Morgan Lewis

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Welcome to the latest issue of our *European Life Sciences Review,* produced by our life sciences lawyers in London, Brussels, Frankfurt, Moscow, and Paris and covering some of the most critical developments in the pharmaceutical and medical technology sectors in the last month. If you have questions on any of these topics, please contact Paul Ranson.

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Brexit Update

The formation of Brexit Health Alliance was announced at NHS Confederation's conference in June 2017 to provide a single voice for the sector on Brexit-related issues. The alliance brings together the NHS, medical research, patients and public health organisations as well as the lead trade associations within the pharmaceuticals, biotechnology, and medical device sectors (The Association of the British Pharmaceutical Industry (ABPI), the BioIndustry Association (BIA), and Association of British Healthcare Industries (ABHI)). It will be co-chaired by Sir Hugh Taylor, the former permanent secretary of the Department of Health, and Niall Dickson, the chief executive of the NHS Confederation.

Amidst signs of a growing consensus behind a pragmatic Brexit, and seemingly recognising sector concerns, the UK ministers for Health (Jeremy Hunt) and Business (Greg Clark), sought to give some reassurance to the sector and other healthcare stakeholders, in a letter to the *Financial Times*. The letter expresses a desire for close collaboration with the EU and sets out three principles for post-Brexit medicines regulatory system in the UK. Patient safety will be at the core of any new regulatory system; innovators should be able to get their products into the UK market as easily as possible; and the UK would seek to maintain its leading role in promoting public health. In particular, the letter highlights the advantages for the development of products for rare diseases through close UK/EU data sharing.

Meanwhile, the European Medicines Agency (EMA) has published a Q&A document considering issues for marketing authorisation holders in anticipation of the UK leaving the EU. Whilst Brexit mechanisms and the UK's future status are still to be determined, the guidance suggests MA holders will need to transfer any MAs held by UK companies to an EU/EEA company based company, ensure that Qualified Persons are resident within the EU/EEA and Pharmacovigilance System Master File must similarly be retained within the bloc. Any active pharmaceutical ingredient manufactured in the UK, after Brexit, will be considered an imported substance and will need to meet EU good manufacturing practice (GMP) requirements. See the Q&A document here. The EMA is preparing a series of further guidance documents that will be published on the Agency's website.

On 22 June 2017, the leaders of the EU 27 agreed on the European Medicines Agency relocation process for moving from London and submissions from interested parties to offer the EMA a new home were required by 31 July 2017. Voting by the Member States on the successful application will take place in November 2017. See a full description of the process here.

Intellectual Property

Scope of Patent Protection

The UK Supreme Court recently considered the scope of patent protection. It concluded that the protection afforded to a patent is not limited to the wording of the claims, but can extend to cover variants that fall outside the meaning of the claims. The Court proposed a two-stage analysis should be applied to assess, from the perspective of the person skilled in the relevant art, whether a variant fell within the scope of protection of a claim:

- Does the variant infringe any of the claims as a matter of normal interpretation?
- Does the variant still infringe because it does not vary from the invention in a material way or ways which is or are immaterial?

Accordingly, the protection afforded to a patent can extend beyond the meaning of the words used in the claim, potentially offering greater protection on patent owners and facilitating the defence of invalidity counterclaims. See the case here.

Patents for Plants and Animals Obtained Exclusively By Means Of an Essentially Biological Process

Recent rule changes to the Implementing Regulations to the Convention on the Grant of European Patents exclude from patent eligibility plants and animals which are obtained solely by essentially biological processes. The new rules entered into force on 1 July 2017 and apply to European patent applications after this date and pending at that time. Under the European Patent Convention, plants and animals are patentable as long as they are not confined to a particular plant or animal variety. See the decision here.

Product Liability and Safety

Vaccine Product Liability in the ECJ

The European Court of Justice (ECJ) recently considered vaccine manufacturers' liability in a case involving a patient who developed multiple sclerosis shortly after being vaccinated against Hepatitis B. The ECJ was asked to determine whether the French evidentiary rule, which allows plaintiffs to prove the vaccine's defect and causation by "serious, specific and consistent evidence" in the absence of establsihed medical link, is compatible with Article 4 of the Product Liability Directive 85/374/EEC. The ECJ decided that if there is no scientific consensus as to whether a vaccine causes a particular kind of injury, EU national courts can allow claimants to use circumstantial evidence to prove that a vaccine injured them, but ruled against mandatory presumptions based on such circumstantial evidence. The claimant still bears the burden of proof as to defect, damage, and causation on a case by case basis. See the case report here.

Metal-on-Metal Hip Implants – MHRA Guidance

The UK Medicines and Healthcare products Regulatory Agency (MHRA) recently issued updated patient management guidance for those with metal-on-metal hip implants suffering from or fearing the release of metal ion particles into the body, which can lead to severe soft tissue reactions. The European Commission has estimated that there are more than 100,000 patients fitted with such devices in the EU. See the guidance here.

Pricing

Abuse of Dominant Position

The European Commission (EC) has opened its first excessive pricing investigation in the pharmaceutical sector, probing into certain alleged excessive pricing practices by Aspen Pharmacare Holdings Limited (Aspen) in relation to generic oncology medicines alleging an infringement of Article 102(a) of the Treaty on the Functioning of the European Union (TFEU). The treaty stipulates that an abuse of a dominant position can consist of "directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions". Aspen is the sole supplier of these medicines and, according to the EC, there are no known substitutes. Aspen started to impose significant price increases on national medicines authorities in various Member States. When national medicines authorities were unable or unwilling to accept the price increases, Aspen threatened to stop its supply. The Italian competition authority has already imposed a fine of 5 million euros ($5.98 million) after concluding that an increase of the price of certain oncology medicines by up to 1,500% amounted to abuse by Aspen of its dominant position.

See the European Commission press release here.

Spain and Portugal Sign Joint Procurement Agreement

Iberian Health Ministers have launched an initiative to increase cooperation between Portugal and Spain to reduce prices of medicinal products and medical devices and promote the sharing of information and technical documents.

This is intended to promote centralised drug negotiations and improve patients' access to more drugs and innovative therapies.

The process will initially be tested with a selected medicine, by running a pilot of the joint procurement process. See MAP Biopharma article here.

In 2015, the Dutch and Belgian health ministries announced that they were teaming up to negotiate prices with drug firms in a bid to gain new leverage and economies of scale.

UK Life Sciences Strategy

The UK Life Sciences Industrial Strategy, launched last month, was written by Life Professor Sir John Bell in collaboration with industry, academia, charity, and research organisations, and provides recommendations to government on the long term success of the life sciences sector.

The strategy focuses on early-stage drug development, and while pricing and reimbursement issues are excluded, there are commitments on access, in particular that:

- the Accelerated Access Review proposals to streamline assessment processes for all new products be adopted;
- there should be early conditional reimbursement for promising medicines;
- there should be a forum for early engagement between industry, NHS, and NICE to agree on commercial deals;
- NICE should use look wider than the 'QALY' (quality-adjusted life year) to conduct value assessment.
- the next PPRS should balance patient access, value, and incentivising industry;
- there should be opportunities for companies to agree on a wider range of deals with NHS England, including outcomes-based pricing and multi-indication pricing.

The strategy may be found here.

Medical Devices Regulatory

Stand-Alone Software as Medical Device

The Advocate General at the European Court of Justice (ECJ) issued an opinion regarding software that supports prescribing physicians with information on contra indications, doses, and interactions between medicinal products. Perhaps unsurprisingly, the software was determined to be a medical device as it was specifically intended for diagnostic or therapeutic purposes and to help physicians with what medicines to prescribe, predict possible allergies, and assess treatment options. The Advocate General is commonly, but not invariably, followed by the ECJ itself. Read the decision here.

The Advocate General has effectively adopted the principles in an already existing guidance on this issue from the European Commission. See the guidance here The UK MHRA has also issued a useful interactive tool on making the determination, found here.

Cranberries as Medical Devices

In another arguably unsurprising decision, the Regulatory Committee on Medical Devices has upheld the European Commission in relation to its determination on the qualification of cranberry products. The Commission's decision stated that the group of products whose principal intended action, depending on proanthocyanidins (PAC) present in cranberry extract, is to prevent or treat cystitis, are not medical devices within the meaning of Article 1(2)(a) of the Medical Devices Directive. See the decision here

Medicinal Products Regulatory

Clinical Trial Regulation Delay

The European Medicines Agency (EMA) has announced that due to technical difficulties with the development of IT systems for the planned EU clinical trial portal and database, the application of the Clinical Trial Regulation has been postponed from the previously scheduled October 2018 to 2019. The Agency says it will provide an update at the next meeting of the Management Board in October 2017. The portal will serve as a focal point for the submission of data and information about clinical trials. The data that are submitted via the EU portal will then be saved in the EU database. The press release is here.

Regulatory Data Protection and the Global Marketing Authorisation

Novartis sought to challenge in the ECJ the Commission's decisions to grant Teva and Hospira marketing authorisations for generic zoledronic acid forms of Novartis' Zometa and Aclasta, arguing that the Commission (and the General Court) wrongly adopted a broad interpretation of the concept of a "global marketing authorisation". Zometa is indicated for a series of oncology indications whilst Aclasta but its therapeutic indications are different and its strength was adjusted in the light of those new indications. The ECJ, however, confirmed application of the broad interpretation, concluding that the Novartis products are covered by the same global marketing authorisation for the purposes of the regulatory data protection period. The Commission was, therefore, entitled to allow Teva and Hospira to refer to the Novartis' Zometa and Aclasta data. Read the decision here.

Personalised Medicines

The EMA has recently published a report from a March 2017 workshop on personalised medicines, which concluded that personalised medicine requires a major change in the way medicines are tested and evaluated and highlights the novel data patient privacy issues. See the EMA slide show here.

Eurasian Economic Union: Common Pharmaceutical Market.

The Eurasian Economic Union ("Union") is a regional trade organisation whose members include Russia, Armenia, Belarus, Kazakhstan, and Kyrgyzstan. In May 2017, the Union launched a common pharmaceutical market to remove country-specific administrative barriers to circulation of pharmaceuticals and facilitate product development, registration, and marketing. By 2021, member states will harmonize their rules governing product development, pre-clinical and clinical trials, quality control, registration, production, and distribution. However, certain other matters such as state procurement, advertising, and pricing regulation will remain regulated at the national level. During an interim period until 31 December 2020, both national and Union procedures will be available for pharmaceutical registration.

For more information, please see links below:

http://www.eurasiancommission.org/ru/nae/news/Pages/5-05-2017.aspx
https://rg.ru/2017/05/06/v-eaes-zarabotal-edinyj-rynok-lekarstv.html
http://www.remedium.ru/news/detail.php?ID=71542

Health Foods Regulatory

Health Claims

The ECJ has confirmed a health claim can be rejected on grounds of generally accepted nutrition and health principles despite scientific substantiation. In this case, Dextro Energy GmbH & Co. KG (Dextro) sold products in Europe that comprised almost entirely of glucose. Various claims were found scientifically substantiated by the European Food Safety Authority (EFSA). However, the European Commission refused to authorise those claims on the basis that the use of the proposed claims would be inconsistent with generally accepted nutrition and health principles in that they would encourage consumption of sugars. The ECJ concluded the EFSA scientific opinion is only one of the elements that the Commission shall take into consideration when evaluating the approval of a health claim, but the Commission is not bound by it. Read the decision here.

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