Editorial

Since the last issue of the European Pharmaceutical Law Review the vaccination campaigns in the Member States with the four currently authorised COVID-19 vaccines Comirnaty (BioNTech/Pfizer), Vaxzevria (AstraZeneca), as well as the Moderna and the Janssen COVID-19 vaccines, have picked up speed. On 17 May, according to the European Centre for Disease Prevention and Control (ECDC), 36% of the adults in the EU/EEA have received at least 1 vaccination dose and 14,4% are fully vaccinated. While currently four vaccines are under rolling review at the European Medicines Agency (CVnCoV; NVX-CoV2373; Sputnik V (Gam-COVID-Vac); and COVID-19 Vaccine (Vero Cell) Inactivated), the political and regulatory attention is shifting towards preparedness for mutations of the virus and the adaptability of the vaccines for such mutations.

In this regard the European Commission has initiated the HERA Incubator - a biodefence preparedness plan and to a certain degree a preview of the agency to be set up under the European Health Union proposal in the future - and adopted Delegated Regulation (EU) 2021/756 which introduces an accelerated variations authorization procedure. Moreover, the Commission has adopted an EU Strategy for COVID-19 therapeutics, promising additional funding, the establishment of a platform to connect relevant stakeholders in the development of therapeutics and access to EU wide clinical trials. This is meant to address the gap in COVID-19 treatments, given that currently only Remdesivir has been authorised in the EU and 4 other treatments have been positively reviewed review under Article 5(3) of Regulation (EC) No 726/2004, while there is urgent need for additional treatments, especially in the context of 'Long-COVID'. Remarkable in the Strategy is the Commissions announcement that it is considering the proposal of new legislation containing an EU emergency-use authorization procedure.

However, although COVID-19 naturally remains the dominating topic in the EU pharmaceutical law and policy discourse, the progress that is made with regard to the EU Pharmaceutical Strategy should also be addressed. The Commission in April has published the Combined Evaluation Roadmap/Inception Impact Assessment: Evaluation and revision of the general pharmaceutical legislation (Ref. Ares(2021)2390324) (see Law and Policy Section in this issue), which very much reflects the willingness of the Commission to review in-depth and overhaul the pharmaceutical regulatory framework in the EU, including re-incentivization especially with regard to unmet medical needs, as well as legislative and administrative simplification and future proofing.

Additionally, on 26 February 2021 the Commission (Vice-President Margaritis Schinas, Commissioner Stella Kyriakides and Commissioner Thierry Breton) launched the

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structured dialogue on the security of medicines supply. At the time the Pharmaceutical Strategy was published, there was some disappointment that it did not yet address the pressing problem of medicines supply and dependence on third countries. The concern about international dependency was also voiced by several stakeholders from industry, NGOs and academia in the public consultation carried out for the Pharmaceutical Strategy. With the structured dialogue launched, the Commission now follows up on these concerns with the aim to first gain knowledge on the global pharmaceutical supply chain and interdependences with a view to identifying vulnerabilities. Subsequently the Commission will draft proposed measures, which will have to comply with EU competition rules and WTO law.

With regard to the inequalities in access to medicines throughout the EU, another key concern which was re-emphasized in the public consultation, the Commission in March has initiated a 18 month pilot project 'Market Launch of Centrally Authorised Products'. It will ask voluntary information from entities, applying for or being in the process of obtaining a centralized marketing authorization for orphan and oncology medicinal products, to share information concerning their market launch strategies, including reasons for not making a product available in certain Member States or delaying their launch there. The information will be confidentially discussed by DG SANTE and EMA, to gain insights into the root causes for divergence in medicines access.

Thus, much is ongoing in terms of European Pharmaceutical Law and Policy and the implementation of the Pharmaceutical Strategy also is a topic for this issue of the EPLR as Christine Mellein and Jürgen Schwarze address one of the fundamental questions of the revision of the pharmaceutical legislation: should the structure of a Directive and a Regulation be maintained, or should the reform transform the Community Code into a Regulation? Mellein and Schwarze conduct an in-depth discussion of legal, administrative and practical considerations of this question from an EU as well as national perspective, coming to the conclusion that the dual structure with a Directive and Regulation should be maintained.

In the article 'Creating a European Health Data Space. Obstacles in Four Key Legal Areas' Anastasiya Kiselev and Paul de Hert critically analyze potential stumbling blocks with regard to the establishment of the European Health Data Space in the context of the Commissions EU Strategy for Data published in February. In this regard, they examine in-depth the competence division for health and the resulting difference in national health care systems; the room for divergence in the regulation of health data processing left by the GDPR; the lack of harmonisation of rules on the processing of non-personal data; and finally, the currently developing framework for the regulation of AI.

In her article on the interplay between parallel imports, compulsory licensing and voluntary licensing, Lorelei Garagancea aims to demonstrate that there is no 'one-size-fits-all' approach with regards to exhaustion regimes of patent rights and shows that

licenses and contractual limitations play an important role in increasing the potential of parallel imports to enhance access to medicines and it is thus important to analyze their synergies.

Additionally, Vicky N. Kriketou and Persefoni Papadimitriou discuss civil liability in the context of vaccines in the pandemic. Examining the Court of Justice judgement in case C-621/15 *Sanofi Pasteur*, which interpreted vaccine liability under Directive 85/374/EC concerning liability for defective products, they apply the ruling to vaccine liability in the pandemic and examine the question whether adverse reactions the potential of which is already known before vaccination would trigger liability. Finally, in the context of the pandemic, they propose the limitation of liability where the vaccine is subject to conditional authorization combined with a publicly funded non-fault compensation system, until a full marketing authorization is obtained and liability will shift to the producers again.

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