Editorial

At the time of writing, the novel coronavirus (COVID-19) is rapidly spreading over Europe and the world, having been declared to be a pandemic by the World Health Organization (WHO). I would like to look at the actions undertaken by the EMA as of 12 March 2020:

First of all, EMA has activated its plan for managing emerging health threats after the COVID-19 was declared a global public health emergency by the World Health Organisation (WHO). The emergency plan structures the coordination between EMA, NCAs, Commission, European Centre for Disease Control (ECDC), the Official Medicines Control Laboratories (OMLC's), and stakeholders including international bodies such as the WHO and the International Coalition of Regulatory Authorities (ICMRA). The aim for EMA is to support the development and prepare for the authorisation and pharmacovigilance of medicines to address the medical needs created through the coronavirus outbreak. As the agency explained in a statement from 4 February 2020, it will support the development of medicinal products to detect, treat and prevent infections, in order to address the currently exiting gap. Currently especially the development of vaccines is clearly of high importance. EMA will use several regulatory tools such as scientific advice, the PRIME scheme, accelerated assessments and conditional marketing authorization procedures. The accelerated assessment, which can be applied for with regard to medicines which are of major interest from the point of view of public health according to Article 14(9) of Regulation 726/2004, reduces the assessment time to 150 days.

Although the coronavirus should not be equated with influenza, in terms of dealing with pandemics, one can look back on the 2009 H1N1 influenza (Swine flu) pandemic where the agency applied fast-track approval procedure for vaccines. EMA authorised 3 vaccines based on previously authorised mock-up vaccines and 2 vaccines on the basis of the 'emergency procedure'. Also the – very strictly delimited - option of compassionate use (Article 83(3) Regulation 726/2004), where an unauthorised medicine in development is made available to a group of patients with life-threatening disease, was used for the first time during the Swine flu pandemic for the use of intravenous formulations of oseltamirir. Based on a CHMP recommendations on the conditions for compassionate use, this is carried out by the Member States. However, while there is a clear legal framework, several regulatory tools and a relatively established scientific assessment structure that can be used in the case of pandemic influenza, it has been noted that the preparation for other pandemic and epidemic diseases is less well organized, as for example shown with regard to Ebola and Zika.[1]

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1 See an elaborate discussion of this by Marco Rizzi, 'Vaccines for Pandemic and Epidemic Diseases: Towards Defining the Space of EU Public Health between Security Policy and a Transnational Market' (2017) 8 European Journal of Risk Regulation 4, 686-699.

As stated above, EMA currently plans on using the accelerated assessment procedure and conditional marketing authorisations in the case of COVID-19 vaccines and other medicinal products.

A second aspect of EMA corona-related activities is that the crisis caused by the outbreak in China (and globally) will potentially also have an impact on the medicines supply in Europe. The dependence of Europe on import of active substances and other ingredients, as well a fully manufactured products from all over the world, has become very visible in the last years for example in case of quality issues resulting from breaches of the Good Manufacturing Practice (GMP). Generally, the availability of medicines has become an increasing priority of regulators in the EU, even more so as Brexit had led to discussions of potential shortages with regulatory authorities and companies preparing for such eventualities. With regard to the corona virus outbreak, EMA announced that currently they have not received any reports of supply disruption, but they also made clear that factory lockdowns and travel restrictions might have this effect at some point. The agency is in the process of reviewing manufacturing authorisations and identifying centrally authorised products at risk of supply shortage. The European medicines regulatory network is monitoring the situation and pharmaceutical companies are called upon to put in place measures for continued supply and report any potential shortage. Measures will be coordinated by the EU executive steering group on shortages of medicines.

The COVID-19 pandemic and the regulatory response with regard to its effects on the pharmaceutical market in Europe will certainly remain central to EU pharmaceutical policy and we explicitly invite contributions on the subject.

The last issue of the EPLR (Issue 4/2019) was a special issue on AI, Machine Learning and Big Data. I would like to take the opportunity to congratulate the Guest Editors Claudia Seitz und Timo Minssen for bringing this core feature of the technical advancement of pharmaceutical innovation to the attention of the EPLR readers. The collection of articles shed a light on questions of data protection and privacy, but also looked at regulatory approaches to AI in healthcare, as well as intellectual property rights, all in a very multi-disciplinary manner. Obviously, one EPLR issue on AI in pharma is not sufficient to explore all the questions that this technological (r)evolution will give rise to, therefore, also in this issue we will follow up with articles on AI in pharma, some of which are very complimentary to articles in issue 4/2019.

Anastasiya Kiseleva in her article 'AI as a Medical Device: Is it Enough to Ensure Performance Transparency and Accountability?' examines the US and EU regulations, showing that AI-based applications can be considered as software medical devices in these legal systems. However, these technologies may undermine transparency and accountability requirements applicable to such devices. How can informed consent be ensured where healthcare professionals might lack the required understanding of the functioning of the devices and the risks they entail? Kiseleva advocates an adaptation of the EU medical devices regulation to ensure transparency and accountability

of AI in healthcare.

Francesca Mazzi has contributed an article addressing the challenges of patentability of machine vs human-made inventions in drug development. Her article provides an introduction to the presence and future of AI in health inventions and shows that the human invention centric patent system might reach its limits where no human intervention is needed for AI generated pharmaceuticals in the future. Additionally, she considers the effects on competition law and especially the question if data might become an essential facility under Art. 102 TFEU.

Our third article by Timo Minssen, Claudia Seitz, Mateo Aboy and Marcelo Corrales Compagnucci assesses the legal challenges of the EU-US Privacy Shield Regime on the transfer of data in the medical sector. After the Safe Harbour Agreement was deemed to violate EU privacy laws by the CJEU in *Schrems I*, now also the EU-US Privacy Shield Framework is subject to review in the case *Schrems II*, and a ruling is awaited in the near future. The authors argue that there is currently a high degree of legal uncertainty with regard to data transfers between the EU and US, which has severe impacts on innovation in drug development. They conclude with a call for a mechanisms that provide legal certainty to those engaging in data transfer, while adequately protecting personal data.

AI and Big Data in healthcare will certainly continue to feature heavily in this journal. The report of the joint Big Data Task Force of EMA and HMA has set proposed 10 key actions on the matter, including the creation of DARWIN (Data Analysis and Real World Interrogation Network) a platform that aims to facilitate access to healthcare data from across the EU to inform regulatory decision-making. Many challenges with regard to privacy, data protection and ethics will arise in this regard and hopefully the EPLR can offer a forum for the continuing debate.

Next to these AI focused articles, reports in this issue from EU Member States provide an introduction to recent developments in national pharmaceutical law and policy: Caranina Colpaert assesses the export bans on medicines adopted by Belgium, Austria and the Czech Republic to prevent medicine shortages, and their questionable nature as public health exceptions to the free movement of goods. This is complemented by a report from Mariana Ricardo discussing the Portuguese regulation on the management of the availability of medicines, which establishes rules and procedures in that respect. Notably it contains a duty to notify of shortages or lack of medicines for marketing authorisation holders and an obligation to take prevention measures through shortage prevention plans. Finally, Ilan Akker and Wolf Sauter in their report 'Therapeutic v Biosimilar Pharmaceutical Competition:

Antitrust in the Netherlands' discuss competition within and between active substances in the context of the recent sector inquiry by the Netherlands' Authority for Consumers and Markets (ACM) on TNF-alpha inhibitors.

The issue is completed by a case note written by Nuria Porxas on the judgment of the General Court in the case T-733/17 *GMPO v. Commission* regarding the orphan designation due to 'significant benefit', which is currently under appeal (Case C-575/19 P). As Porxas explains, the case – together with case T-329/16 *Bristol-Myers* – confirms the Commissions interpretation of Article 5 of Directive 2001/83, as envisioning the orphan designation procedure as a two-step process, consisting of an initial designation and a reassessment of this designation before the marketing authorisation is granted. Moreover, the Court clarified that in order to proof 'significant benefit' a benefit for patients in practice must be evident, which the Court did not see establish where a marketing authorisation is sought for all Member States while the reference product is only available in one Member State.

I would like to conclude this editorial with a little teaser, announcing that also this year we will conclude our quarterly publication cycle with a special issue. More information and a call for paper will follow soon, but I can already say that this time we will look beyond the EU borders. In the meantime, we as usual invite publications in the form of full articles, shorter reports from Member States, as well as case notes for issues 2/2020 and 3/2020. Please get in touch with our Executive Editor Jakob McKernan.

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