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Brexit - The Malta Medicines Authority ensures accessibility to medicines

The Malta Malta Medicines Authority enhances the accessibility to medicinal products for the public. The decision of the UK to leave the EU has an impact on the European health products sector and the regulatory network. The effect on countries dependent on the UK market, especially Malta, presents a challenge. Protecting the availability of medicines for Maltese patients and the integrity of our market are key strategic goals of the Malta Medicines Authority, keeping in focus the special situation presented by the size of the Maltese market for pharmaceutical companies.

In early 2017, as soon as there were signs that Brexit was soon becoming a reality, the Malta Medicines Authority established an internal working group focusing on several aspects of Brexit to mitigate the impact. Stakeholders, including pharmaceutical companies in Malta, in the UK and the EU, were supported and offered solutions to maintain EU compliance and ensure continued and uninterrupted availability of the products on the Maltese market. Meetings with stakeholders and individual communications with marketing authorisation holders were carried out on a regular basis since 2016. As a result of this effort, many companies have carried out their due diligence in moving activities from the UK to the EU. To date, companies have moved the marketing authorisation holder from the UK to the EU for over 900 products authorised in Malta, bringing them in line with the requirements. These products can continue to be made available together with all the other authorised products.

During the past 5 years, the Malta Medicines Authority has lobbied, in the interest of patients, together with Ireland and Cyprus, with the European Commission, industry representatives and local stakeholders, both public and private. As a result of these interventions, the European Commission published a Commission Notice to give more time to companies to continue to make UK products available to Malta and other small Member States. A number of impacted products have been exempted as allowed by the Notice to ensure their continued availability in Malta. Discussions to highlight the difficulties that Malta is facing as a result of Brexit to secure accessibility to medicines are continuing until a long term and sustainable solution is reached.

The pharmaceutical industry, in general, has been approached directly and given every opportunity to discuss their problems in order to address the Brexit impact to their business. They are continuously encouraged to register and market their products in Malta. The local fees for registration of medicines already available in other European countries have been kept to a minimum, €250 per product. Moreover, any flexibilities allowed by the legislation are being applied to minimise the regulatory and administrative burden on companies.

Simplified registration of medicines is used extensively to avoid shortages of essential medicines. This is to keep documentation required to the barest minimum, although this is not the optimal route for registration in line with the high prestige that the Malta Medicines Authority is

renowned for. Over the last 5 years, 2350 products were authorised through this simplified route, to continue to make medicines available to the public. Additionally, more than 1700 medicines were authorised in Malta through the normal registration channels since 2016. Where registration was not possible, other means were used to ensure continued availability - 134 medicines were imported on the basis of special permits, both from the UK and other European countries since October 2020 mainly to cover critical medicines for hospital use, where it is determined that the benefit to the patients outweighs the risk.

The Malta Medicines Authority has been actively approaching European competent authorities to assist in the registration of medicines. Many of the Member States are now carrying out simplified European registration exclusively for Malta, even lowering their fees drastically. This has resulted in an 80% increase in companies registering their products in Malta through this route. In the case where benefit to risk to the patient is considered to be positive, such as when no alternatives are available, exemptions to language of the packs and safety features requirements, are also being allowed. This is done on a temporary basis for emergency use, keeping the patient needs at the forefront. These exemptions have been granted to over 400 medicines in the past 3 years, whilst the Malta Medicines Authority has made recommendations to ensure that other controls are applied to reduce risk, such as attaching a package leaflet in English to the product and ensuring that the product is obtained from reliable sources. Companies are also being encouraged to create multilingual packs that can be used in more than one European Member State.

The implementation of other European legislation that has come into effect in the last few years, mainly the Falsified Medicines Directive, and the COVID-19 pandemic have also had an impact on pharmaceutical companies. In the case of the Falsified Medicines Directive, the expense for local pharmaceutical companies is invoked by the MAMVO, that has in its membership representatives from the bodies representing pharmaceutical stakeholders.

From time to time, shortages of medicines impact all countries. However, alternative medicines can be made available to ensure continuity of care. The pharmacist, as an expert in medicines, is in a prime position to advise when some medicines are not available and to recommend suitable alternatives.

Shortages and availability of medicines are current topics being discussed between the European Commission and the Member States in the context of proposed upcoming updates to the European pharmaceutical legislation. Amongst others, the Malta Medicines Authority is actively participating in these discussions to continue to highlight the difficulties encountered by our unique scenario.

The Malta Medicines Authority continues to monitor the situation with regards to availability, keeping in constant dialogue with the stakeholders to ensure that the interest of the patients continue to be well served. Arrangements have been made by the Malta Medicines Authority to ensure that essential medicines that are only available from the UK are accessible to patients in Malta.