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A Simplified Approach for the Registration of Medicines in Small European Countries

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INTRODUCTION

A medicine requires a Marketing Authorisation (MA) before it could be made available on the EU market (Directive 2001/83/EC[1]) to ensure its safety, quality and efficacy. The requirements to obtain a MA are complex and may adversely influence accessibility to medicines.[2,3] The problem of accessibility to medicines is of particular interest to small countries such as Malta. The research question of this study was: Can registration of medicines in small EU countries such as Malta be simplified?

AIMS

- To review the processes by which medicines are registered in the EU, with particular interest to small countries such as Malta
- To analyse the strengths and weaknesses of these registration processes and identify problems in the registration process in Malta
- To compile a guide intended to simplify the process for the registration of medicines in Malta and in small EU countries

METHOD

Part 1: Qualitative Research

- Functions of the regulatory bodies and legislation related to the registration of medicines were reviewed.
- The 15 pharmaceutical companies with the largest number of products licensed on the Maltese market were identified from the Malta Medicines Database of the Malta Medicines Authority and the regulatory personnel were contacted.
- Semi-structured interviews with 2 QPs and 8 RPs from 10 of the 15 identified companies were conducted to obtain a better insight on the present situation of the registration procedure in Malta.

Part 2: Development of a Guide

- The qualitative research was used to compile a guide to the registration procedure of medicines.
- The compiled guide was validated by the Director of the Licencing Directorate and the Head of Quality at the Malta Medicines Authority and a pharmacist working in academia.
- The guide was designed in booklet format, printed and disseminated.
- An online version of the guide was designed and launched.

RESULTS

- Authorisation of medicines according to Article 126(a) of Directive 2001/83/EC1 is the most followed procedure for the registration of medicines in Malta (n=6).
- When evaluating the right route to register their product on the market, companies consider factors including the finances and resources required to place and maintain the product on the market (n=10) , the type of product (n=8), how much the company is willing to invest (n=8), and the urgency of the product to be placed on the market (n=7).
- The main challenges encountered when registering a product in Malta are obtaining medicine packs in English language (n=10) and regulatory support from the MA holder (n=4). Delays in the evaluation process are usually due to missing or incorrect information in the application form (n=6).

The compiled guide consists of two sections:

1. 'The Registration Procedure', which describes National and European medicine authorisation procedures, post-authorisation requirements and information on the validity and renewal of a MA;
2. 'The Marketing Authorisation Application', which provides information on the format of the MA application, including the Common Technical Document format, and the different types of MA applications (Figure 1).

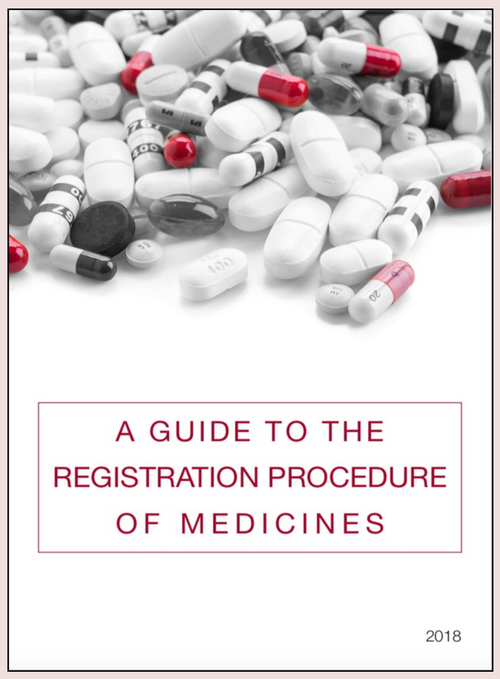

Figure 1: Front cover of the guide

The online version of the guide is available at: www.registrationofmedicinesmalta.com

CONCLUSION

- The compiled guide is intended to simplify the process of the registration of medicines and outlines the process and requirements involved in the application of a MA. By preparing a simplified guide clearly explaining national procedures required to apply for a MA, the opportunity to support access to medicines within small markets is presented. Harmonisation between Member States , increasing financing and resources, developing of guides and increasing consultations between companies and the regulatory authorities may improve the efficiency of the drug registration procedure.

REFERENCES

1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to Medicinal Products for Human Use. Official Journal 2004;L311:67-128.
2. Bugeja V. The Impact of EU legislation on medicines in Malta. Journal of the Malta College of Pharmacy Practice 2008;14:34-39.
3. Pace A, Azzopardi L, Serracino-Inglott A, Wismayer L, Zarb Adami M. Development in the European Union and Access to Medicines. International Journal of Comprehensive Pharmacy 2013;6(2):7.