

Kathlene Cassar<sup>1,2</sup>, David Zammit Dimech<sup>3</sup>, Louise Grech<sup>1,2</sup>, Dustin Balzan<sup>1</sup>, Anthony Cutajar<sup>1</sup>, Paul John Cassar<sup>3</sup>

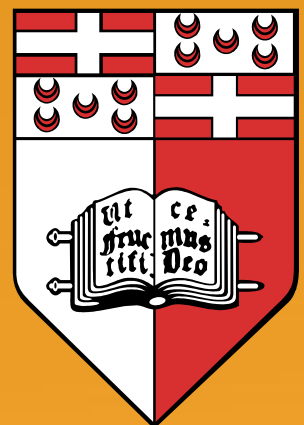
<sup>1</sup>Department of Pharmacy, Mater Dei Hospital, Msida, Malta

<sup>2</sup>Department of Pharmacy, Faculty of Medicine and Surgery, University of Malta, Msida, Malta

<sup>3</sup>Department of Medicine, Mater Dei Hospital, Msida, Malta



Mater Dei Hospital



University of Malta

**INTRODUCTION**

A biosimilar product is biologic in origin. It is highly similar to another biological medicinal product (reference product), which has already been authorised by a competent regulatory authority such as the European Medicines Agency. It must have no clinically meaningful difference in terms of safety, purity and potency when compared to the reference product.<sup>1</sup>

The availability of biosimilar infliximab on the National Health System in Malta introduced issues related to safety, switchability and interchangeability.

**AIMS**

- To assess the perception and awareness of Maltese clinicians working within the National Health System on the concept of biosimilars.

**METHOD**

The questionnaire developed by the Alliance for Safe Biologics Medicines (ASBM) which was previously run in European countries (excluding Malta) was chosen for the study.<sup>2</sup> Permission to use this questionnaire was granted from the ASBM. The questionnaire which is a 15 minute online self-administered questionnaire was adapted to reflect the logistics of the Maltese National Health System.

The questionnaire was sent to a total of 942 eligible practising clinicians working within the Maltese National Health System. A total of three reminders were sent throughout a 30 day period during which the clinicians were asked to complete the online questionnaire.

**RESULTS**

- A total of 132 prescribers participated in the study giving a 14% response rate. Approximately 34% prescribed biologics within their practice, whereas 40% of the respondents treated patients who were prescribed biologics by another specialist.
- Familiarity with the concept of biosimilars was low, with only 6% of the clinicians stating that they were very familiar. Only 35% had a basic understanding whereas 59% stated that they could not define biosimilars or had never heard of them.
- The majority of the clinicians (53%) were aware that although the biosimilar has the same international non-proprietary name (INN) as the reference product, it may not necessarily have the same indications.
- Less than half of the clinicians (36%) believe that patients can receive either the reference product or the originator and expect the same result.
- Only 27% of the clinicians believe that patients can be switched between products.
- Having the sole authority to decide whether to prescribe the reference product or the biosimilar is considered to be very important or critical for 46% of the clinicians.

**CONCLUSION**

The awareness on biosimilars in Malta (6%) is much less than that achieved in other European countries (22%). Switchability is an aspect where Maltese clinicians are not comfortable with. Only 27% believe that patients can be safely switched between products. This correlates to results of the ASBM European survey where only 39% agree with switchability. Increased awareness on biosimilars together with more robust data on switchability between biologic products will help Maltese clinicians prescribe biosimilars in their practice with less concerns on patient safety and product efficacy.

**References**

1. EMA. Guideline on similar biologic medicinal products. CHMP/437/04. London:2005
2. O’Dolinar M, Reilly MS. Biosimilars naming, label transparency and authority of choice—survey findings amongst European physicians. GaBI Journal. 2014;3(2):58-62.

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