Our last two regional reports have addressed the EU – UK relationship. We will leave this topic to rest, because it seems that we will not know exactly what will happen in the coming months and years. In the meantime, other interesting issues in Europe remain, especially initiatives undertaken to address access to medicines for all and early access to innovative medicines.

AFFORDABLE MEDICINES
The Dutch EU presidency (in the first half of 2016) organized a large meeting about, among other things, pricing and reimbursement of medicinal products, rewards for investments in innovation, and the importance of affordability of medicines. This led to “Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States.” Interestingly, while emphasising the EU’s limited remit to issues relating to free movement of goods, services, persons and capital, Health Ministers expect EU level actions as well as collaboration between (clusters of) Member States above the Member State level. Note 16 of this document mentions one reason: “Increasing number of examples of market failure in a number of Member States, where patients access to effective and affordable essential medicines is endangered by very high and unsustainable price levels, market withdrawal of products that are out-of-patent, or when new products are not introduced to national markets for business economic strategies and that individual governments have sometimes limited influence in such circumstance.”

It seems that one of the problems in the EU is to balance the principle of a single market with the principle of solidarity, which leads to the desire to treat all EU citizens at the same level. The problem with this is that huge GDP differences exist between north and south, and between east and west, which leads to a completely different meaning of “affordable” depending on where you are. This discussion is not only relevant to the EU and politicians in its Member States, but even more important for European health care professionals and their patients. Last but not least, squaring this circle requires pharmaceutical industry input; after all, if patients cannot afford to use their products, the companies manufacturing and marketing them cannot recoup their investments.

MAPPS: TIMELY ACCESS TO INNOVATION
To develop an innovative medicinal product takes a long time and getting the product approved creates even more delay. But patients with life threatening diseases do not have time to wait. The Medicines Adaptive Pathways to Patients (MAPPS) project aims at early access to medicines via Adaptive Pathways, which uses alternatives to the normal marketing authorisation procedures. The idea is to approve early use of the medicinal product in a narrow therapeutic area, then allow broader use incrementally. Competent authorities will
approve early use in return for agreement on strict product monitoring and postmarketing commitments. Adaptive pathways is not a new route of marketing authorization. It makes use of existing approval tools, in particular the conditional marketing authorization available in the EU since 2006. It also builds on experience gained with strengthened postmarketing monitoring tools introduced by the 2012 Pharmacovigilance Legislation. The EMA conducted an adaptive licensing pilot project between March 2014 and July 2016, and reported on its promising outcomes in July 2016. The pilot also helped to identify a number of aspects for further reflection: These include the need for increased patient involvement in the selection of candidates for adaptive pathways, the definition of methodologically-sound strategies for real-world evidence collection to support both the efficacy and effectiveness assessment and the potential involvement of payers – Member States’ organizations responsible for decision on pricing and reimbursement – to provide input on pricing strategies. The MAPPS project is part of the Innovative Medicines Initiative (IMI), the world’s largest public private partnerships in life sciences with a €3.3 billion budget for the period 2014-2024.

ACCESS TO AUTHORIZED MEDICINAL PRODUCTS
In the EU, as in other parts of the world, medicinal products are used off-label to a large extent. This means that many patients are treated with medicines that have not been tested or evaluated for the purpose they are used for in medical practice. This topic is being addressed by the Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP), formed to provide a forum for the Commission and Member States to discuss off-label use and what to do about it on the basis of a report by the Belgian Healthcare Knowledge Centre. One of the most attractive strategies for solving the issue of off-label use is to turn off-label into on-label use by authorizing the off-label use, often referred to as drug repurposing or rediscovery. One of the main problems in this strategy is the lack of incentive for the marketing authorization holder to invest in clinical development after the patent and supplementary protection certificate have already expired.

IN CONCLUSION
Many exciting developments, all focusing on better and earlier access to medicinal products that have been assessed by competent authorities, can lead us to hope that all these initiatives may lead to better treatment options for our patients.

References available upon request.