Morgan Lewis

EUROPEAN LIFE SCIENCES REVIEW

Issue 3 – July 2016

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Welcome to the third issue of our EU Life Sciences Review that covers some of the most critical developments in the pharmaceutical and medical technology sectors in the last month and is produced by our life sciences lawyers in London, Frankfurt, and Paris. If you have any questions on any of these issues, please contact Paul Ranson.

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Brexit

On 23 June 2016, the United Kingdom voted in favour of leaving the European Union (EU). This decision could have complex short - and long-term legal implications regarding the UK and the EU itself across all industry groups including life sciences. We will be circulating a detailed paper on this topic within the next couple of weeks.

To gain immediate access to our most recent guidance on Brexit, please visit the Brexit Resource Centre.

Devices Regulation

Medical Device and IVD EU Legislation – Update

After eight years of negotiations and following the tripartite meeting among the European Parliament, the Council, and the European Commission on 25 May, a political agreement has been reached on EU Medical Devices Regulation and In Vitro Diagnostic Devices Regulation. The procedure is expected to finish later this year with the legislation to be adopted by the end of 2016 or in early 2017 and becoming effective respectively 3 and 5 years later. Sticking points upon which the negotiations finally hinged included re-use, periodic update safety reports (PSURs), proposals in relation to genetic counselling in relation to in vitro devices, and obligatory liability insurance for manufacturers. Read the report.

EU Guidelines mHealth Apps

The European Commission recently released a first draft of proposed mHealth app assessment guidelines. This follows the Commission's public consultation titled 'Green Paper on mobile health' in April 2014 with the results published in January 2015.

The guidelines are designed to address the handling and assessment of the health and safety risks related to mHealth apps, with a particular focus on clinical evidence, claims on the purpose and functions of mHealth apps, and test and validation of the apps' performance.

A final version of the guidelines is anticipated by the end of 2016. See the first draft.

Pharmaceuticals Regulation

Off-label Pharmacovigilance

Following questions and comments by the European Federation of Pharmaceuticals Industries and Associations, the European Medicines Agency (EMA) has released for public consultation a reflection paper on collecting and reporting information on off-label use in pharmacovigilance. The paper outlines a proposal for the collection and reporting of information on off-label use by Marketing Authorisation Holders (MAHs) in relation to their pharmacovigilance obligations. The paper distinguishes between off-label use which does and does not result in harm to a patient and considers the requirements and possible consequences for the MAH in each case. Some member states already have in place specific national guidance regarding the notification by MAHs of practices of off-label use of medicines at the national level. The consultation is open until 29 July 2016 and can be found here.

Draft Guideline on Clinical Trials and Human Frailty

The EMA has recently consulted on a new draft guideline—Points to consider on frailty: Evaluation instruments for baseline characterisation of clinical trial populations EMA/CHMP/778709/2015. Older persons make up a large portion of the drug consumer population for a number of chronic diseases, but despite this they have often been excluded from clinical trials. The purpose of the guideline is to ensure that older members of the population as well as individuals considered to be frail for medical purposes are properly represented in clinical trials. See here.

Early and Accelerated Access Developments

The early access to medicines scheme (EAMS) is a UK scheme introduced in 2014 which aims to give patients with life-threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation when there is a clear unmet medical need and introduces the concept of the 'promising innovative medicine'.

In May, information on EAMS, including its principles and operational guidance, was published. 'Early access to medicines scheme (EAMS): how the scheme works is now available.

However, the UK Accelerated Access Review (relating to early licensing of medicines) which was due to be published in April has been deferred until after the 23 June EU referendum in the UK.

Public Access to Safety Hearings

As the move to transparency in regulatory affairs continues, the EMA's Pharmacovigilance Risk Assessment Committee has adopted the final rules of procedure on the process and practical arrangements for the preparation, conduct, and follow-up of public hearings of the committee.

Article 20 of Regulation (EC) 726/2004 (the rules for the centralised procedure) and Article 31 and Article 107i of Directive 2001/83/EC (the legislative code governing medicinal products) provide for public hearings as part of certain safety reviews of medicines, particularly in relation to their therapeutic effects and available therapeutic alternatives, as well as the feasibility and acceptance of proposed risk-management and -minimisation activities.

An internal dry run is scheduled to take place at the committee meeting in July 2016. Public hearings could take place as early as the fourth quarter of 2016, as soon as a relevant topic is identified. See here.

Pricing and Reimbursement

EUnetHTA Paper on Personalised Medicine and Co-dependent Technologies

EUnetHTA has recently concluded a public consultation on the draft methodological reflection paper 'Personalised medicine and co-dependent technologies, with a special focus on study design issues'. The paper addresses the methodological challenges encountered by those carrying out health technology assessments (HTAs) while performing relative effectiveness assessments of personalised medicine technologies. The consultation can be found here.

Global Regulation of Medicine Prices on Agenda of G7 Summit

It is reported that the international regulation of drug prices were on the agenda when G7 leaders met in Ise-Shima, Japan on 26-27 May. . France's president, Francois Hollande, sought an 'irreversible' global process to control the prices of new medicines, part of a global drive to make life-saving drugs more affordable. It is understood that there are pressures from developing countries to reform the patent system to facilitate more affordable treatments. It is further reported that health ministers will continue work on it in Kobe in September 2016 when other parties, such as the pharmaceutical companies themselves, could potentially be involved. Further information.

NHS England Launches Consultation on a Proposed Method to Support Investment Decisions in Specialised Commissioning

NHS England has recently conducted a consultation on developing a transparent method to assist in making investment decisions (except for treatments for which the National Institute for Health and Care Excellence is performing a Technology Appraisal or Highly Specialised Technology decision) in order to prioritise funding for new medical treatments more efficiently within its £14 billion budget. See here.

Report of the Pilot on Parallel Regulatory/HTA Advice Services

The EMA has recently reported positively on its pilot on parallel scientific advice where developers could receive simultaneous feedback from both regulators and Health Technology Assessment Bodies (HTABs) on their development plans for new medicines. It is suggested that:

- **the evidence needs of different stakeholders can be met within one trial design or one development programme**
- **a Best Practice Guide be agreed to between regulators and participating HTABs**
- **a sustainable model of parallel scientific advice whereby the regulator-HTAB interactions through parallel advice be achievable.**

It is therefore recommended that such parallel procedures continue on an operational basis. View the report.

Competition

New CMA Investigation into Anti-competitive Agreements in the Pharmaceutical Sector

The Competition and Markets Authority (CMA) has launched a new investigation into a suspected breach of EU Competition Law under Chapter I CA98 and Article 101 TFEU in the pharmaceutical sector. The investigation was opened on 12 April and will continue until July 2016. A decision on whether to proceed with the investigation is expected in August 2016.

New CMA Investigation into Suspected Anti-competitive Conduct in the Med-Tech Sector

The CMA has launched a new investigation of a suspected breach of EU Competition Law under Chapter I CA98 and Article 102 TFEU in the medical devices sector. The initial investigation was opened on 12 April 2016 and will go on until October 2016, at which time a decision is expected to be made whether to proceed with the investigation.

Trade Issues

TTIP Update

On 24 May 2016, the European Commission published a report that provides information about the progress achieved during the 13th round of Transatlantic Trade and Investment Partnership (TTIP) negotiations that took place from 25 to 29 April 2016. Pharmaceuticals is one of nine sectors that have been identified for looking at how to enhance regulatory compatibility. Discussions are led by the respective EU and US regulators in these sectors.

Both the EU and the United States tabled first legal text proposals on pharmaceuticals. According to the Commission's proposal for an annex in the TTIP on medical products, the regulatory cooperation would take place in three areas:

- **the conditions under which each competent authority makes decisions on marketing authorisations,**
- **mutual recognition of GMP inspections, and**
- **the exchange of confidential information, including trade secrets and for bilateral regulatory cooperation.**

The next round of negotiations is scheduled for July 2016.

Data Protection

EMA on Access to Medicines Data and Information

The EMA has issued guidance on what kind of information may be published on medicines undergoing evaluations and other regulatory procedures at various stages of their life cycles.

This guide describes the different types of information the EMA currently publishes for both centrally and non-centrally authorised medicines, as well as publication times and location on EMA's website. See here.

US Privacy Shield Not Robust Enough

The European Data Protection Supervisor (EDPS) recently published his opinion on the proposed EU-US Privacy Shield solution to replace Safe Harbour. He concluded that the Privacy Shield as it stands is not robust enough to withstand future legal scrutiny before the court. Significant improvements are needed should the European Commission wish to adopt an adequacy decision to respect the essence of key data protection principles, since it was time to develop a longer-term solution for transatlantic data transfer.

In April 2016, the Article 29 Working Party also expressed a number of concerns. In October 2015, the Court of Justice of the European Union ruled that the Safe Harbour framework was invalid because it did not provide a sufficient level of data protection for personal data transferred by companies from the EU to the United States as required by EU law. In February 2016, the EU-US Privacy Shield was announced by the European Commission and the US Department of Commerce and was developed as a replacement for Safe Harbour.

See here.

General Data Protection Regulation (GDPR) and Data Re-use

The new GDPR, which will become effective directly throughout the EU beginning 25 May 2018, will result in major changes to the processing of personal data in the EU.

The reform will go some way towards harmonising EU law and affording more certainty to business and data subjects. However, there are still some 40 areas where derogations to individual member states are offered (where the member states can exercise national discretion).

The Health Select Committee of the UK Parliament recently requested that the Government clarify its interpretation of the GDPR on the re-use and de-anonymisation of personal data in that the regulation 'appears to leave it open for data to be re-used, and potentially de-anonymised, if "legitimate interests" or "public interest" considerations are invoked'. The Government has therefore stated in its response to the Committee that it will use the implementation phase of the GDPR to work closely with the UK Information Commissioner's Office to ensure that it provides appropriate guidance to organisations on the issue of anonymisation and sanctions to be imposed for misuse of data. Further information.

German/French Paper on Data and Market Power

Germany's Bundeskartellamt (BKartA) and France's Autorité de la Concurrence looked at the potential effects of the collection of large sets of personal users' data on competition in digital markets, resulting in a joint paper published in May. The paper considers the extent to which data can translate into market power, how certain conduct may give rise to abuse, and the relationship between competition and data protection/privacy rules. It was acknowledged that possession of 'big data' may raise market entry barriers if new entrants are unable to obtain the same kind or volume of data as established players. However, the paper concluded that any competition law response has to be assessed on a case-by-case basis. See here.

Anti-corruption

New German Healthcare Law

Germany has passed legislation on fighting corruption in making certain practices subject to criminal law for the first time (in the past they have been considered a breach of unfair competition law or professional codes of conduct).

The law which relates to healthcare professions prohibits giving or seeking that which requires benefit for themselves or a third person in return for an unfair preference to another when prescribing or purchasing drugs or devices or introducing patients. The legislation provides for up to three years' imprisonment or a fine.

Discounts or rebates received relating to OTC medicines are not covered by the new law, whereas products used by physicians will be.

Morgan Lewis – Update

WEBINAR ON CLINICAL TRIAL DATA TRANSPARENCY: AN EU & US PERSPECTIVE

Lawyers from our Washington DC and London offices recently held a 1 hour webinar to discuss recent changes in clinical trial data regulation in the EU and US.

Topics included:

- **EU general reactive disclosure rules**
- **The European Medicines Agency's proactive disclosure policy**
- **Trial disclosures under the new EU Clinical Trials Regulation**
- **The US approach to CCI and comparable US/National Institutes of Health requirements and US industry practices**
- **Strategic consequences for the conduct of international research programs**

The recording can be heard here.

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