

# The impact of EU legislation on medicines in Malta

Vanessa Bugeja BPharm(Hons), PQ Dip(Nutrition & Dietetics)

Pharmacist, Pharmaceutical Unit, Public Health Regulation Division, Malta  
Email: vanessa.a.magro@gov.mt

## Key words

EU accession, rational use, quality, availability, affordability

**The impact of EU accession on the medicines in Malta has been quite strong, especially with regards to the availability of medicines. The new regulations affected many policies either by totally changing them or by highlighting the need for action and change. EU legislation has brought difficult changes which however promise to be fruitful once there is agreement of all key players and necessary action is taken and systems are implemented so that Malta can operate within the EU legislative framework with the aim of ensuring availability and affordability of high quality medicines and their rational use.**

## Introduction

Today pharmaceutical policy is a global concern, with the overall goal of achieving rational medicines use. Such goal

makes policy analysis issues dynamic and constantly under evolution.<sup>1</sup> Pharmaceutical policy is both problem solving and policy making. So policy analysis is both a tool

of the problem-solving process and the democratic process.<sup>2</sup> It is the process of predicting impacts of possible policies and evaluating past policies.<sup>1</sup> The value of policy analysis lies in its contribution to the understandings that citizens have of issues and therefore to the making of policies with outcomes supported by the public.<sup>2</sup>

Pharmaceutical policies made on national, international, supranational or global level, will always ultimately affect everyone.<sup>3</sup> The Europeanisation of medicines regulation harmonises the standards of regulatory evaluation in order to accommodate a single European pharmaceutical market, and thus eliminates conflicting regulatory decisions made by national authorities in the European Union (EU).<sup>1</sup> Member states have the challenge of strengthening their capacity to manage the complexities of relevant trends, options for change, evidence assessment, setting of priorities, drafting and implementing action plans, measuring outcomes and taking corrective action.<sup>4</sup>

Following EU accession in May 2004, Malta faced its own challenges in the pharmaceutical area. Accession brought with it a change in the legislation regarding medicinal products for human use (Table 1). EU legislation regarding good manufacturing practice, importation and parallel importation, marketing authorisations, packaging and labeling, wholesale distribution, reimbursement and selection of medicines, clinical trials, pharmacovigilance and advertising had to be transposed into the Maltese legislation. Thus, new regulations were established.

The quality, access, and rational use of medicines were effected, especially by the newly introduced procedures by which medicinal products are placed on the Maltese market. Between 1998 and 2002 the procedure involved the submission of a World Health Organisation (WHO) Certificate of Pharmaceutical Product (CPP).<sup>5</sup> Products registered with a CPP were included in the transition list which was drawn up in November 2002. The products were bound to benefit from a derogation. The derogation period in which products in the transition

Table 1. Maltese pharmaceutical legislation

**Legislation covering medicinal products and pharmaceutical activities in Malta**

1. The Medicines Act, 2003, and its subsidiary legislation (mainly covers regulation of medicines and pharmaceutical activities)
2. Dangerous Drugs Ordinance 1939 (narcotic drugs)
3. Medical and Kindred Professions Ordinance 1901 (psychotropic substances)

list could be registered via a Provisional Marketing Authorisation (PMA) followed by a Marketing Authorisation (MA), ended in December 2006.

Upon accession into the EU, medicinal products could be placed on the Maltese market not only through the PMA-MA process but also through the Mutual Recognition Procedure (MRP). From February 2005 Article 126a of Directive 2001/83 on the Community code relating to medicinal products for human use, as amended by Directive 2004/27/EC of the European Parliament and of the council of 31<sup>st</sup> March 2004, could be used, while starting from November 2005, the Decentralised Procedure (DCP) could also be used.<sup>6</sup>

A legislative framework is necessary for the implementation and enforcement of policies. The legal basis for the control of activities in the public and private pharmaceutical sectors can only be provided by legislation and regulations.<sup>7</sup> EU legislation can and does have an impact on medicines and health. On the other hand, national governments attempt to retain control.<sup>8</sup>

Public oversight and stewardship are required for the production and

distribution of medicines (Table 2). Unlike other goods and services, medicines have to be regulated so that the market is successful and safe for the users.<sup>11</sup> Medicines regulation operates within a legal framework and is based on the application of medical, scientific and technical knowledge and skills. It involves interactions with various stakeholders whose economic, social and political motives may differ, making the implementation of regulation quite challenging.<sup>12</sup>

An efficient regulatory system for medicines provides timely access to effective treatments for patients and protects patient safety. The patients, doctors, pharmacists, government and the pharmaceutical industry share a common interest which is ensuring that the system is efficient, transparent and robust and makes decisions based on sound scientific evidence.<sup>13</sup> They access quality and rational use of medicines depend on such a regulatory system.

The issue of the impact of EU legislation on the access, quality and rational use of medicines was looked at from three approaches so as to obtain a holistic picture. The types and number

of authorisations were reviewed, local newspapers were scanned, and group discussions with major stakeholders were held.

The impact was multifaceted. The regulatory changes triggered actions and reactions from the main stakeholders including the Malta Chamber of Pharmacists, the Malta Chamber of Commerce and Enterprise (CoCE), the Malta Chamber for Small and Medium Enterprises (GRTU), the Federation of Industry (FOI) and the government. The affects of EU legislation on the various pharmaceutical areas were discussed, agreements reached and necessary action taken to amend and improve the situation.

**Quality of medicines**

Poor quality medicines are ineffective, harmful and can result in therapeutic failure. The availability of high quality medicines promotes and ensures confidence in health systems, health professionals, pharmaceutical manufacturers and distributors. A strong national regulatory authority is the key to the effective regulation of manufacture, trade and use of medicines and therefore the protection and promotion of public health.<sup>12</sup>

Prior to accession, Malta had 7020 EU and non-EU products placed on the market via a WHO CPP. The latter was not enough to ensure the good quality, safety and efficacy of medicines available in Malta.<sup>14</sup> EU regulatory regime and the registration of medicinal products via PMA, MA, 126a, MRP or DCP brought with it an improvement in the quality, safety and efficacy of products (Table 3).

The implementation of EU legislation was considered a painful process which safeguards the community, by ensuring that the medicines available are of a certain standard and quality and of known impact on patients. Non-EU generic products may be of good quality but the EU legislation and standards provide safeguards for professionals and patients.

However, there is not sufficient scientific evidence in terms of patient outcomes to support this claim of better quality and therefore better outcomes in Malta. In spite of complaints on the drugs which were available in the years previous

Table 2. Pharmaceutical Regulatory Bodies

**Bodies safeguarding the quality, access and rational use of medicines in Malta**

The **Medicines Authority (MA)** in Malta is the National Competent Authority for the regulation of medicines for human use and has the mission "to contribute to the protection of public health in Malta through regulation of the safety, quality and efficacy of medicines for sale or supply on the Maltese market."<sup>9</sup>

The **Pharmaceutical Unit**, within the Public Health Regulation Division of the Ministry for Social Policy, is responsible for and co-ordinates the administrative and technical aspects of legislation, policies and guidelines regarding pharmaceutical policy on a national level.<sup>10</sup>

to EU accession, the quality of the drugs in question was never checked.

### Access to good quality medicines

Access is defined as the ability to obtain health care, as determined by factors such as the availability and affordability of goods and services.<sup>15</sup> Medicines can be essential to save lives, reduce suffering, and improve the functioning and well-being of people who have access to them. Access to affordable and appropriately used high-quality medicines boosts both the productivity and economy.<sup>7</sup>

### Availability

Post-EU accession, the number of medicinal products which had a marketing authorization in Malta, was quite less than the approximate 3750 products which were previously available on the market (Table 3). EU legislation and medicines registration caused a negative impact on the availability of medicine, as confirmed by Galea in September 2007.<sup>14</sup> Some stakeholders blamed EU directives for the reduction in medicines availability because importers and their suppliers failed to register new medicines, while others believed shortages

were increasing from pre accession and continued post accession. Following the stakeholders indication of the need for a system that guarantees availability and choice, the government set up a commission to study medicine status and give recommendations. Eventually, authorization via 126a was introduced and registration fees were amended so as to improve availability and promote competition.

### Labelling and packaging

Stakeholders were concerned with the cost implications of the labeling regulations

Table 3. Authorisations issued for medicinal products in Malta

Period	Type of authorization or medicinal product list	Number
May 2004	Derogation List / WHO CPP <sup>a</sup>	1823 different active ingredients
		7020 medicinal products
		5162 medicinal products from EU
Up to December 2004	PMA <sup>b</sup>	3750 medicinal products on the private market 2200 medicinal products
Year 2005	MRP <sup>c</sup>	6% (108 out of 1770 applications)
	DCP <sup>d</sup>	5% (1 out of 22 applications)
January to May 2006	MRP	10% (22 out of 211 applications)
	DCP	5% (7 out of 134 applications)
May 2006	PMA	2230 medicinal products
	MA <sup>e</sup>	570 medicinal products 1299 under process
November 2006	126a list <sup>f</sup>	1376 medicinal products
		776 active ingredients
Up to March 2007	126a authorisations <sup>g</sup>	7 authorisations
		103 applications under process
	MA	1437 from PMA-MA process
		148 from MRP process
		19 from line extensions (PMA-MA)
		1 national
		MRP/DCP
Unlicensed <sup>h</sup>	132 medicinal products	

a. World Health Organisation Certificate of Pharmaceutical Product;

b. Provisional Marketing Authorisation;

c. Mutual Recognition Procedure;

d. Decentralised Procedure;

e. Marketing Authorisation;

f. list of medicinal products with no authorisation and therefore medicinal products not marketed in Malta. N.B. Some were being imported directly by the Government Pharmaceutical Services through Article 20 of Medicines Act, 2003;

g. authorisation through Article 126a of Directive 2001/83 as amended by Directive 2004/27/EC;

h. authorisation for the use of products which are not registered in Malta in line with DH Circular 270/06 Guidelines for the supply of medicinal products for human use through processes which are not covered by the Medicines Act, 2003 and its subsidiary legislation.

requirements. Labelling issues could have induced companies not to register products thus resulting in reduced availability and increased prices. The language issue was solved by an agreement to have either one of the two official national languages, Maltese or English, used for packaging and labelling.

### **Registration system and registration fees**

EU accession brought with it what has been called a cumbersome bureaucratic registration process, as predicted in the study by Vella Bonanno (2003).<sup>5</sup> Malta suffered a shortage of medicines because the pharmaceutical companies were finding it too expensive to register their products for a small market of 400,000 people.

The government had been assured that registration costs were not high. But, pharmaceutical companies withdrew due to labour intensive, disproportionate costs and registration fees. The stakeholders were concerned with the impact that the strict implementation of EU legislation was having on the access to medicines. On the other hand, the well-run registration system attracted pharmaceutical manufacturers to Malta, as it provided the necessary regulatory support crucial for sustaining the local industry.

Eventually, the EU introduced a clause to overcome the problem of reduced availability through the issuing of a qualified licence (authorization via article 126a). However, up to mid May 2006, no one had applied for this simpler registration procedure. The industry had to be pressured for medicines to be registered in Malta. Between January 2005 and June 2006, Malta was included only in 130 applications for MRP and in 8 applications for DCP. The problem of high registration and variation fees was solved by an agreement on a system of uncomplicated fees comprising only a Lm50 (€116.47) annual registration fee.

### **Local manufacturing industry**

EU legislation provided strong support through the Medicines Authority for the local manufacturing industry, and the latter

grew steadily as the benefits of the local industry were adequately acknowledged and safeguarded. Discussions led to the provision of a mechanism which ensures availability and overall reduced prices for the local consumers, while still keeping the regulatory frameworks which govern medicinals in Malta.

### **Affordability/pricing**

Upon EU accession, the prices of medicines in Malta increased drastically. Cheap reasonably priced medicines were replaced by expensive ones. The mark-ups for the wholesale dealer and pharmacists were no longer regulated and instead were left up to market forces. Where, due to these same market forces, only one medicine is available, monopoly resulted.

The regulatory system was blamed for the elimination of competitor products so that originator more expensive products remain. Availability and affordability are highly linked as decreased number of products leads to decreased competition and therefore increased prices.<sup>14</sup> The need to promote the use of generics became evident, as this would cut down costs and increase choice and accessibility. Discussions led to consideration of reference pricing to control prices and of a system which favours the importation of generics. The Consumer Competition Division (CCD) within the former Ministry for Competitiveness and Communications (MCMP) was to monitor prices and discussions were held to establish a system whereby action could be taken as necessary to induce the market forces to interact and thus abolish price increases.

### **Rational use of medicines**

WHO states that rational use requires patients to receive medications appropriate to their needs, in doses that meet individual requirements, for an adequate period of time, and at the lowest possible cost. This is essential for the promotion of quality care and cost-effective therapy. Rational use ensures that medicines are used only when needed and that patients understand what medicines are for and how to use them.<sup>16</sup> At the same time the concept of rational use of

medicines should be applied in a contextual manner.<sup>17</sup>

### **Pricing, internet, counterfeit medicines**

The problem of expensive medicines is at times solved by buying through the internet at one third of the local price because all one needs is a prescription. This aids rational use as doctors can prescribe medicines recommended by clinical guidelines even if they are not available on the Maltese market or are too expensive for low-income patients. However, the significant risk of counterfeit medicines exists. In Malta there is not enough awareness on this problem, and it is of concern that prescribers are recommending online buying to patients.

### **Availability and choice**

The rational use of medicines in Malta, though supported by the new legislation, was limited by the unavailability of medicines resulting from the implementation of this same legislation. Following EU accession there was a reduced consumer choice of children's medicine and of dosage types. Consumers did not find their medicines and believed they were being offered inferior alternatives.

Compared to the British National Formulary (BNF), the Malta Medicines List (MML) was limited thus affecting choice and rational use of medicines.<sup>18</sup> Similarly, the Government Formulary List (GFL) was also considered to be limited.<sup>19</sup> However, following EU accession, the transposition of the Transparency Directive (EU Council Directive 89/105/EEC of 21<sup>st</sup> December 1988) gave the medicines agents the possibility of having their products introduced on the list.<sup>20</sup>

### **Culture, habits and practice**

The medicines available through EU brought to the fore issues of changes in practice e.g. the use of suppositories, when most other EU countries use tablets, soluble tablets or syrup. Authorisation via 126a aids maintenance of usual preparations when a change in culture, habit or practice is not accepted.

### Generics, rational prescribing and substitution

The EU system ensures generics are chemically, biologically and clinically equivalent, and of high quality and so can be used with full confidence. The local industry argued that the promotion of generic dispensing, patient awareness on generics and knowledge on the available generic substitutes would ensure rational use and affordability. In Malta the use of generics is supported by legislation which allows substitution of medicines so that pharmacists may offer an alternative brand or cheaper generic equivalent.<sup>21</sup>

### Summary of Product Characteristics (SPC) /Patient Information Leaflet (PIL)

EU legislation promotes dissemination of information, but more enforcement as regards the distribution of SPCs to doctors was considered necessary. The dispensing of PILs with the medicine pack was also not being enforced and practiced by everyone. Awareness on the use of medicines could be improved by empowering people in line with the safeguards of EU legislation.

### POM and OTC

Following EU accession, the OTC range available became smaller. This was probably due to products not being registered and due to the new classification of products into POM and OTC. This classification may in certain cases reduce irrational use, but in others it disrupts the usual rational practice.

### Practice Points

- The pharmaceutical policy arena deals with conflicting goals of maximizing access, ensuring quality, minimising costs and promoting rational use of medicines.<sup>23</sup>
- The evaluation of the change in policies brought about by EU legislation, can drive policy learning by being integrated into ongoing discussions, by sustaining the advocacy of evidence and by helping policy makers think.<sup>24</sup>
- EU accession has ensured that medicines available in Malta are of high quality.
- EU legislation had a negative impact on access to medicines in Malta but discussions led to reflexive learning and policy making with the aim of improving the situation, while maintaining the other benefits of the EU regulatory regime.
- The use of medicine which can seem irrational in certain contexts, may in other contexts seem quite rational.<sup>17</sup>

Both prescribers and patients resist change. Patients often could not understand why a good medicine to which they were used, is no longer available, or why they need a prescription to buy it.

### Advertising and promotion

The fact that industry can market OTCs directly to consumers, has increased the emphasis on this target group.<sup>3</sup> The ease with which the OTCs could be advertised was compensating for the reduced availability of OTCs. Aggressive advertising was resulting in presumably informed consumers asking the pharmacist for a specific product rather than for advice.

The Legal Notice 380 of 2005, Medicines Act 2003, entitled Medicinal Products (Advertising) Regulations governs advertising and promotion with the healthcare professionals and the public.<sup>22</sup>

However, the regulations do not cover the communication between pharmaceutical companies and patient organizations. This could be due to the fine line between information and advertising.

### Conclusion

The conflicting goals of access, quality and rational use of medicines, make broad qualitative and quantitative knowledge essential for good pharmaceutical policymaking.<sup>23</sup> The implementation of EU legislation in Malta, caused a decrease in the availability and affordability of medicines, an improvement in the quality of medicines, and conflicting positive and negative effects on the rational use of medicines. Such contribution to practical reason and informed discourse, can be appreciated and expanded to reshape and make better policies.<sup>2</sup>

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