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

**DH Circular 95/2019**
DH 1194/2019

16th September 2019

**Attention All**: Consultants
Medical Officers
Pharmacists
Pharmacy Technicians
Nurses

**Re: Biosimilar Adalimumab 40mg Pre-filled Syringes**

Adalimumab is a human monoclonal antibody that treats autoimmune diseases by inhibiting tumour necrosis factor (TNF). Adalimumab is indicated for the treatment of rheumatoid, juvenile idiopathic and psoriatic arthritis; ankylosing spondylitis; Crohn's disease and ulcerative colitis; psoriasis, paediatric plaque psoriasis; hidradenitis suppurativa and uveitis.

Adalimumab is a biological medicine produced in Chinese Hamster Ovary cells. Humira® is the brand name of the original adalimumab medicine. However, there are now new versions of adalimumab called biosimilars. A biosimilar medicine is a medicine highly similar to another biological medicine already marketed in the EU.

The biosimilar Hulio® has now been procured to replace Humira® when stock of the latter is exhausted. The adalimumab biosimilar Hulio® is equally safe and effective in reducing inflammation as Humira®. It also has the same licensed indications as Humira® including the indications for paediatric use. Moreover, each pre-filled syringe is citrate-free and has a safety feature that retracts and covers the needle after the plunger is released following administration.

Adalimumab 40mg injection is not listed on the Government Formulary List and is currently procured on a Named-Patient Basis.

Prescriptions for Adalimumab should include the brand name 'Hulio®'.

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

More information on adalimumab biosimilar Hulio® is available on the European Medicines Agency website.

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 **adalimumab**.

Adalimumab 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 adalimumab is *Humira*®. 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 adalimumab 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 *Hulio*® is just as safe and effective as the original biological medicine *Humira*®.

In view of updated recommendations based on clinical evidence, the Department of Health will be switching patients who are currently on Humira® to the biosimilar product Hulio®.

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 adalimumab or have any queries regarding your condition:

Department of Dermatology – 2298 7173

Department of Rheumatology – 2545 4429

Department of Gastroenterology – 2545 4888

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