-only medicinal products by a pharmaceutical undertaking on a website is not prohibited if this information is accessible only to someone who seeks to obtain this information and if that dissemination consists solely in the faithful reproduction of the packaging of the medicinal product, in accordance with Article 62 of Directive 2001/83, and in the literal and complete reproduction of the package leaflet or the summary of the product's characteristics approved by the competent authorities. On the other hand, if the dissemination of information relating to a medicinal product has been selected or rewritten by the manufacturer and can only be explained by

advertising purposes, it is prohibited to publish this information on such a website

The second case of 5 May 2011 (C-249/09) was about a company who had published an advertisement for a prescription-only medicinal product in a medical journal for professionals. The competent authority asked the company to cease the publication of the advertisement for the medicinal product and not to publish any information on this product which was not part of the official summary of product characteristics in advertisements for that medicine.

According to the Court, Article 87 of Directive 2001/83 underlines the general nature of the obligation that information contained in advertising for medicinal products must comply with the particulars of the summary of product characteristics. Thus, Article 87(2), that provides that all parts of the advertising of a medicinal product must comply with the particulars listed in the summary of product characteristics, encompasses quotations from medical and scientific literature, as it does any other part of an advertisement for a medicinal product. Those rules also apply to all parts of advertisements directed towards persons qualified to prescribe or supply medicinal products, since in that type of advertising too, incorrect or incomplete information can clearly endanger people's health and thus jeopardize the fundamental objective pursued by Directive 2001/83.

Article 87(2) of Directive 2001/83, as amended by Directive 2004/27, easily leads to the interpretation that the publishing of advertisements for pharmaceuticals which are directed at professionals involved in the supply or prescription of medicinal products is prohibited by this directive if the advertising includes claims which conflict with the summary of product characteristics.

However Article 87(2) of Directive 2001/83 cannot be interpreted such that it requires that all claims which are made in advertisements for a medicinal product and which are directed to professionals who are qualified to prescribe or supply them should be included in that summary of product characteristics or be derivable from information in that summary. Indeed, such an interpretation would render Article 91(1) and Article 92 of that directive meaningless, since those provisions authorize the publication of supplementary information in advertisements addressed to healthcare professionals, provided that it is compatible with the summary. Such information, firstly, may not be misleading and is to encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties. Secondly, the information must be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion in regard to the therapeutic benefit of the medicinal product concerned. Finally, quotations, tables and other illustrations taken from medical journals or other scientific works are to be clearly identified and the precise sources indicated, so that health professionals are informed of these and able to verify them.

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MAIL ORDER PHARMACIES: CURRENT DEVELOPMENTS IN GERMANY

The Bundesgerichtshof (German Federal High Court, in short: BGH) interprets the German Pharmaceutical Law (Arzneimittelgesetz, in short: AMG) in favor of mail order pharmacists.

By decision of 14 April 2011 (file n°: I ZR 129/09) the BGH has decided that a pharmacist who owns the permission to sell prescription drugs by mail order is allowed to dispatch drugs that are prepared in advance in the pharmacy (formulation drugs) by mail order. This question had before been judged differently by the Higher Regional Courts of Munich and Hamburg.

Pharmacy-manufactured drugs are principally considered as finished drugs according to German pharmaceuticals law, since they are not made for the individual case, but are prepared in the assumption of prescriptions and in advance of these.

Therefore, they are subject to the common obligation for registration of finished drugs acc. to section 21 AMG. But section 21 para. 2 n° 1 AMG also includes an exemption from the obligation for registration of pharmacy-prepared drugs which requires among other things that these drugs are prepared in the frame of the common pharmacy operations.

In the decision of 14 April 2011 the BGH has now decided that the common pharmacy operations in section 21 para. 2 n° 1 AMG also include the distribution by mail order dispatch. In the opinion of the BGH, the concept of common pharmacy operations does not refer to a mere empiric and traditional component but to all activities which are permitted under current law. In regard to section 11a of German pharmacy law which allows mail order pharmacies, this distribution channel is to be considered to be part of the common pharmacy operations.

Also if the decision only treats a single question of mail order pharmacies, several comments of the BGH indicate the current understanding of the nature of pharmacy operations and/or pharmaceutical trade. The concept of common pharmacy and its traditional connotation have changed: mail order pharmacies are an integral part of the German pharmacy system.

Tobias Volkwein

THE APPLICATION OF COMPETITION RULES IN THE HEALTHCARE SECTOR: THE IMPORTANCE OF SERVICES OF GENERAL ECONOMIC INTEREST (SGEI) COURT OF JUSTICE DECISION OF 3 MARCH 2011

One of the key issues when applying the principles of competition law to the health care sector is how to find a balance between the protection of competition and the protection of public interest, such as e.g. the quality of health care. In literature it is often argued that free competition does not necessarily lead to the best quality of care.

A solution to this issue can be found in the TFEU (Treating on the Functioning of the EU) itself, namely through the concept of SGEI (Services of General Economic Interest). Undertakings entrusted with SGEI are subject to competition rules, but only in so far as the application of such rules does not obstruct the performance, in law or in fact, of the particular tasks assigned to them (article 106, §2 TFEU).

The importance of the concept of SGEI was confirmed in the AG2R-case (ECJ, 3 March 2011, C-437/09). Here the question was raised if the statutory provisions for compulsory membership in a supplementary healthcare scheme which are given for specific sectors are in compliance with the current competition rules. The affiliation to a complementary insurance (health, accident) is obligatory for specific sectors and provided by assigned bodies as in this case the insurance company AG2R. The designated insurer has the official mandate to offer the supplementary insurances without that the companies of a respective sector are granted a waiver of the affiliation obligation.

The ECJ confirmed that an exclusive right was granted to AG2R to receive and manage the contributions paid by the employers and employees in that sector under that scheme. A scheme for supplementary reimbursement of healthcare costs such as that managed by AG2R is, however, characterized by a high degree of solidarity. In addition, particular constraints are placed on AG2R, notably constraints of a financial nature, with a view to ensuring the continuity of cover granted to the persons insured. For these reasons, the ECJ found that AG2R was entrusted with the provision of SGEI. Therefore, the ECJ decided that article 106, § 2 TFEU must be interpreted as not precluding for public authorities from granting a provident society an exclusive right to manage a scheme for supplementary healthcare cover in circumstances such as those of the case.

The decision shows that to avoid antitrust scrutiny, governments must clearly entrust health care players with the responsibilities of the provision of SGEI. This is not only of importance when governments assign exclusive rights, but also when they provide financial aid to health care players.

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