Editorial

Infamously, several crises have driven much pharmaceutical law reform. So-called ‘patent medicines’ were instrumental in labelling laws, requiring ingredients to be listed. And perhaps most infamously, the thalidomide scandal mid-way through the last century led to laws requiring manufacturers to provide both a list of side effects and the efficacy of their drugs. An eminent Australian judge, Justice Windeyer, once described the law as ‘marching with medicine but in the rear and limping a little’.1 Windeyer was analysing tort law when he made the statement. Nonetheless, the expression aptly describes the motivations for some reforms in pharmaceutical law: that the law is in immediate need of (medical) attention. The expression conjures magnificent imagery too.

The extent to which the EU Commission’s strategy for pharmaceutical law is limping is debatable, especially if we think of limping as dealing with an event poorly or in a disorganized way. It is also debatable whether the strategy is reacting to problems as opposed to proactively addressing them (the idea of controlling a situation as it unfolds as opposed to reacting after it happens). Another useful description of pharmaceutical legislation is whether it is the product of foresight or horizon scanning. Perhaps a fair assessment is that the Commission’s strategy bears the hallmarks of all these descriptions.

The Commission’s strategy is divided into four pillars. The first pillar is titled ‘delivering for patients: fulfilling unmet medical needs and ensuring accessibility and affordability of medicines.’ The pillar is split into three areas: i) ensuring affordability of medicines for patients and health systems’ financial and fiscal sustainability ii) ensuring patients’ access to medicines; and iii) prioritising unmet medical needs. Global responses, including the EU’s to the last area are probably limping, and the strategy implicitly acknowledges this when it states, ‘there are over 7,000 known rare diseases, including rare cancers, of which 95% still have no treatment option’.2 Many of these diseases and the lack of treatment have been known about for a long time. The strategy acknowledges a similar problem for pregnant women, amongst other groups of people, who are often excluded from clinical trials.

The second pillar is titled ‘supporting a competitive and innovative European pharmaceutical industry’. This pillar is split into three areas too: i) providing a fertile environment for Europe’s industry; ii) a sound and flexible regulatory system; and iii) enabling innovation and digital transformation. The digital component of the strategy can be described as proactive. The EU often leads the world in policy responses to issues

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posed by advances in information technology. Of course, it is easy to be critical, too, especially accusing the Commission of delayed inactivity. However, we cannot expect the Commission to be blessed with perfect foresight because so many possibilities are foreseeable; take the current situation on artificial intelligence and machine learning! This area includes issues such as real world data, repurposing, and the European Health Data Space, which are all issues that scholars’ have addressed in this issue of EHPL.

The third pillar has the longest title ‘enhancing resilience: diversified and secure supply chains; environmentally sustainable pharmaceuticals; crisis preparedness and response’. The three areas of this pillar are: i) secure the supply of medicines across the EU and avoid shortages; ii) high quality, safe and environmentally sustainable medicines; iii) enhancing Europe’s health crises response mechanisms. The third area includes the European Health Emergency Response Authority (HERA), which ‘fills a major structural gap in the EU’s crisis preparedness and response infrastructure, and will strengthen the coordination of operations across … investments for research, development, manufacturing, deployment, distribution and use of medical countermeasures.’

For instance, it will support the development of crosscutting vaccine platform technologies. HERA is clearly a response motivated by the pandemic. However, the best description of the programme is foresight, albeit one learned at a high cost from recent experiences.

The fourth pillar is titled ‘ensuring a strong EU voice globally’. This is the only pillar that is not split into three areas. An aim of this pillar is to level the playing field for global regulation of drugs. Another aim is to make the procedures for issuing opinions on medicines intended exclusively for markets outside the EU more appealing. This pillar contains a mix of being reactive and proactive. For instance, one could argue that there has been a need for harmonised regulation across the world for years and that the Commission has dragged its feet. On the other hand, perhaps the time is right to pursue further harmonisation of pharmaceutical laws. The Commission emphasises the idea of opening dialogues with low- and middle-income countries, and the world is changing. For example, a few middle-income countries now have renowned pharmaceutical industries and some of the highest GDPs in the world.

Three pillars of the Commission’s strategy consist of three areas, and the last pillar has only one area. Therefore, the strategy, in total, addresses 10 broad areas. Each one of these areas could be the subject of several books and PhD theses. Consequently, we should not be surprised that this edition of European Health and Pharmaceutical Law, which consists of three articles and two reports, only touches on a handful of the areas. Nevertheless, one of the attractions of academic commentary is that it often involves horizon scanning. Commentators are constantly encouraged to turn their eyes to the horizon. And each of the contributions in this edition does

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3 Ibid 28.
just that.

The first article is titled ‘The Estonian Electronic Health Record – a Prototype for Data Governance in the European Health Data Space?’ The Estonian Electronic Health Record (EEHR) contains genetic data on 200,000 of Estonia’s 1.3 million people. The authors, Michael Deng and Thomas Hoffmann, contrast the EEHR with the proposed European Health Data Space (EHDS), which was mentioned several times in the Commission’s strategy. The EHDS refers to the idea of a digital space for sharing data across borders in the EU. Deng and Hoffmann compare some of the challenges the EEHR and the EHDS face. The authors focus on the interface with the General Data Protection Regulation (GDPR), especially on the issue of ‘secondary uses’. Deng and Hoffmann recount some interpretive difficulties at the interface with the GDPR and, in response, describe some approaches taken by the EEHR that could be implemented in the EHDS to help resolve these challenges.

The second article also addresses the EHDS. It is titled ‘What Will Become of Our Health Data When We Die? The European Health Data Space Might Have an Answer’. Anastasiya Kiseleva and Iñigo de Miguel Beriain argue that the EHDS might be a game changer for how data on deceased people are managed. They explain that the GDPR does not protect dead people’s data, but uncertainty remains about whether their data can be processed. This topic has attracted quite some debate, especially for secondary uses, and the authors interpret the proposed EHDS as providing partial solutions to this thorny problem.

The third article, by Vincenzo Salvatore, is titled ‘The Regulatory Challenges of Digital Therapeutics’. Salvatore explains that digital therapeutics refer to a variety of tools that have the capacity to improve the prevention and treatment of medical disorders via patient-facing software. He also explains that digital therapeutics are a key part of various EU strategies and that they deserve unique legislation because they raise issues not adequately dealt with under existing legislation. The author points to a recent bill in the US that could be used as a model in the EU.

The first report by Ashleigh Hamidzadeh, Kathleen Liddell and I is titled ‘Should Europe Adopt a Policy Like the US MODERN Labeling Act.’ This report describes recent legislation in the US. The legislation allows the FDA to look for new uses of generic drugs and, if they believe sufficient evidence exists, compel generic manufacturers to update their labels. Finding new uses for drugs, commonly known as ‘repurposing’ is a part of the Commission’s second pillar, and we recommend the Commission track the success of this legislation.

The second report, ‘The EU Pharmaceutical Strategy and the Promotion of Real World Data: Recent Welcome (?) Developments’ is by Kaat Van Delm. The report critically considers the concept of real-world data (RWD), the Commission’s Strategy for RWD and four initiatives that have begun to realise the potential of RWD in the EU. Van Delm comments that the EU has met all its early goals in the Commission’s strategy
for RWD. However, she also notes it’s early days for these initiatives and we should continue to assess their impacts.

This special edition makes wonderful contributions to several discussions and debates. Each article helps ensure the law does not limp behind medicine. Excellent scholarship is a key pillar (to reuse the Commission’s term) of improving pharmaceutical law. However, one cannot help but notice that most of the topics in the Commission’s strategy were not analysed in this edition. There is lots of work to do!

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