OFFICE of the DEPUTY PRIME MINISTER
MINISTRY for HEALTH
15, PALAZZO CASTELLANIA, MERCHANTS STREET, VALLETTA, MALTA

DH CIRCULAR No. 70/2020
DH 911/2020

7th October 2020

Attention All: Consultants
Medical Officers
Pharmacists
Pharmacy Technicians
Nurses

Re: Biosimilar Etanercept 50mg Pre-filled Pen

Etanercept is a biologic tumour necrosis factor (TNF) inhibitor that blocks the effects of TNF-alpha, a pro-inflammatory cytokine that becomes elevated in psoriasis, rheumatoid arthritis, psoriatic arthritis, juvenile idiopathic arthritis, and ankylosing spondylitis.

Enbrel® is the brand name of the original etanercept medicine. However, there are now new versions of etanercept called biosimilars. A biosimilar medicine is a medicine highly similar to another biological medicine already marketed in the EU.

The original etanercept medicine Enbrel® and the biosimilar Benepali® were to date available within the Government Health Services. The biosimilar Erelzi® has now been procured to replace both Enbrel® and Benepali® when stock of these is exhausted. The etanercept biosimilar Erelzi® is equally safe and effective in reducing inflammation as Enbrel® and Benepali®. It also has the same licensed indications as Enbrel® and Benepali®.

Etanercept 50mg injection is listed on the Government Formulary List and can be prescribed by Consultant Dermatologists and Consultant Rheumatologists.

Patients currently on Enbrel® or Benepali® are to contact their Consultant for a physician-led switchover. Prescriptions for etanercept should include the brand name Erelzi®.

The attached 'Patient Information Letter Regarding Biological and Biosimilar Medicines' is to be given to the patient when collecting Erelzi®.

Instructions for use of the Erelzi® pen is available on the following link
https://www.erelzi.eu/home/sensoreadypen/

More information on etanercept biosimilar Erelzi® is available on the European Medicines Agency website.

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Additionally, further information for professionals and patients on biosimilars is also available on the dedicated European Medicines Agency webpage.

For your attention please.

Dr Denis Vella Baldacchino
Chief Medical Officer

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Patient Information Letter Regarding Biological and Biosimilar Medicines

Dear patient,

You are being provided this information as you are currently being treated with a medicine called **etanercept**.

Etanercept belongs to a group of medicines called **biological medicines.** Initially these medicines were manufactured by a single pharmaceutical company. The brand name that the original manufacturer gave to etanercept is *Enbrel*®. However, after an agreed number of years, other pharmaceutical companies are allowed to produce their own similar version of the biological medicine.

Copies of biological medicines are called **biosimilar medicines -** medicines developed to be similar to an existing biological medicine.

Biosimilar versions of etanercept have been authorised and granted a marketing authorisation valid throughout the European Union, including Malta. The authority that regulates medicines in Malta has confirmed that the biosimilar *Erelzi*® is just as safe and effective as the original biological medicine *Enbrel* ®.

The Department of Health will be switching patients on etanercept to the recently procured biosimilar. In order to better monitor your condition, a dedicated clinical team has been selected to assist the consultant. You may contact the nurse of this team on the following numbers if you either wish to get more information regarding the biosimilar of etanercept or have any queries regarding your condition:

Department of Dermatology – 2545 8404

Department of Rheumatology – 2545 4429