

BREXIT

THE PHARMA INDUSTRY & MALTA'S AVAILABILITY OF MEDICINES

EDITORIAL



Twenty-third June 2016. This is the referendum date when British, Irish and Commonwealth citizens living in the UK and Gibraltar, as well as UK nationals who have lived overseas for less than 15 years will decide whether the UK will withdraw from the EU or not. Although EU citizens living in the UK and Gibraltar will not have a vote, citizens from the Commonwealth countries of Malta and Cyprus can vote. The reason for this is that, apart from the UK, only these two European countries are in Commonwealth.

Those in favour of UK's withdrawal from the EU, or Brexit as it is commonly referred to, are mainly Eurosceptics who argue that such move would allow for better control of irregular migration, as well as gain more control on UK's own trade negotiations and reduce unnecessary EU bureaucracy. However, those arguing against a possible Brexit claim that this would risk the UK's current prosperity, undermine current employments, as well as increase trade barriers with the EU.

A possible Brexit also would undoubtedly impinge on the healthcare sector. According to a letter published last February in the Financial Times the UK receives more EU funding per capita for health research than any other EU country. The letter, penned by the *UK life sciences sector* also states that *"Not only would an exit from the EU negatively impact the life sciences sector, but changing the current arrangement would lead to disruption, expense, and significant regulatory burdens for a new authorization system."* This would possibly translate into less funding for innovative research projects stemming from the various European funding programs such as Horizon 2020.

Another concern relates to the issue of patents, including pharmaceutical ones. Currently, different authorities can decide on the validity and infringement of European patents. However, this may give rise to various challenges - when either a patent proprietor seeks to enforce a patent or when a third party seeks to revoke a patent in different countries - such as high costs and possible divergent decisions. This is all set to change with the

establishment of a new Unitary Patents Court of Europe, part of which is set to open in the forthcoming months in London. This will have exclusive jurisdiction for litigation relating to European patents. Obviously, if a Brexit materialises, this Court would have to re-locate outside the UK.

Apart from the European Banking Authority, London also houses the European Medicines Agency which is the regulatory body responsible for the scientific evaluation, supervision and safety monitoring of medicines developed by pharmaceutical companies for use in the EU. It is Europe's equivalent of the US Food and Drug Administration. Obviously, if a Brexit materialises, the Agency would have to move as well. This transition would definitely slow the approvals of pharmaceuticals across Europe. It also goes without saying that if Britain were to exit Europe it would produce a lacuna in the technical capability of EMA since British experts are renowned to be the biggest contributor to its drug evaluation system.

Another aspect is that Malta has over 1400 medicines licensed in Malta which are sourced from the UK market through various European procedures. Most notably, parallel importation licences, and authorisations in accordance with article 126(a) of Directive 2001/83/EC [for justified public health reasons] are issued in Malta specifically on the premise that they are licensed in another EU /EEA country; the regulatory lifecycle of these medicines shadows that of the source country. So, if indeed, the UK leaves the EU [and possibly the EEA, negotiating a separate trading relationship with the EU], would this lead to a revocation of these licences by the Maltese authorities? ❓❌

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