Accessibility to Generic Medicines

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INTRODUCTION

Health care costs are one of the key concerns for many countries. As the price of innovative and complex therapies increases, availability and access to generic medicines is critical for the sustainability of healthcare systems.[1] Globally, the level of patient acceptance to generic medicines is variable.[2]

In 2012, the generics market in Malta was still in its early stage, indicating the need for more awareness among the Maltese population.[3] In Malta, the experience gained by the authorisation and marketing of generics over the years implied that generic medicinal products are well accepted, however the local accessibility of generics is yet to be explored.[4]

AIM

To identify available generic medicines on the Maltese market for oncology drugs and drugs acting on the nervous system

SETTING

The National drug regulatory agency, the Malta Medicines Authority (MMA). Within the Authority, the Licensing Directorate processes all applications for product pre- and post-authorisation activities through established national and European procedures. This includes the granting, withdrawal, variation, revocation or suspension for all product related licences and authorisations. The Directorate also processes applications for work-sharing of European procedures.

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METHOD

- This study was a descriptive, quantitative study, focusing on the availability of generic products on the Maltese market for oncology drugs and drugs acting on the nervous system. Innovator drugs for oncology are expensive and nervous system drugs are widely prescribed in Malta and not broadly represented on the national health service scheme, requiring patient out of pocket payment.
- All authorised products in Malta were reviewed by accessing the national database available on the MMA website. [5]
- Data compiled includes classification, medicine name, active ingredient, dosage, pharmaceutical form, Anatomical Therapeutic Chemical (ATC) code, Authorisation date and Marketing Authorisation Holder.
- The generic products available for each active ingredient, and their corresponding classification, dosage and pharmaceutical forms were analysed. The classification was based on the ATC code classification system and the British National Formulary classification.[6] Biological and biosimilar medicines were excluded from the analysis since interchangeability and substitution in this area is not at the same level as practiced with non-biologic drugs.

Table 1. Number of Generics and Originators for Oncology by Classification

CLASS	SUB-CLASS	GENERICS		ORIGINATORS	
		SUB*	CLA**	SUB*	CLA**
Alkylating Agents	Nitrogen Mustard Analogues	8	16	4	4
	Alkyl Sulfonate	1		0	
	Nitrosourea	1		0	
	Other Alkylating Agents	6		0	
Antimetabolites	Folic Acid Analogues	14	63	1	5
	Purine Analogues	3		3	
	Pyrimidine Analogues	46		1	
Plant Alkaloids and Natural Products	Vinca Alkaloids and Analogues	6	26	0	1
	Podophyllotoxin Derivatives	10		1	
	Taxanes	10		0	
Cytotoxic Antibiotics	Actinomycin	1	18	0	0
	Anthracyclines	9		0	
	Other Cytotoxic Antibiotics	8		0	
Other Antineoplastic Agents	Platinum Compounds	16	36	0	5
	Methylhydrazine	2		0	
	Protein Kinase Inhibitor	3		0	
	Other Antineoplastic Agents	15		5	
TOTAL		159		15	

* Total number per subclassification
** Total number per classification

Table 2. Number of Generics and Originators for Drugs for Nervous System by Classification

SUBCLASS	GENERICS	ORIGINATORS
Antiepileptics	104	33
Antipsychotics	146	34
Hypnotics, Sedatives and Anxiolytics	65	14
Antidepressants	128	16
CNS Stimulants	8	14
Drugs Used in Addictive Disorders	16	3
TOTAL	467	114

RESULTS

- For oncology, 159 generics for 15 originators are available, namely: Alkylating agents (n=16), antimetabolites (n=63), plant alkaloids (n=26), cytotoxic antibiotics (n=18), and other antineoplastic agents (n=36) (Table 1). From the identified generic drugs for oncology, 139 are parenteral dosage forms, with cytarabine having the greatest number (n=18).
- For nervous system drugs, 467 generics for 114 originators are available, namely: Antiepileptics (n=104), antipsychotics (n=146), hypnotics, sedatives and anxiolytics (n=65), antidepressants (n=128), central nervous system (CNS) stimulants (n=8), and drugs used in addictive disorders (n=16) (Table 2). The majority of generic drugs for nervous system are oral preparations (n=435). Oral risperidone has the highest number (n=34).
- There are 9 originators for oncology drugs which do not have generic products for the following active ingredients; cyclophosphamide, ralitrexed, oral fludarabine, topical fluorouracil, oral etoposide, amsacrine.
- There are 60 nervous system drugs which do not have generic counterparts. There are no identified originators for antipsychotics, such as olanzapine and aripiprazole.

CONCLUSION

- The study shows that there is an overall good representation on the Maltese market of generic medicines for oncology and drugs used in nervous system disorders.
- For oncology drugs, antimetabolites had the most generics available, while alkylating agents have the least.
- Drugs for nervous system disorders are generally well-represented, with antipsychotics having the greatest number of generic products. Antidepressants were shown to have several available generics for a relatively small number of originators. CNS stimulants have more available originators than generics, which however had the least among the subclassifications.

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