Editorial

In the area of pharmaceutical regulations, frequently calls for more transparency are addressed to regulators, the pharmaceutical industry or other stakeholders in the health care system, such as doctors. However, as the movement towards enhanced transparency increases, conflicts between transparency and other rights and legal values, such as commercial confidentiality, or the protection of personal data, become more pronounced. The concept of transparency has fueled an ongoing debate in the field of pharmaceutical law and policy, especially as it seems to have a particularly ambiguous and evolving meaning within the pharma context.

That being said, in a series of cases which have been ruled on by the General Court, the relationship between the EMA transparency policy and commercially confidential information has been clarified. The judgments in the cases T-235/15 *Pari Pharma v EMA*, T-718/15 *PTC Therapeutics International v EMA*, and T-729/15 *MSD Animal Health Innovation and Intervet International*, has confirmed the EMA approach that similarity and superiority reports, clinical study reports, and toxicological study reports, are not in their entirety, commercially confidential *per se*. Although these cases shine some light on the relationship between transparency and commercially confidential information, the debate on this subject will continue. Naturally, the EPLR will provide the space for this conversation to go on.

With this mind, Giulia Schneider's article on commercial confidentiality in clinical trials data already provides some timely food for thought. In her article she argues that the intellectual property framework should not be regarded as an enemy of transparency, but rather that it actually provides enough room to reconcile clinical trial data transparency and IP rights even within TRIPS, EU Trade Secret Protection and pharmaceutical data exclusivity.

Closely related to debate on transparency in the context of pharmaceuticals, is the issue of corruption and inducement of health care professionals. Tillmanns in his report from Germany discusses the Act on Fighting Corruption in the Healthcare Sector, which came into effect in June 2016 and requires the careful attention of industry, hospitals and health care professionals. In the Netherlands, as reported on and further discussed by Van den Bos and Franken, a new law has entered into force as of 1 January 2018, banning inducements of healthcare professionals by medical devices companies.

Of course, other interesting developments in the world of pharmaceutical law and policy have to be discussed as well. Khalil and Natterer report on the state of online-pharmacies in Austria, which continue to be tightly regulated and still remains a mar-

ginal business 15 years after the C-322/01 *Doc Morris* decision, which should have paved the way for online sale of OTCs. Casting an eye over developments in Italy, de Morpurgo discusses the delegation law on clinical trials, which constitutes the starting point for the implementation of the Clinical Trials Regulation in Italy, while further regulatory measures are still required. In their country report, Waxberg, Romin and Montgomery examine two decisions by the Committees of the Swedish Association of the Pharmaceutical Industry in the context of advertising, specifically with regard to press releases and communication in procurement procedures.

In the case note section, Eveline van Keymeulen and Jacqueline Bore discuss the C-329/16 *Snitem and Philipps France* case on the qualification of prescription software as a medical device. The ruling, especially in the context of the existing guidance and the new Medical Device Regulation, is not particularly groundbreaking in its qualification of the software as a medical device. However, the authors argue that more pressing questions in relation to the certification of prescription software and, ultimately, their effect on the management of national healthcare budgets, remain unanswered.

Finally, as this issue of the EPLR marks the beginning of our first full EPLR year ahead, I would like to thank everybody who provided feedback on the first issue and anyone who contributed to the launch of the journal. Whether you submitted an article or report, offered advice or provided us with guidance, please know that your assistance is very much appreciated. The editorial team of the EPLR and the Editorial Board is looking forward to the receiving your contributions in the year ahead and if you plan on submitting an article, report or case note please note that the deadline for submission has been extended to 1 March.

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