INTRODUCTION

A medicine requires a Marketing Authorisation (MA) before it could be made available on the EU market (Directive 2001/83/EC). This registration process ensures the safety, quality and efficacy of medicines on the market. The requirements to obtain a MA are complex and may adversely influence accessibility to medicines. The problem of accessibility to medicines is of particular interest to small countries such as Malta. The availability of high quality medicines that are not very expensive promotes confidence in health systems, health care professionals and the pharmaceutical industry. 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
- To analyse the strengths and weaknesses of registration procedures and identify challenges 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 (European Medicines Agency, Malta Medicines Authority), committees and organisations (World Health Organisation, Committee for Medicinal Products for Human Use, International Conference on Harmonisation, International Coalition of Medicines Regulatory Authorities) 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 qualified persons and 8 responsible persons from 10 of the identified companies were conducted to obtain a better insight on the present situation and challenges faced regarding the registration of medicines in Malta.

Part 2: Compilation of a Guide to the Registration Procedure of Medicines

- 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 Licensing Directorate and the Head of Quality at the Malta Medicines Authority and a pharmacist working in academia.
- An online version of the guide was designed and launched.

RESULTS

- The 10 persons interviewed stated that authorisation of medicines according to Article 126(a) of Directive 2001/83/EC is the most followed procedure for the registration of medicines in Malta.
- Factors identified by the 10 persons interviewed that are considered by companies when evaluating the right route to register their product on the market are: (i) finances and resources required to place and maintain the product on the market, (ii) the type of product, (iii) how much the company is willing to invest, and (iv) the urgency of the product to be placed on the market.
- The main challenges encountered when registering a product in Malta identified by the 10 persons interviewed are: (i) obtaining regulatory support from the MA holder and (ii) availability of medicine packs in the English language. Six persons stated that delays in the evaluation process are due to missing or incorrect information in the application form, while 4 persons stated that they do not usually encounter delays. Two persons identified the re-packaging process as another cause for delay in placing a product on the market.
- The 10 persons interviewed agreed that regulatory costs for the registration of a medicinal product do not directly influence the price of medicines since they are included with other costs when evaluating the feasibility of registering a product on the local market.
- 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. A list of abbreviations, glossary and references list are included in the guide (Figure 1). The online version of the guide is available at: www.registrationsofmedicinesinmalta.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 approach and clearly indicating national procedures required to apply for a MA, the opportunity to support access to medicines within small markets is presented.