The Show Must Go On for Animal Health

The UK's decision to leave the EU will no doubt engender a number of changes for the veterinary medicines industry, which may lead to challenges, but also to opportunities. Our initial analysis flags up a number of areas for immediate focus, such as avoiding legal and regulatory uncertainty, harmonising licensing systems for veterinary medicines, encouraging further innovation in our sector and, most importantly, guaranteeing continued access to the necessary veterinary medicines that safeguard animal health.

Negotiations now started between the EU 27 and the UK will no doubt herald a slew of trials and tribulations for many industries at large, and it will be our job to ensure that the vital role played by the veterinary medicines industry is well-understood during the process. The one thing we must not lose sight of in this Brexit process, is that animal disease will not heed any border, be it soft or hard. Food safety standards should not be held hostage to political discussion. And, most importantly, ensuring the health and welfare of Europe's animals through continued access to licensed medicines must not become a pawn in the game of 'Who will get the EMA?'

This decision to detach from the EU will almost certainly change the current dynamics of the European animal health environment and the wider agri-food sector. It is likely to have as yet indeterminable repercussions on market access, trade, and regulatory standards. For UK-based companies in particular, whether the nation remains in the European Economic Area, joins the European Free Trade Association or distances itself entirely from the EU, there will clearly be ramifications for the licensing of and further innovation in veterinary medicines in the foreseeable future.

Need for Continued Access to Medicines and Vaccines

Veterinary surgeons, farmers and other animal owners will continue to need access to a wide range of veterinary medicines to treat and prevent the range of diseases they encounter. The message[1] delivered by the European Medicines Agency and the European Commission early May was clear. Once the UK leaves the EU it becomes a 'third country'. This means that certain legal repercussions will need to be considered in due time by animal health companies as the 'marketing authorisation holders'. EU law requires that marketing authorisation holders are established in the EU (or EEA) and some specific activities must also be performed in the EU (e.g. related to pharmacovigilance, batch release). The notice served as a reminder that companies may be required to adapt processes or change the terms of their marketing authorisation to ensure continuous validity and use post-Brexit.

Under the current regulatory framework, companies can have a new product authorised by the EMA via the centralised route, leading to a marketing authorisation to sell the product in all 28 member states. As much as the industry would wish to avoid extra excessive regulatory burden, it is likely that in addition to the EU centralised authorisation, a separate UK authorisation may need to be applied for. A further complication is that UK-based companies currently holding centrally approved EU authorisations, may need to move operations to an EU member state, in order to retain their access to the EU market. Some form of 'mutual recognition' may be sought and the UK may wish to adopt the full acquis on medicines, just as the EFTA countries have. EFTA members implement the EU legislation on veterinary medicines, have access to EMA activities and can participate in its committees (CVMP, CMDv). Centralised marketing authorisations also automatically cover both EU and EFTA member states.

Maintaining Efficiencies and Avoiding Administrative Burden – Objective of New EU Legislation

Avoiding further administrative burden and reducing regulatory uncertainty are industry's main concerns in the authorisation process, something the current proposal for new EU legislation on veterinary medicines is trying to redress.

From a regulatory perspective, given the UK's leading role within the EU regulatory network for registering veterinary medicines, Brexit will cause a massive headache and a large regulatory burden for marketing authorisation holders. It will create a resource gap that will need to be filled by the other national competent authorities. Within the EU's authorisation process, when it comes to new product applications, or for certain variations to marketing authorisations, the work is carried out by one or two 'lead' EU countries and then is generally recognised by the other EU countries. This has introduced efficiencies, reduced resource needs across the EU authorities, and even sometimes led to a reduction in the fees involved with licensing products.

The UK is currently the reference member state or 'lead' country for more than 600 products authorised via the mutual recognition and decentralised procedures. In 2015, for example, the UK acted as reference member state in 43% of mutual recognition procedures, being the lead regulatory agency for 73 out of 168 applications.

Moving forward, companies may be forced to make some tough business decisions. To which member state do they transfer the rapporteurship from the UK? Will they have to get a separate marketing authorisation for the UK, or will they decide to withdraw certain marketing authorisations from the UK entirely? Will they have to relocate manufacturing sites or their 'qualified persons'? Will UK-based licence holders have to re-apply from scratch for marketing authorisations that have been authorised via EU systems? All of these questions sound alarm bells regarding the issue of administrative burden within the regulatory process.

The current EU Directive on Veterinary Medicinal Products has been transposed into UK law but, depending on the timing of the ongoing legislative process for the future EU regulation on veterinary medicines, there may be a significant risk of divergences. The UK will be left with the old legislation that will refer to European procedures, structures and IT systems that may no longer apply, and the EU will have quite a different new regulation that aims to deliver on greater efficiencies!

Retaining Expertise and Talent Diversity
If, or once, the UK's VMD are no longer part of the European regulatory network, this would mean the loss of a certain amount of expertise. Not only within the process for approving medicines but also for the 'qualified persons' for manufacturing authorisations or pharmacovigilance, for example. EU qualified persons for pharmacovigilance (QPPV) are required to reside in the EU. Yet another issue that must be addressed as efficiently as possible.

Then there is the question of the movement of people and the workforce. We've already mentioned some of the impacts of losing the expertise of the VMD but there will be a need for reassurance over arrangements for the status of EU citizens working in UK-based companies and institutions and of UK nationals working in the animal medicines sector in EU countries. Ease of movement for high-qualified workers, talents and researchers will be necessary to retain a European lead on technological innovation and to further stimulate creativity. Our industry needs highly-skilled workers who can travel freely across Europe while feeling confident and secure in their jobs.

The UK as a Pragmatic Scientific Reference
With the UK's strong science base, a number of British scientific institutions play important roles in many projects initiated and funded from Brussels. This is particularly applicable for food safety research. While being located in a non-member state is not a complete barrier to receiving EU funding, it will be interesting to see if there is a shift towards other member states getting a larger slice of the funding pie. The UK is considered to be a global leader for research, and is currently one of the largest recipients of EU funding. Withdrawing this financial help will certainly undermine the UK's top-ranking position for R&D, but what would a UK withdrawal mean for the EU's innovation prowess?

Guaranteeing Consumer Protection
Another concern that will arise post-Brexit, is adherence to procedures that ensure consumers across Europe are protected from residues that may occur from the use of veterinary medicines during animal-derived food production. The maximum residue limit setting is again agreed under EU law. This regulation provides the basis for setting withdrawal periods (i.e. the time between an animal receiving the last dose of a veterinary medicine and the first collection of foodstuffs, e.g. milk) and for monitoring food safety. The EU also participates in Codex, a body responsible for setting international MRLs, and helping facilitate trade in food. So, for consumer protection and continued trade of animal-sourced food products, it will be necessary to seek a mutually acceptable solution to this maximum residue limit procedure.

With this in mind, food safety standards will most likely come into question. A lack of harmonised standards on vaccination of animals or health status controls may have an impact on the high levels of food safety currently enjoyed across the EU. This may also affect the freedom of movement of goods. Currently, the UK exports the majority of its agri-food products to the EU and it is also heavily reliant on food imports from the EU. To keep up this trading partnership, putting the question of trade tariffs aside, negotiations will need to cover the aspect of how future food safety will be measured and assured.

Avoiding Trade Issues and Adapting to Change
On the subject of the free movement of goods, the creation and maintenance of the EU single market has been one of the main reasons for companies investing in Europe. The single market ensures that there are no unnecessary barriers to products, including veterinary medicines, being traded freely between EU/EEA member states. For governments, this means that they must not put in place tariff barriers to trade (e.g. custom duties) or non-tariff barriers to trade (e.g. unnecessary regulatory requirements).

It is clear that the EU and the UK should find a solution to remain sustainable commercial partners to keep costs down for companies and to help ensure our customers' (and the animals') rights to access the best medicines. Any additional custom duties, import VAT and border controls will hamper trade and may have a negative effect on animal disease control and prevention.

Smoothing the Transition of the EMA
When it comes to the EU body holding the power to license animal medicines, the current discussion in Brussels spheres is mainly centred on which city will become the new host of the European Medicines Agency, and it seems that a new location is put forward every few weeks. The Commission is keen to ease the practical and financial burden for the experts working there, as if they stay with the agency they will have to relocate and move to another city within the EU. Our initial asks are for easy access to the host city, good local logistics, and retention of expertise. During the transition period for the EMA, our main concerns are that delays on approvals are kept to a strict minimum.

Keep Calm and Carry On
At a recent event organised at the EMA HQ in London, where industry and regulators meet to update on the latest developments in scientific review, regulation and marketing authorisation procedures, a journalist remarked to me that he was very surprised that Brexit was not once mentioned over the two days of the event. This, to me, is a clear demonstration of our sector's ability and willingness to adapt and get on with business to the best of our ability.

We will retain our good relationship with the UK National Office for Animal Health and continue dialogue with the negotiating teams over the various issues outlined in brief above. We don't yet know all of the 'where' and 'how' Brexit will have an impact on our industry. But what we do know is that vets, farmers, pet lovers and other animal owners will continue to need access to a wide range of animal health products to ensure the health and wellbeing of their animals. For this reason alone, we must keep calm and carry on!

1. http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/05/WC500226603.pdf

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With membership covering 90% of the European market, IFAH-Europe represents innovators and generics alike, as well as large, medium-sized and small companies. Employing some 50,000 people in Europe, the sector is resilient and innovative. IFAH-Europe's member companies invest over €500 million in research and development each year.

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