

Unhealthy Outlook: Part Four

Gaetana Mak, September 2019

Rounding off our series on health care and Brexit, industry analyst Gaetana Mak discusses how tariffs and regulatory changes are expected to affect the sector in the future.

At present, most finished medicines and medical devices do not attract tariffs under the EU's Common External Tariff (CET). The United Kingdom also benefits from the World Trade Organisation's (WTO) Pharmaceutical Tariff Elimination Agreement (PTEA) by being a signatory nation to the WTO.

Under the PTEA, specified pharmaceutical products and components are not subject to import duties. The agreement is extended on a Most-Favoured Nation (MFN) basis and signatories extend tariff eliminations to all WTO members. In essence, all WTO members enjoy the benefits of tariff-free trade to signatory countries, irrespective of whether or not they themselves are members of the agreement. As a result, even if the United Kingdom leave the European Union without a deal, it will still be able to trade some pharmaceutical products with the European Single Market on a zero-tariff basis.

However, not all pharmaceutical products are covered by the PTEA, which is based on a negotiated list of finished products and ingredients. Despite a clause to review the tariff exemption list every three years, it has not been updated since 2010. The Association of British Pharmaceutical Industry and the UK BioIndustry Association have estimated that there are approximately 1,000 finished products and 700 ingredients not currently included in the list. These will be subject to duties when traded on WTO terms, should the United Kingdom exit the European Union without a new trade agreement.

Marketing authorisation and distribution

Medicine and medical devices are subject to rigorous and comprehensive licensing systems and regulation due to their high-risk nature, which is harmonised across the European Economic Area. The European

What are marketing authorisations?

Marketing authorisations (MAs) are the European licensing system for medicines. There are several routes that applicants can take to obtain an MA, at the EU and national level.

- **Centralised procedure:** Allows applicants to apply for an MA to the EMA, which will then apply across the EU and EEA countries. This approach is compulsory for certain medicines such as orphan medicine products and biotechnology products.
- **Mutual recognition procedure:** Applies to most medicines that do not have to be licensed through the centralised procedure. This process means that if a medicine has been assessed and licensed in one EU member state, it can be recognised throughout the EU and EEA countries under the EMA.
- **Decentralised procedure:** This procedure can be used for most conventional medicines. An application for an MA is submitted to several member states at one time. One of these is then allocated to be the 'reference member state' and will undertake the assessment. When the licence is granted, it applies in the reference state and other concerned member states.
- **National procedure:** An MA application can be made to one national authority, to apply only in that country (e.g. the MHRA in the UK).

Unhealthy Outlook: Part Four

Medicines Agency (EMA) is the regulatory body responsible for ensuring that all medicines available on the EU market are safe, effective and of a high quality.

Under current arrangements, the EMA provides a centralised approval procedure for licensing to bring a product to the market. This is also known as a marketing authorisation (MA). There are four types of MA procedures. The most beneficial and common is the centralised procedure which permits pharmaceutical companies to submit a single marketing authorisation to the EMA, which once granted, is valid across the European Union and the EEA.

The licensing and distribution of medical devices is also governed by the European Union. Instruments are approved by a registered body in a member state and once approved, devices can be sold across the European Union and the EEA through the CE marking scheme. Products manufactured outside of the European Union must also be compliant with CE requirements to be made available on the EU market.

The United Kingdom also has its own national regulatory agency, the Medicines and Healthcare products Regulatory Agency (MHRA). However, the MHRA currently only deals with national authorisations intended for marketing in the United Kingdom only.

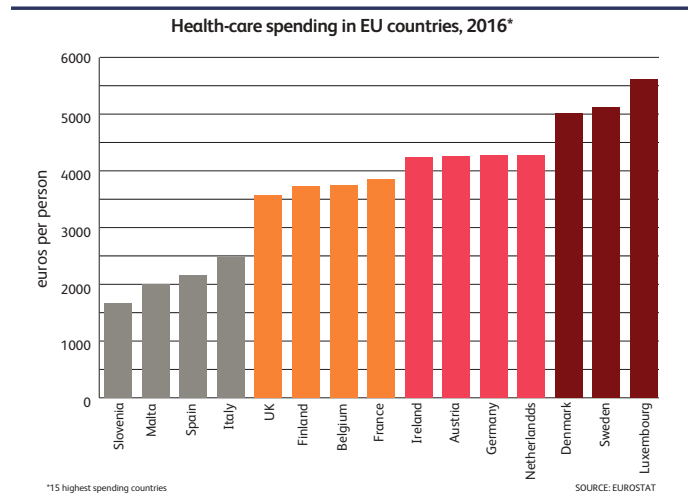
In accordance with EU requirements, companies that hold an MA that wish to import or manufacture products outside of the EEA must apply for an MIA licence, which is issued by the MHRA. Medicine manufactured in or imported to any EEA country may be distributed in any other EEA country where the MA applies.

Implications of withdrawal

Once the United Kingdom formally withdraws from the European Union, it will no longer be under the jurisdiction of the EMA. Should the United Kingdom adopt a different regulatory framework on the licensing, marketing and monitoring (also known as pharmacovigilance) of medicines, medical supply chains could be severely disrupted. For the health-care sector, there are two key factors of that are anticipated to be affected by the UK's exit from the European Union: delayed access to medicine and devices and post-approval regulation and monitoring

Delayed access to medicine and devices

The move away from a centralised regulatory system is likely to be both costly and administratively challenging. Following the UK's formal withdrawal from the European Union, the United Kingdom and EEA members will be third countries to each other. As a result, marketing authorisations currently issued by the MHRA will no longer be valid in the EEA. UK companies will require licences to import EEA-manufactured products, and must also ensure that they conduct thorough sample



testing and due diligence. Companies would need to submit new applications for marketing authorisation, both to the European Union and separately to the MHRA, for authorisation for use in the United Kingdom. Additional licensing requirements are likely to result in delayed access to medicine and devices.

Further, the Confederation of British Industry estimates that the MA for new medicine costs approximately £45,000. Owing to its relatively low population and medical expenditure, the United Kingdom could become a less attractive destination for innovative medicines, as pharmaceutical companies and device manufacturers may prioritise the EU market due to its greater size. This would compound concerns surrounding delayed access.

Access to medical devices follows a similar story. The strength of UK medical devices lies in orthopaedics, imaging and cardiovascular equipment. The vast majority of other tools and components are imported from the European Union. Establishing a separate accreditation system from the current CE marking regime would increase the burden on device manufacturers through the need to satisfy different safety, health and environmental protection requirements. This would likely lead to delays in devices developed in other countries reaching the UK market.

Post-approval regulation and monitoring

Alongside the European Commission, the EMA and other national health bodies play a central role in the surveillance and sharing of information on medicines and medical devices. The collaborative approach enables data to be collated across a large population for all EEA states, safety concerns to be quickly identified and information to be shared across a wider coverage area. Should the United Kingdom adopt a different approach to surveillance data and information sharing, it would significantly lessen the capacity to detect and manage issues such as adverse drug reactions, possibly putting patient safety at risk.

Unhealthy Outlook: Part Four

Conclusion

Overall, the UK's exit from the European Union will likely have a profound impact on staffing, funding and access to medicines. With 5.5% of NHS staff in England originating from EU countries (excluding the United Kingdom), the health-care sector faces considerable uncertainty over the future supply of labour and wages following the UK's withdrawal.

Public-sector funding is likely to remain under pressure. Despite attempts to increase funding, growth rates remain below historic averages. The economic fallout from the UK's exit poses a further threat to public funding through tax receipts, and the potential loss of access to EIB funding would limit infrastructure investment, hindering efforts to reform health-care services.

Access to medicine and patient safety will continue to remain key point of contention. Although the DHSC has implemented numerous contingency plans to ensure access to medicine, stockpiling and express freight contracts are short-term options and are not feasible in the long run. The absence of any trade agreements is expected to have a severe effect on supply chains.

In the long term, the move away from the EMA and a centralised regulatory system is likely to result in delayed access to medicine and devices due to marketing and licensing requirements, and access to medical devices follows a similar story. A different approach to the regulation and surveillance of medicines is also likely to put patient safety at risk, unless the MRA can work collaboratively with the EMA and keep standards consistent.

IBISWorld Industry reports used in this special report:

Q Human Health & Social Work Activities in the UK

Subscribe and become an industry expert

Subscription packages can be tailored to meet your individual or company's needs. Benefits of subscription include substantial discounts on report prices, exclusive data access and rates on customised research to help you move quicker than the competition. Including key statistics, analysis, historical data and future forecasts, IBISWorld Industry Reports provide the information you need to make sound business decisions – now and into the future.

For more information, please visit www.ibisworld.co.uk or call us on 020 7222 9898

www.ibisworld.co.uk | 020 7222 9898 | info@ibisworld.co.uk

At IBISWorld, we know that industry intelligence is more than assembling facts
It is combining data with analysis to answer the questions that successful businesses ask

Identify high-growth, emerging and shrinking markets
Arm yourself with the latest industry intelligence
Assess competitive threats from existing and new entrants
Benchmark your performance against the competition
Make speedy market-ready, profit-maximising decisions

IBISWorld

WHERE KNOWLEDGE IS POWER

Who is IBISWorld?

We are strategists, analysts, researchers and marketers. We provide answers to information-hungry, time-poor businesses. Our goal is to provide real-world answers that matter to your business. When tough strategic, budget, sales and marketing decisions need to be made, our suite of Industry and risk intelligence products give you deeply researched answers quickly.

IBISWorld Membership

IBISWorld offers tailored membership packages to meet your needs.