Editorial

Covid-19 vaccines continue to be a central topic in our daily lives and in EU pharmaceutical law and policy. According to the data of the European Centre for Disease Prevention and Control (ECDC) as of the 5 July, 61,4% of adults in the EU/EEA countries had received at least one dose and 40.1% were fully vaccinated. Although no further vaccines have been authorised since March, four vaccines continue to be under rolling review (CVnCoV; NVX-CoV2373; Sputnik V (Gam-COVID-Vac); COVID-19 Vaccine (Vero Cell) Inactivated). The good news is that the vaccine manufacturing capacity of the authorised vaccines in the EU is increasing, as several new production sites have received a manufacturing authorisation. Also in terms of the paediatric use of the vaccines, progress has been made, as Comirnaty (BioNTech/Pfizer) was authorized for use in 12 to 15 year old children at the end of May 2021 and the EMA evaluation of the extension for use in 12 to 17 year old children of Spikevax (Moderna) has started.

Moreover, in an update from the last Editorial which referred to the EU Strategy for COVID-19 therapeutics, it should be mentioned that progress has been made as five products have been identified as potential COVID-19 therapeutics: 4 monoclonal antibodies are now under rolling review of EMA: a combination of Bamlanivimab and Etesevimab (Eli Lilly), a combination of Casirivimab and Imdevimab (Regeneron Pharmaceuticals, Inc. and F. Hoffman-La Roche), Regdanvimab (Celltrion), and Sotrovimab from (GlaxoSmithKline and Vir Biotechnology). In addition, Eli Lilly applied for an extension of use of its immunosuppressant Oluminat (the active substance is baricitinib) for the treatment of COVID-19 for hospitalized patients requiring supplemental oxygen. The Commission is currently working on composing a portfolio of a minimum of 10 potential treatments by October.

Against this background of the ongoing vaccination campaigns, the EU Digital COVID Certificate started operating on the 1st of July, aiming to re-establish the free movement of persons within the EU for people fully vaccinated with a centrally authorised vaccine, or those having recovered from an infection or with a recent negative test result. The certificate itself is not undisputed for many reasons, including the questions surrounding the efficacy of the vaccines in terms of the new virus variants such as the Delta variant, or its potential for creating and exacerbating inequalities due to different national conditions regarding access to vaccination and testing. Moreover, ambiguities are created due to the fact persons vaccinated with a centrally authorised vaccine fully benefit from the certificate, whereas recognition of other vaccines such as Sputnik V or Covishield is a decision to be taken by each individual Member State. Indeed, the EU's certificate and comparable initiatives in other regions has fuelled pre-existing concerns surrounding the un-equal access to vaccines especially on a global level. This is closely connected to the question of the IP waiver for the COVID-19 vac-

cines and treatments.

Indeed, this question, as one of the most pressing legal debates surrounding the COVID-19 vaccines and treatments, is addressed in the article 'No-one is safe until Everyone is safe – Patent Waiver, Compulsory Licensing and COVID-19' by Behrang Kianzad and Jakob Wested. They provide an insightful and balanced overview of this complex venture, by mapping the multifaceted IP but also human rights questions related to a potential COVID-19 patent waiver and compulsory licensing. In this regard, they shed light on legal and practical dimensions of these questions surrounding an IP waiver. Moreover, they look beyond the current pandemic pointing towards a potential steep price increase of the vaccines after the acute stage of the COVID-19 pandemic and also the questions of the broader impact of a waiver on the balance between access to medicines and pharmaceutical innovation.

Martin Dræbye Gantzhorn and Emil Bjerrum in the report 'Pharmaceutical Advertising in Digital Media: A Danish Perspective' discuss online pharmaceutical marketing, which raises many interesting issues in terms of jurisdiction. They provide insights in the current Danish regulatory practices and give insights into potential strategies for businesses in terms of online advertising.

We conclude this issue of the EPLR with two case notes. Elettra Gaspari discusses a ruling from the Italian Supreme Court on liability of pharmaceutical companies for injuries of clinical trial participants, and places into context with the regulation of clinical trials in Italian and EU law. Meanwhile, Guram Gobechia analyses the recent Pharmaceutical Works Polpharma v EMA judgement of the General Court, the Tecfidera case, surrounding the concept of a global marketing authorization.

As always, I want to thank our contributors, the Editorial Board, our Executive Editor Jakob McKernan and our anonymous reviewers for their work. I wish all our readers an amazing and hopefully healthy summer break.

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