MINISTERU TAS-SAĦĦA

MINISTRY FOR HEALTH

MALTA

Direttorat tat-Tabib Ewlieni tal-Gvern

Office of the Chief Medical Officer

DH CIRCULAR No. 428/2016
DH 3229/2015/II

7th October 2016

Attention All: Consultants
Medical Officers
Pharmacists
Pharmacy Technicians
Nurses

Re: Switchover implementation plan from Remicade® to Biosimilar Infliximab (Inflectra®/Remsima®)

Biological medicines have made a substantial impact at improving the effectiveness of therapies in many disease areas and are expected to continue to do so in the future. Through the expiration of patents and other intellectual property rights of biological medicines, opportunity has now opened for introduction of biosimilars to enter the market.

Infliximab biosimilar has been procured and newly diagnosed patients with Inflammatory Bowel Disease, Psoriasis and Rheumatoid Arthritis have been initiated successfully on the biosimilar.

An agreement has also been reached with the Gastroenterology Department of Mater Dei Hospital to initiate a switchover implementation plan from Remicade® to Biosimilar Infliximab (Inflectra®/Remsima®).

A working process has been established in order to ensure a safe and effective switching (Annex 1).

Patients will be provided with a *Patient Information Letter* in English or Maltese (Annex 2 and 3). A helpline has also been set up in order to support patients as necessary.

The entitlement protocol for Infliximab 100mg Powder for Concentrate for Infusion has been updated and uploaded on the Directorate for Pharmaceutical Affairs website (Annex 4).

Your kind co-operation is being requested.
For your attention please.

Dr. Denis Vella Baldacchino
Chief Medical Officer

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Annex 1

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Office of the Chief Medical Officer

Implementation Plan for Switchover from Remicade® to Biosimilar (Inflectra®/Remsima®)

1. The Gastroenterology consultant decides which patients currently taking Remicade® are ideal candidates for the switchover from Remicade® to the biosimilar - Inflectra®/Remsima® (currently Inflectra® is being procured by CPSU).

2. The consultant and/or firm explains the switchover process to the patient in question (either at the Outpatients' Department or at the Medical Investigations and Treatment Unit when the patient is due for the next Infliximab infusion) and provides the patient with a 'Patient Information Letter' in English and Maltese.

3. The consultant and/or firm writes a note in the patient's file to confirm the decision taken to switchover from Remicade® (Infliximab) to the biosimilar - Inflectra®/Remsima®

4. The consultant and/or firm or IBD nurse will then send an official email to inform the following of the switchover decision for each patient in question:

   a) Nurses in charge at MITU :
   Ms. Mary Grace Cardona (Nursing Officer) - mary-grace.cardona@gov.mt
   Ms. Mary Ann Buttigieg (Deputy Nursing Officer) - mary-ann.buttigieg@gov.mt

   b) IBD Nurse
   Ms. Marie-Claire Yvonne Pellegrini - marie-claire-yvonne.pellegrini@gov.mt

   c) Senior Pharmacist (Clinical) (Gastroenterology)
   Ms. Emma Manduca - emma.manduca@gov.mt

   d) Medicines Approval Section (MAS) / Pharmacy Of Your Choice (POYC)
   Generic email - schedulev.mfh@gov.mt
   Ms. Helga Farrugia (Pharmacist) - helga.farrugia@gov.mt
   Ms. Stephanie Torpiano (Pharmacist) - stephanie.torpiano@gov.mt

   e) Directorate of Pharmaceutical Affairs (DPA)
   Ms. Sylvana Magrin Sammut (Senior Pharmacist) – sylvana.magrin-sammut@gov.mt

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5. An email will be sent by the Senior Pharmacist/s to Central Procurement and Supplies Unit (CPSU) to update on the number of patients switched over in order to balance stocks accordingly, as follows:
   Ms. Alison Anastasi (Assistant Director Procurement) – alison.anastasi@gov.mt
   Mr. Neil Bugeja (Pharmacist CPSU) - neil.c.bugeja@gov.mt
   Ms. Tracy West (Pharmacy Technician CPSU) - tracy.west@gov.mt

6. The nurse in charge at MITU is to place a copy of the email in the patient's MITU file, ideally on the same day the email is sent and a sticker reading 'Patient Switched from Remicade to Inflectra®/Remsima®' should be stuck onto patient's treatment chart .

7. MAS/POYC will update the entitlement database and will issue the updated permit for Infliximab (Inflectra®/Remsima®) which will be rubber stamped in red ink to easily identify the new permit accordingly. This will be sent by post to the patient.

8. Patient Medical files are to be available at MITU whenever a patient is due for an Infliximab infusion.

9. Doctors at MITU will be responsible to write up treatment charts once a week for all the patients who will be going in for an Infliximab infusion that week.

10. When a patient presents with a permit for Infliximab (Remicade®), nurses at MITU are to check the patient's file for any note regarding the switchover and the MITU file for an email sent regarding the switchover.

11. If documentation regarding the decision to switchover is present in the patient's file and an email regarding the switchover is present in the MITU file but the patient's permit still states Infliximab (Remicade®), nurses are to check with clinical pharmacist or pharmacy to make sure that the permit for Infliximab (Inflectra®/Remsima®) has been processed by MAS/POYC.

12. Nurses to check whether patient is fit for the Infliximab infusion on the day of their appointment and to ascertain that the correct treatment is written on the treatment chart. Any problems/queries should be discussed with the medical firm under whose care the patient is.

13. Doctors are to prescribe according to brand name.

14. Nurses should ensure that any old permit is discarded following confirmation of the switch.

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15. Patients switched to the Infliximab biosimilar should be presented with a new alert card and *Patient Diary for Infliximab Infusion (Inflectra®/Remsima®)* and a sticker reading 'Patient Switched from Remicade to Inflectra®/Remsima®' should be stuck onto their now redundant Remicade® alert card.

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Annex 2

MINISTRY FOR HEALTH

15, PALAZZO CASTELLANIA, MERCHANTS STREET, VALLETTA, MALTA

Patient Information Letter Regarding Biological and Biosimilar Medicines

Dear Patient,

You are being provided this information as you are currently being provided with a medicine called **infliximab** used for the treatment of Ulcerative Colitis or Crohn's Disease.

Infliximab belongs to a group of medicines called **biologic medicines.** Initially these medicines were manufactured by a single pharmaceutical company. The brand-name that the original manufacturer gave to Infliximab was *Remicade*®. 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** where the medicines are developed to be similar to an existing biological medicine.

The biosimilar version for infliximab has been authorised and granted a marketing authorisation valid throughout the European Union, including Malta. This biosimilar is available from two different companies and have two different brandnames (*Inflectra*® and *Remsima*®), however, both products contain the same biosimilar version which has been thoroughly tested and analysed. The authority that regulates medicines in Malta has confirmed that the biosimilar is just as safe and effective as the original biological medicine Remicade®.

To make best use of our resources, the biosimilar version for infliximab is already being provided by the Department of Health to those patients who are starting treatment with the medicine infliximab. In view of updated recommendations based on clinical evidence, the next phase is to consider switching patients who are currently on *Remicade*® to the biosimilar product. This decision will be taken together with your caring Consultant after considering your clinical situation.

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 if you either wish to get more information on the biosimilar infliximab or queries regarding your condition.

If you would like any more information regarding the biosimilar of infliximab or if you have any questions, please feel free to call on 79001964 or leave a message on 2545 4888.

Dr. Denis Vella Baldacchino
Chief Medical Officer

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Annex 3

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15, PALAZZO CASTELLANIA,
TRIQ IL-MERKANTI, IL-BELT VALLETTA, MALTA

Ittra ta' Informazzjoni għall-Pazjent Dwar Mediċini Bijoloġiċi u Bijosimili

Għażiż pazjent,

Din l-informazzjoni, qed tiġi mogħtija lilek, peress li inti qed tingħata l-mediċina ***infliximab*** li tintuża għall-kura tal-Kolite Ulċerattiva jew il-marda ta' Crohn's.

Il-mediċina *infliximab* tifforma parti minn grupp ta' mediċini msejħa **bioloġiċi**. Inizjalment dawn il-mediċini kienu jiġu magħmula minn kumpanija farmaċewtika waħda. Il-mediċina *infliximab* ingħatat l-isem kummerċjali ta' *Remicade*® mill-kumpanija li żviluppatha. Wara numru ta' snin hekk kif awtorizzat mil-liġi, kumpaniji oħra jkunu jistgħu jipproduċu verżjoni simili ta' din il-mediċina.

Dawn il-verżjonijiet tal-mediċina bijoloġika jissejħu **bijosimili**. Mediċina bijosimili hija mediċina li tiġi żviluppata biex tkun simili għal mediċina bijoloġika diġa' eżistenti.

Il-verżjoni bijosimili tal-prodott *Remicade*® ġie awtorizzat biex jitpoġġa fis-suq tal-Unjoni Ewropea kollha, inkluż Malta. Dan il-bijosimili ġie mqiegħed fis-suq minn żewġ kumpaniji differenti taħt żewġ ismijiet differenti (*Inflectra*® u *Remsima*®), għalkemm iż-żewġ prodotti huma l-istess. Din il-mediċina bijosimili ġiet analizzata u ttestjata b'mod intensiv. L-awtorita' li tirregola l-mediċini f'Malta tikkonferma li l-mediċina bijosimili hija sigura u effettiva daqs il-*Remicade*®.

Bl-għan li jsir użu aħjar tar-riżorsi tagħna, il-mediċina bijosimili tal-prodott *Remicade*® diġa' bdiet tingħata mid-Dipartiment tas-Saħħa lill-pazjenti li jkunu għadhom ħa jibdew it-trattament bil-mediċina *infliximab*. Fid-dawl ta' rakkomandazzjonijiet aġġornati bbażati fuq evidenza klinika, issa waslet il-fażi fejn pazjenti li diġa' jieħdu l-mediċina *Remicade*®, jiġu kkunsidrati li jinqalbu fuq il-prodott bijosimili. Din id-deċiżjoni se tittieħed mil-konsulent li qed jieħu ħsieb il-kura tiegħek wara kunsiderazzjoni tas-sitwazzjoni klinika tiegħek.

Ġie maħtur tim kliniku ddedikat biex jassisti lill-konsulent biex isegwi aħjar il-kundizzjoni tiegħek. Inti tista' tikkuntattja l-infermiera ta' dan it-tim kemm jekk tixtieq iktar informazzjoni dwar il-mediċina bijosimili tal-*infliximab*, kif ukoll jekk minn żmien għal żmien ikollok xi mistoqsijiet rigward il-kundizzjoni tiegħek.

Jekk tkun tixtieq iktar informazzjoni fuq il-mediċina bijosimili tal-*infliximab*, jew jekk għandek xi mistoqsijiet oħra, tista' ċċempel fuq 79001964 jew ħalli messaġġ fuq in-numru 2545 4888.

Dr. Denis Vella Baldacchino
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Infliximab 100mg Powder for Concentrate for Infusion

Prescriber Criteria: Consultant Dermatologist
Consultant Gastroenterologist
Consultant Paediatrician
Consultant Rheumatologist

In-patient use:

1. Inflammatory Bowel Diseases
2. Extensive Psoriasis
3. Rheumatoid Arthritis

1. IBD - Crohn's Disease:

- Treatment of severe, active Crohn's disease, in patients who have not responded despite a full and adequate course of therapy with a corticosteroid and an immunosuppressant; or who are intolerant to or have medical contraindications for such therapies, or
- Treatment of fistulising, active Crohn's disease, in patients who have not responded despite a full and adequate course of therapy with conventional treatment (including antibiotics, drainage and immunosuppressive therapy).

IBD - Ulcerative Colitis:

Treatment of moderately to severely active ulcerative colitis in patients who have had an inadequate response to conventional therapy including corticosteroids and 6-MP or AZA, or who are intolerant to or have medical contraindications for such therapies.

2. Extensive Psoriasis:

Treatment of moderate to severe plaque psoriasis in adult patients who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapy including cyclosporine, methotrexate or PUVA.

3. Rheumatoid Arthritis - Stage II or III:

In combination with methotrexate, for patients with Stage II or III Rheumatoid Arthritis having failed standard therapy as defined by failure to respond to adequate therapeutic trials of:

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- at least 2 standard disease-modifying anti-rheumatic drugs (DMARDs) one of which must be methotrexate
- etanercept therapy.

Gastroenterology:
Kindly note that the brand Remsima®/Inflectra® will be provided, unless Consultant decides that patient cannot be switched over to Infliximab Biosimilar (Remsima®/Inflectra®) due to individual circumstances.

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