PHARMA SUMMIT 24

Exploring Values of Healthcare

18th April 2024

Croke Park conference centre

Speaker Slides:

Bernard Duggan, Medicines Management Programme

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MINDMAP MEDICAL MARKETING

Bernard Duggan,

Chief Pharmacist

"Health Technology Management: Ensuring Safe, Effective & Cost-Effective Use of Medicines "

Bio:

Bernard is Chief I Pharmacist in the HSE-Medicines Management Programme. His work involves delivery and oversight of health technology management programmes in the Irish healthcare service, that is, measures put in place to enhance the safe, effective and cost-effective use of medicines on a national level. Bernard's role includes leading the best-value biological medicine initiative, which has focused on increasing the prescribing and utilisation of biosimilar medicines, including TNF-a inhibitors (adalimumab and etanercept) and teriparatide. In addition, he has led the development and implementation of managed access processes to facilitate reimbursement of innovative medicines. Bernard obtained his undergraduate pharmacy degree from Trinity College Dublin and registered as a pharmacist in 2005. In addition, he has been awarded diplomas in project management and health economics. He has previously worked in both community pharmacy and regulatory roles.

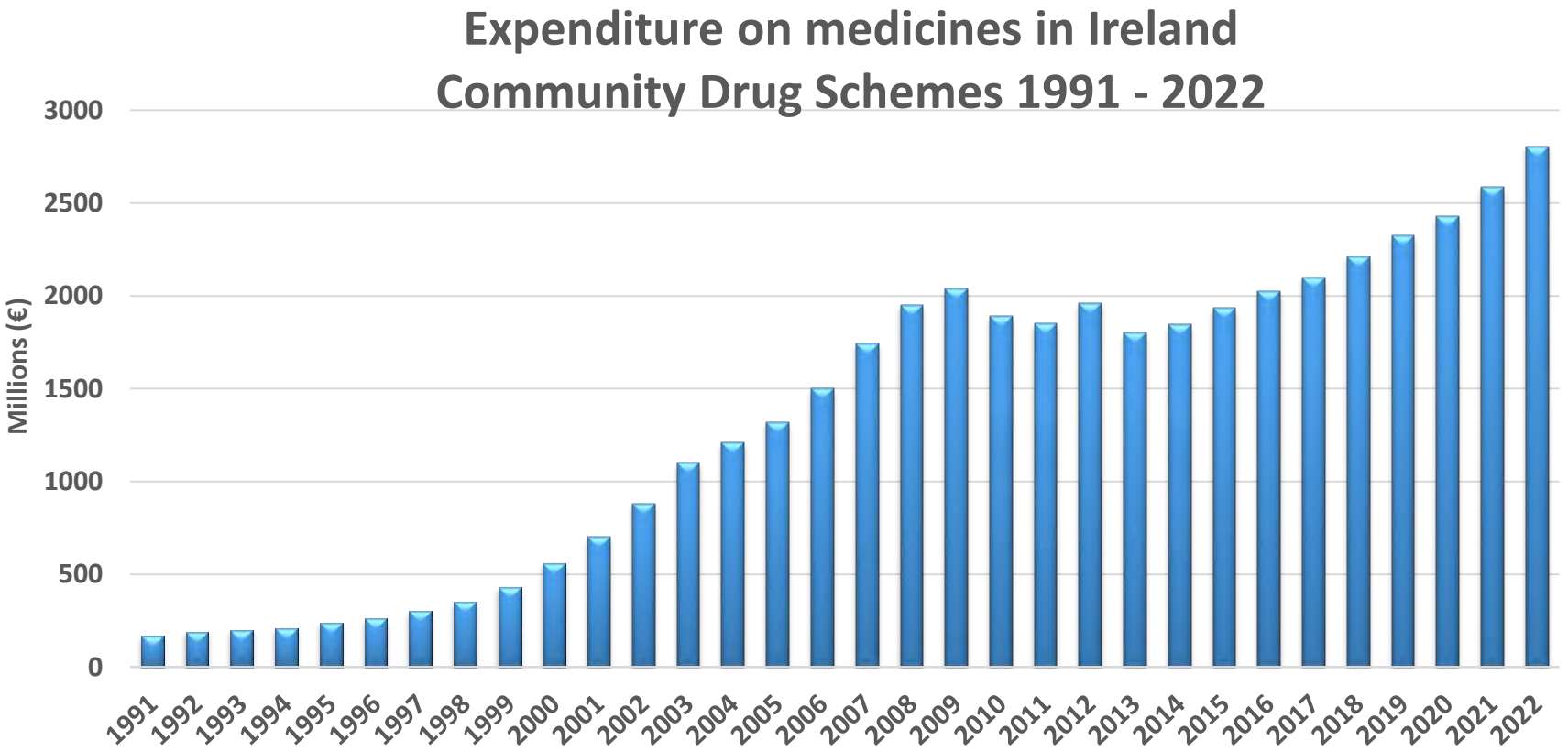
Health Technology Management

Ensuring safe, effective and cost-effective use of medicines

Medicines Management Programme

PMI Annual Pharma Summit
18 April 2024

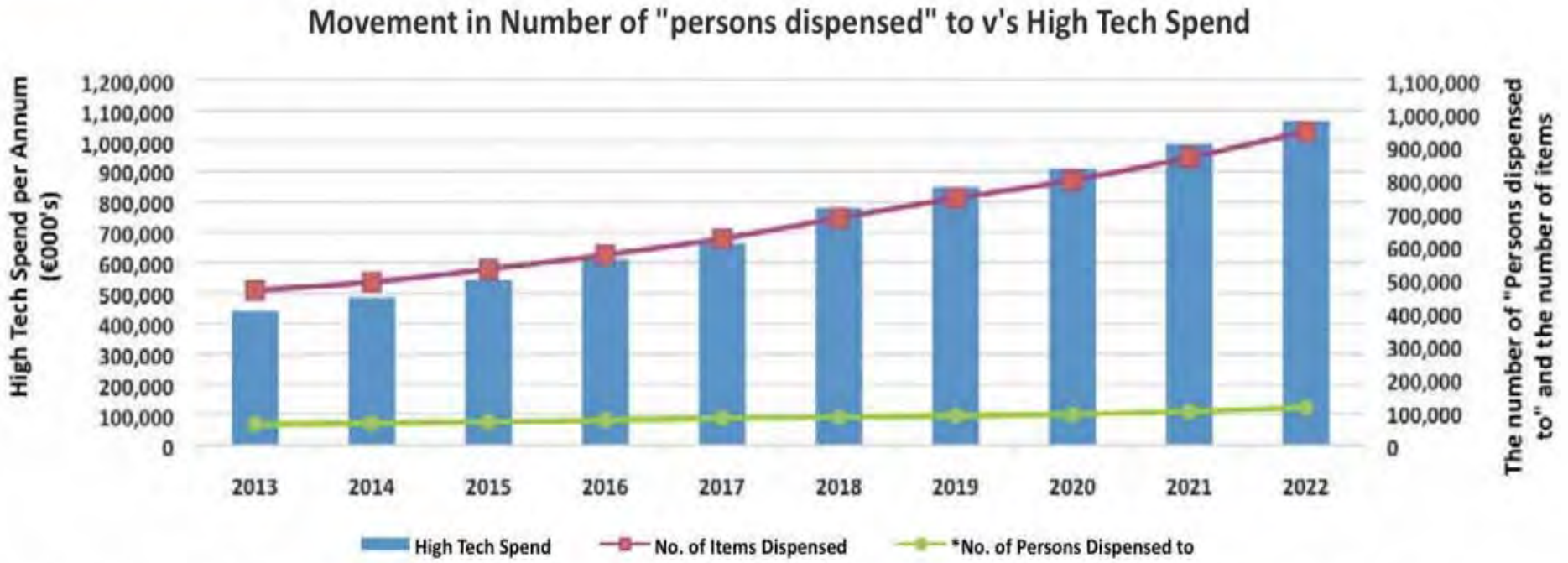
Background



Medicines Management Programme

Background

High Tech Trends 2013 - 2022



The graph illustrates the High Tech spend over a 10 year period from 2013 -- 2022 and the trend in the number of items and people dispensed to.

Health Technology Management (HTM)

HTM refers to measures being put in place to enhance the safe, effective and cost-effective use of medicines thereby controlling utilisation and expenditure

- **Reimbursement Application Systems**
- **Managed Access Protocols (MAPs)**
- **Best-Value Biological (BVB)/Best-value medicine (BVM) initiatives**

Medicines Management Programme

High Tech Arrangement 2021: Top 20 Expenditure

Medicine	Total expenditure	Medicine	Total expenditure
1. Adalimumab	€117 million	11. Golimumab	€19.8 million
2. Ustekinumab	€50.1 million	12. Pomalidoamide	€17.4 million
3. Lenalidoamide	€45 million	13. Enzalutamide	€16.3 million
4. Etanercept	€43.3 million	14. Ivacaftor and Lumacaftor	€14.9 million
5. Ivacaftor	€37.1 million	15. Pegfilgrastim	€14.5 million
6. Fingolimod	€28.6 million	16. Palbociclib	€14.3 million
7. Ibrutinib	€28.1 million	17. Tocilizumab	€14.2 million
8. Abiraterone	€26.5 million	18. Dimethyl Fumarate	€11.1 million
9. Secukinumab	€26 million	19. Follitropin Alfa	€10.7 million
10. Ivacaftor, Tezacaftor and Elexacaftor	€21.9 million	20. Abatacept	€10.2 million

Medicines Management Programme

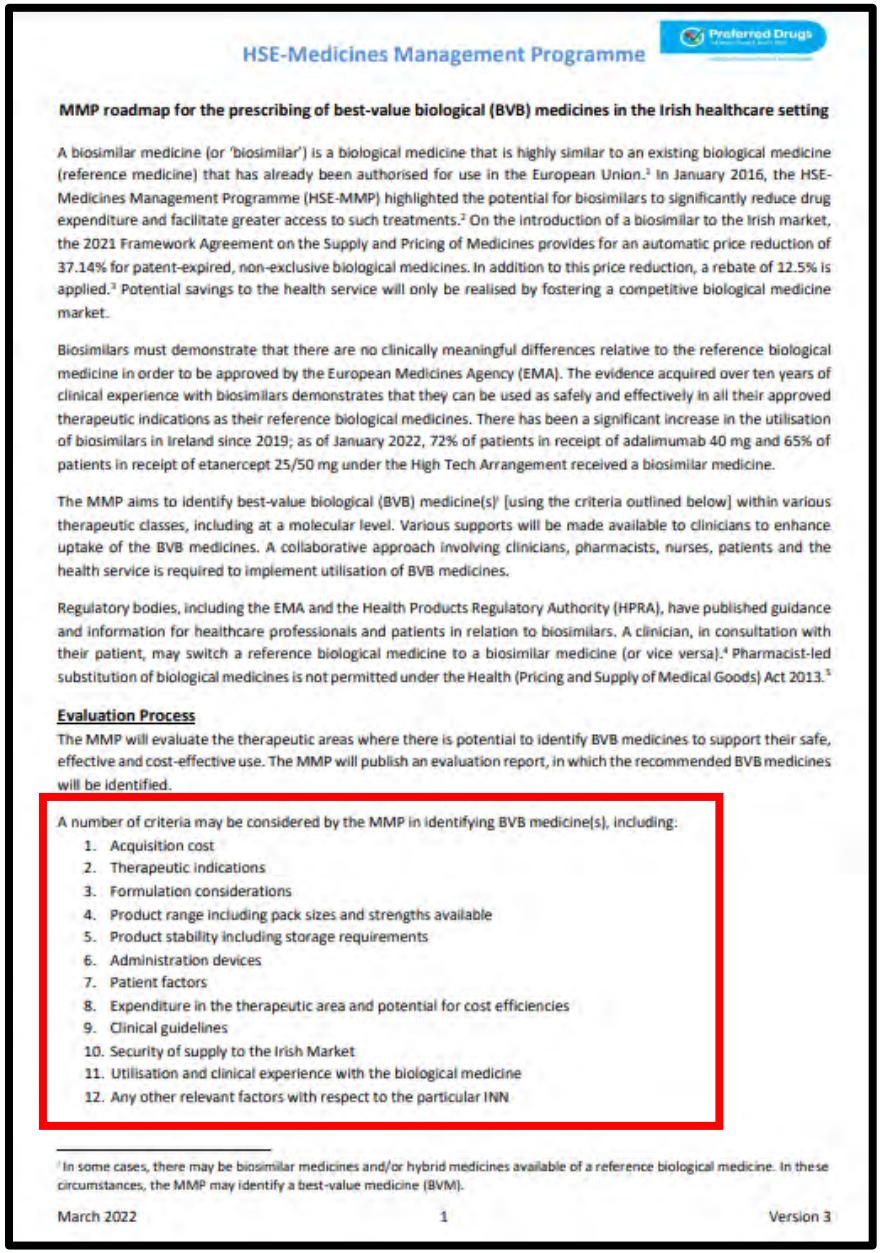
High Tech Arrangement 2021: Top 20 Expenditure

Medicine	Total expenditure	Medicine	Total expenditure
1. Adalimumab	€117 million	11. Golimumab	€19.8 million
2. Ustekinumab	€50.1 million		
4. Etanercept	€43.3 million		
		15. Pegfilgrastim	€14.5 million
		17. Tocilizumab	€14.2 million
9. Secukinumab	€26 million	19. Follitropin Alfa	€10.7 million
		20. Abatacept	€10.2 million

Medicines Management Programme

MMP Roadmap

- Outlines criteria for identification of BVB medicines
- Formal consultation phase
- Submissions from stakeholders, including MAHs



HSE-Medicines Management Programme

Preferred Drugs

MMP roadmap for the prescribing of best-value biological (BVB) medicines in the Irish healthcare setting

A biosimilar medicine (or 'biosimilar') is a biological medicine that is highly similar to an existing biological medicine (reference medicine) that has already been authorised for use in the European Union.[1] In January 2016, the HSE-Medicines Management Programme (HSE-MMP) highlighted the potential for biosimilars to significantly reduce drug expenditure and facilitate greater access to such treatments.[2] On the introduction of a biosimilar to the Irish market, the 2021 Framework Agreement on the Supply and Pricing of Medicines provides for an automatic price reduction of 37.14% for patent-expired, non-exclusive biological medicines. In addition to this price reduction, a rebate of 12.5% is applied.[3] Potential savings to the health service will only be realised by fostering a competitive biological medicine market.

Biosimilars must demonstrate that there are no clinically meaningful differences relative to the reference biological medicine in order to be approved by the European Medicines Agency (EMA). The evidence acquired over ten years of clinical experience with biosimilars demonstrates that they can be used as safely and effectively in all their approved therapeutic indications as their reference biological medicines. There has been a significant increase in the utilisation of biosimilars in Ireland since 2019; as of January 2022, 72% of patients in receipt of adalimumab 40 mg and 65% of patients in receipt of etanercept 25/50 mg under the High Tech Arrangement received a biosimilar medicine.

The MMP aims to identify best-value biological (BVB) medicine(s)[1] [using the criteria outlined below] within various therapeutic classes, including at a molecular level. Various supports will be made available to clinicians to enhance uptake of the BVB medicines. A collaborative approach involving clinicians, pharmacists, nurses, patients and the health service is required to implement utilisation of BVB medicines.

Regulatory bodies, including the EMA and the Health Products Regulatory Authority (HPRA), have published guidance and information for healthcare professionals and patients in relation to biosimilars. A clinician, in consultation with their patient, may switch a reference biological medicine to a biosimilar medicine (or vice versa).[4] Pharmacist-led substitution of biological medicines is not permitted under the Health (Pricing and Supply of Medical Goods) Act 2013.[5]

Evaluation Process

The MMP will evaluate the therapeutic areas where there is potential to identify BVB medicines to support their safe, effective and cost-effective use. The MMP will publish an evaluation report, in which the recommended BVB medicines will be identified.

A number of criteria may be considered by the MMP in identifying BVB medicine(s), including:

1. Acquisition cost
2. Therapeutic indications
3. Formulation considerations
4. Product range including pack sizes and strengths available
5. Product stability including storage requirements
6. Administration devices
7. Patient factors
8. Expenditure in the therapeutic area and potential for cost efficiencies
9. Clinical guidelines
10. Security of supply to the Irish Market
11. Utilisation and clinical experience with the biological medicine
12. Any other relevant factors with respect to the particular INN

[1] In some cases, there may be biosimilar medicines and/or hybrid medicines available of a reference biological medicine. In these circumstances, the MMP may identify a best-value medicine (BVM).

March 2022 1 Version 3

Medicines Management Programme

MMP Roadmap

SCHEDULE 2

Processes for

The Assessment and Selection of Best Value Biologic Medicines

1. Each January the HSE will publish a list by ATC/ INN from which it may initiate a BVB or BVM process in that calendar year. The MMP have previously indicated that colony –stimulating factors, erythropoietins, and fertility medicines are therapeutic areas under consideration.

2. The HSE will give a month's notice to each supplier of initiating a BVB or BVM process for a particular INN

3. The BVB or BVM process will follow that already set out in the MMP Roadmap for the prescribing of best value medicines in the Irish healthcare setting

    a. Six weeks formal consultation phase
    b. Review period (typically two months but may require longer)
    c. Publication of Prescribing and Cost Guidance to relevant stakeholders

4. A number of Criteria may be considered by the MMP in identifying BVB or BVM medicine(s) including

    a. Acquisition cost
    b. Therapeutic Indications
    c. Formulation Considerations
    d. Product Range including pack sizes and strengths available
    e. Product stability including storage requirements
    f. Administration devices
    g. Patient factors
    h. Expenditure in the therapeutic area and potential for cost efficiencies
    i. Clinical Guidelines
    j. Security of Supply to the Irish Market
    k. Utilisation and clinical experience with the biological medicine
    l. Any other relevant factors with respect to the particular INN

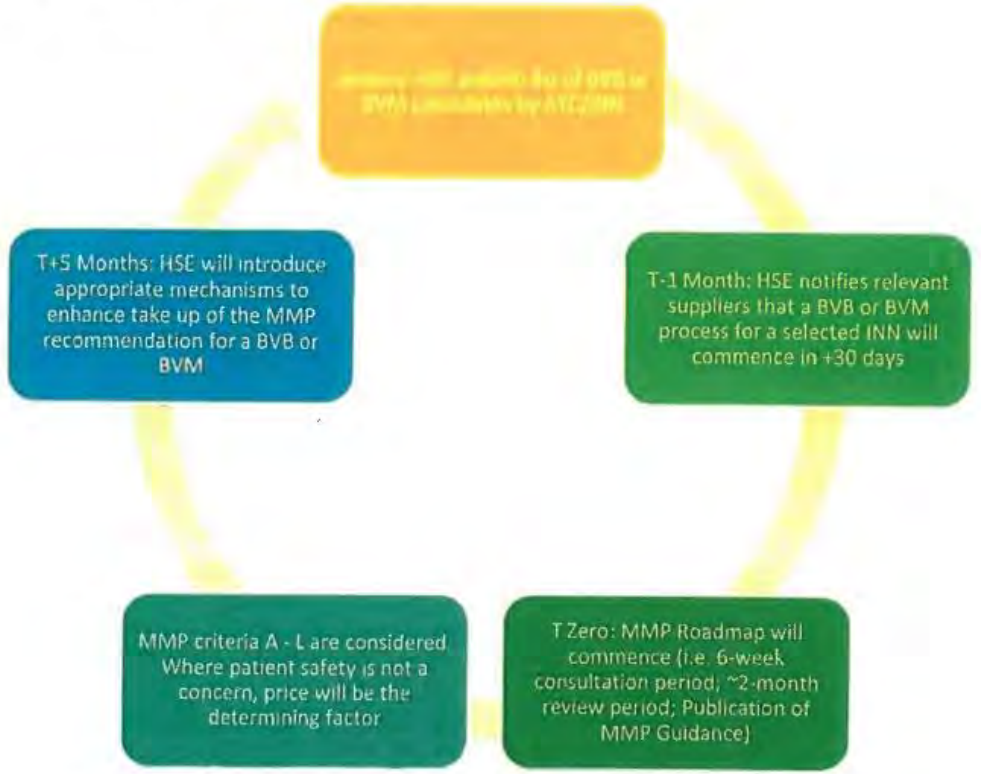
5. Where the MMP is satisfied that all other factors are similar and comparable such that patient safety is not a concern, price will be the determining factor

6. The HSE will publish the MMP recommendation for a BVB or BVM and introduce as appropriate mechanisms to enhance take up of the MMP recommendation for a BVB or BVM.

Medicines Management Programme

MMP Roadmap

Figure 1: Illustrative process flow

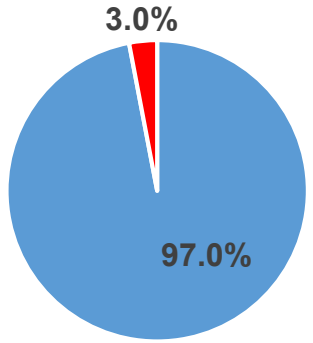


T = time point, e.g., T minus 1 is one month before a key point; T Zero is a key point; T+5 Months is 5 months after T Zero

Medicines Management Programme

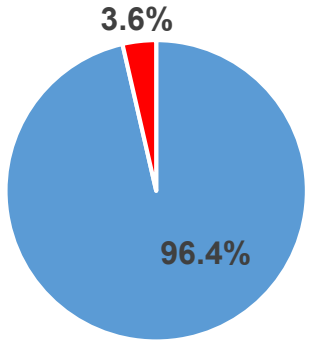
The Challenge!!

Adalimumab – June 2019



Biosimilar medicine available since November 2018

Etanercept – June 2019



Biosimilar medicine available since September 2016

- National framework agreements with industry mandated reduction in price of reference medicine upon biosimilar launch
- Automatic substitution of biosimilar medicines not permitted
- Clinicians not embracing availability of biosimilar medicines

Medicines Management Programme

Medicines Management Programme

Best-Value Biological Medicines:

Tumour Necrosis Factor-α Inhibitors on the

High Tech Drug Scheme

Preferred Drugs
THE RIGHT CHOICE, RIGHT NOW
MEDICINES MANAGEMENT PROGRAMME

Approved by:	Prof. Michael Barry, Clinical Lead, Medicines Management Programme (MMP).
Date approved:	02/05/2019
Version:	1.0

Medicines Management Programme

BVB Medicines – Adalimumab & Etanercept

Adalimumab

Amgevita®

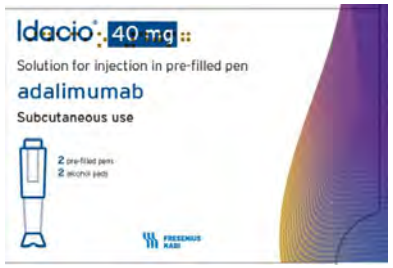
Imraldi®

Yuflyma®

Hukyndra®

Etanercept

Benepali®



Idacio®

Hulio®

Hyrimoz®

Humira®

Erelzi®

BVB Medicines: Implementation

- **High Tech Hub**
- Gainshare arrangement
- Policy for new patients
- Site visits to provide information sessions
- Resources for & regular communication with clinicians and their team
- Collaboration with stakeholders
  - National Clinical Programmes
  - Patient Support Groups

Medicines Management Programme

High Tech Hub

adalIMUMAB -AMGEVITA SOLN FOR INJ PREFILLED PEN (Best Value Biological Medicine)

ADALIMUMAB

ADALIMUMAB -AMGEVITA SOLN FOR INJ PREFILLED PEN (Best Value Biological Medicine)

ADALIMUMAB -AMGEVITA SOLN FOR INJ PREFILLED SYRINGE(Best Value Biological Medicine)

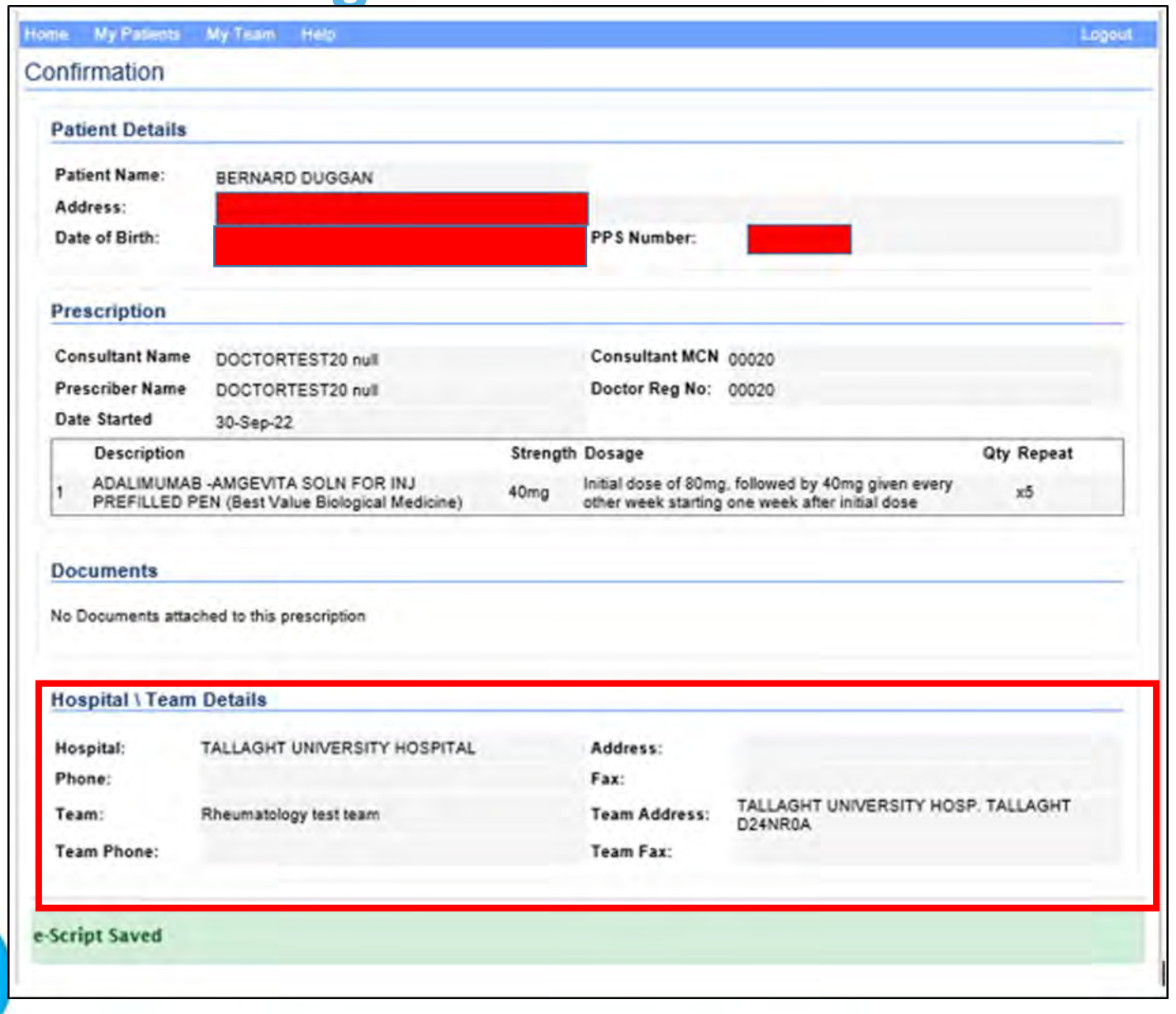
ADALIMUMAB -HUKYNDRA (STADA) SOLN FOR INJ IN PRE FILLED PEN (Best Value Biological Medicine)

ADALIMUMAB -HUKYNDRA (STADA) SOLN FOR INJ IN PRE FILLED SYRINGE (Best Value Biological Medicine)

ADALIMUMAB -HULIO SOLN FOR INJ PRE-FILLED SYRINGE (Best Value Biological Medicine)

ADALIMUMAB -HULIO SOLN FOR INJ PREFILLED PEN (Best Value Biological Medicine)

High Tech Hub



Home My Patients My Team Help Logout

Confirmation

Patient Details

Patient Name:	BERNARD DUGGAN		
Address:	[redacted]		
Date of Birth:	[redacted]	**PPS Number:**	[redacted]

Prescription

Consultant Name	DOCTORTEST20 null	**Consultant MCN**	00020
Prescriber Name	DOCTORTEST20 null	**Doctor Reg No:**	00020
Date Started	30-Sep-22		

	Description	Strength	Dosage	Qty	Repeat
1	ADALIMUMAB -AMGEVITA SOLN FOR INJ PREFILLED PEN (Best Value Biological Medicine)	40mg	Initial dose of 80mg, followed by 40mg given every other week starting one week after initial dose	x5	

Documents

No Documents attached to this prescription

Hospital \ Team Details

Hospital:	TALLAGHT UNIVERSITY HOSPITAL	**Address:**	
Phone:		**Fax:**	
Team:	Rheumatology test team	**Team Address:**	TALLAGHT UNIVERSITY HOSP. TALLAGHT D24NR0A
Team Phone:		**Team Fax:**	

e-Script Saved

Medicines Management Programme

BVB Medicines: Implementation

- High Tech Hub
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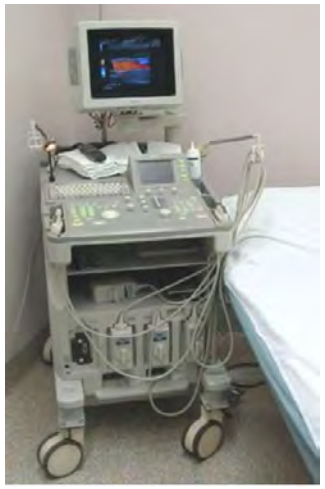
Medicines Management Programme

Gainshare Arrangement



Medicines Management Programme

BVB Medicines: Implementation

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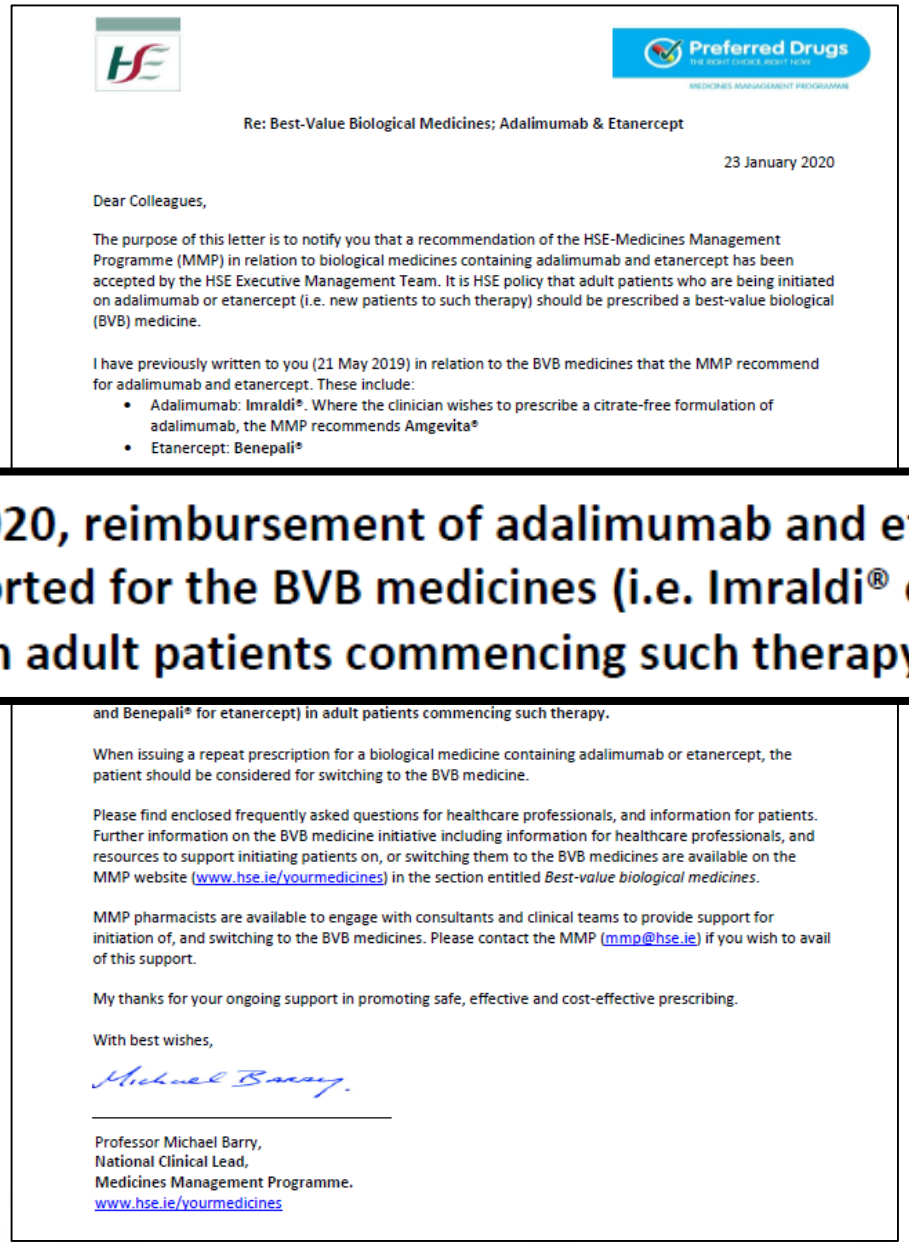
Medicines Management Programme

Policy for new patients



Preferred Drugs
THE RIGHT CHOICE, RIGHT NOW
MEDICINES MANAGEMENT PROGRAMME

Re: Best-Value Biological Medicines; Adalimumab & Etanercept

23 January 2020

Dear Colleagues,

The purpose of this letter is to notify you that a recommendation of the HSE-Medicines Management Programme (MMP) in relation to biological medicines containing adalimumab and etanercept has been accepted by the HSE Executive Management Team. It is HSE policy that adult patients who are being initiated on adalimumab or etanercept (i.e. new patients to such therapy) should be prescribed a best-value biological (BVB) medicine.

I have previously written to you (21 May 2019) in relation to the BVB medicines that the MMP recommend for adalimumab and etanercept. These include:

- Adalimumab: **Imraldi®**. Where the clinician wishes to prescribe a citrate-free formulation of adalimumab, the MMP recommends **Amgevita®**
- Etanercept: **Benepali®**

Accordingly, from 1 February 2020, reimbursement of adalimumab and etanercept under the High Tech Arrangement will only be supported for the BVB medicines (i.e. Imraldi® or Amgevita® for adalimumab, and Benepali® for etanercept) in adult patients commencing such therapy.

When issuing a repeat prescription for a biological medicine containing adalimumab or etanercept, the patient should be considered for switching to the BVB medicine.

Please find enclosed frequently asked questions for healthcare professionals, and information for patients. Further information on the BVB medicine initiative including information for healthcare professionals, and resources to support initiating patients on, or switching them to the BVB medicines are available on the MMP website (www.hse.ie/yourmedicines) in the section entitled *Best-value biological medicines*.

MMP pharmacists are available to engage with consultants and clinical teams to provide support for initiation of, and switching to the BVB medicines. Please contact the MMP (mmp@hse.ie) if you wish to avail of this support.

My thanks for your ongoing support in promoting safe, effective and cost-effective prescribing.

With best wishes,

Michael Barry.

Professor Michael Barry,
National Clinical Lead,
Medicines Management Programme.
www.hse.ie/yourmedicines

Medicines Management Programme

BVB Medicines: Implementation

- High Tech Hub
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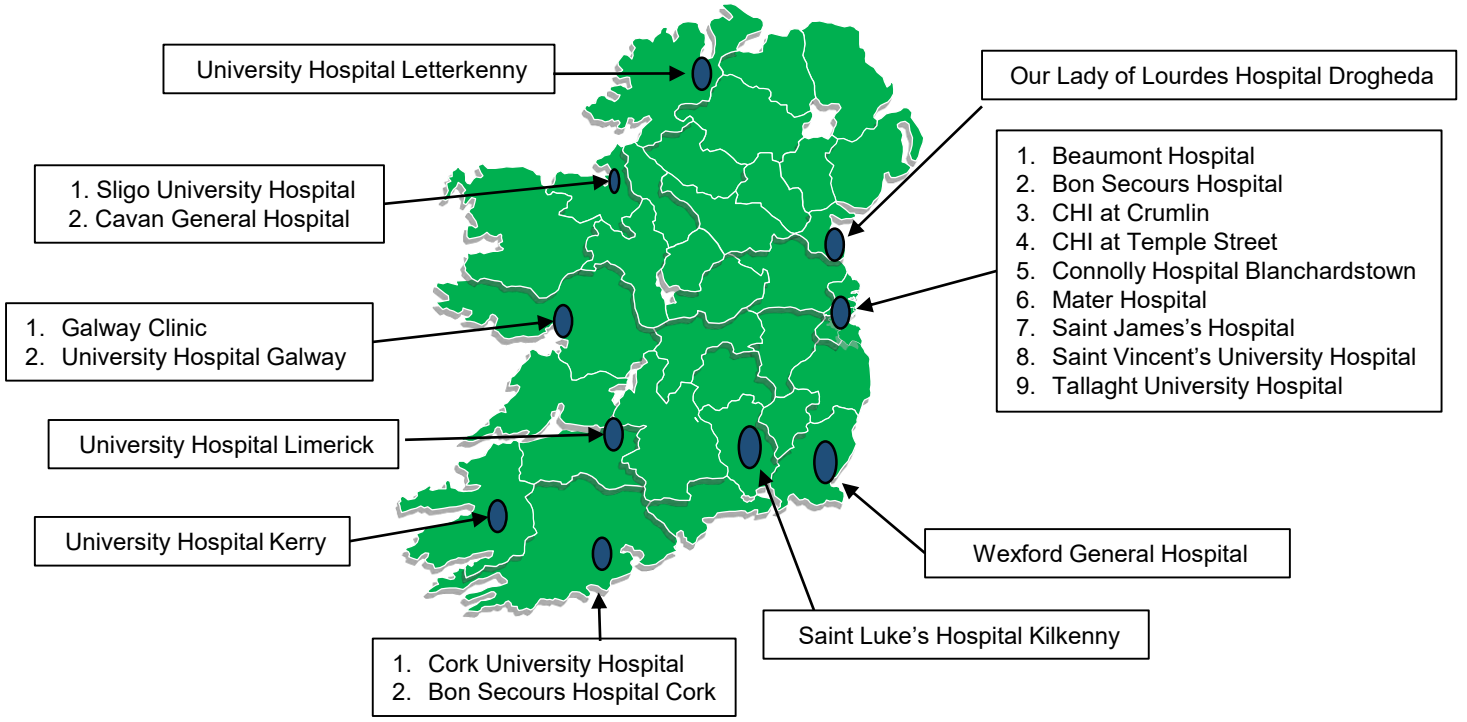
Medicines Management Programme

Information Sessions



Medicines Management Programme

BVB Medicines: Implementation

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Medicines Management Programme

Best-value biological medicines

The Medicines Management Programme has identified best-value biological (BVB) medicines for TNF-α inhibitors under the High Tech Arrangement.

The MMP recommends the following BVB medicines for adalimumab and etanercept:

- Adalimumab:
  - Citrate-containing: Hyrimoz, Idacio
  - Citrate-free: Amgevita, Hukyndra, Hulio, Humira, Imraldi, Yuflyma
- Etanercept: Benepali, Erelzi

Clinicians should give due consideration to the prescription of these agents when prescribing a TNF-α inhibitor. Implementation of the BVB medicines will lead to significant savings for the health service, in the order of millions of euros.

The MMP recommends Humira 80 mg and Yuflyma 80 mg as the BVB medicines for presentations of adalimumab 80 mg solution for injection that are available as self-administered injection devices on the High Tech Arrangement.

The MMP recommends Amgevita as the BVB medicine for presentations of adalimumab 20 mg solution for injection that are available as self-administered injection devices on the High Tech Arrangement. This presentation of adalimumab is predominately used in paediatric patients. The MMP wrote a letter to prescribers in relation to this in May 2021.

Resources to support prescribing of the BVB medicines are located in the Related Files section below:

- Questions and Answers for Healthcare Professionals.
- MMP Product Information Sheets for Amgevita, Benepali, Erelzi, Hukyndra, Hulio, Humira, Hyrimoz, Idacio, Imraldi and Yuflyma
- Contact information for MMP support.
- Contact information for patient support services for Amgevita, Benepali, Erelzi, Hukyndra, Hulio, Humira, Hyrimoz, Idacio, Imraldi and Yuflym
- Templates for switching letters for Benepali and Erelzi

April 2023

Medicines Management Programme

Re: Best-Value Biological Medicines; Adalimumab & Etanercept

4 April 2023

Dear Colleagues,

The purpose of this letter is to:

In September 2022, the European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA) issued a joint statement on interchangeability of biosimilar medicines. This confirmed that biosimilar medicines approved in the EU are interchangeable with their reference medicine or with an equivalent biosimilar medicine. Interchangeability in this context means that a prescriber can replace the reference medicine with a biosimilar medicine without a patient experiencing any changes in the clinical effect. The EMA highlighted that the experience obtained from clinical practice has shown that in terms of efficacy, safety and immunogenicity, biosimilar medicines are comparable to their reference medicine and therefore can be prescribed interchangeably.

In recognition of the efficiencies that result from the prescribing of the BVB medicines, the gainshare arrangement is available to consultant-led teams to fund service delivery or enhancement, when they initiate a patient on, or switch them to a BVB medicine on the High Tech Hub. The gainshare arrangement will end on 30 June 2023. Queries in relation to the release of gainshare funds should be directed to the HSE-Primary Care Reimbursement Service High Tech Co-ordination Unit at PCRS.HiTech@hse.ie.

Non-BVB Medicines

Non-BVB medicines for adalimumab or etanercept (i.e. Humira®, Enbrel®) are substantially more expensive than the recommended BVB medicines. As of January 2023, approximately 3,800 patients remain in receipt of the non-BVB medicines for adalimumab or etanercept on the High Tech Arrangement.

In September 2022, the European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA) issued a joint statement on interchangeability of biosimilar medicines. This confirmed that biosimilar medicines approved in the EU are interchangeable with their reference medicine or with an equivalent biosimilar medicine. Interchangeability in this context means that a prescriber can replace the reference medicine with a biosimilar medicine without a patient experiencing any changes in the clinical effect. The EMA highlighted that the experience obtained from clinical practice has shown that in terms of efficacy, safety and immunogenicity, biosimilar medicines are comparable to their reference medicine and therefore can be prescribed interchangeably.

In light of the EMA/HMA joint statement on interchangeability and the substantial difference in cost between the recommended BVB medicines and non-BVB medicines, all patients who are currently prescribed a non-BVB medicine (i.e. Enbrel®, Humira®) should be considered for switching to a BVB medicine.

Medicines Management Programme

The MMP will review the uptake of BVB medicines in July 2023 and may engage with clinical teams whose uptake is below the expected level. Where a decision is made to continue a patient on a non-BVB medicine (i.e. Enbrel®, Humira®), the reason for such should be recorded in the patient's clinical notes; this information may be required to support an application for continued reimbursement support of a non-BVB medicine.

resources to support initiating patients on, or switching them to the BVB medicines are available on the MMP website (www.hse.ie/yourmedicines) in the section entitled *Best-value medicines*.

Given the significant financial challenges facing the Health Service this year, it is vital that prescribing of the BVB medicines is optimised. I would ask that you continue to support this important initiative, which helps to secure ongoing access for patients to new and innovative medicines.

With best wishes,

Michael Barry.

Professor Michael Barry,
National Clinical Lead,
HSE-Medicines Management Programme.

Medicines Management Programme

April 2023

Medicines Management Programme

Re: Best-Value Biological Medicines; Adalimumab & Etanercept

4 April 2023

Dear Colleagues,

The purpose of this letter is to:

- Update you on the uptake of the best-value biological (BVB) medicines.
- Inform you that the gainshare arrangement will end on 30 June 2023.
- Request that all patients who remain on a non-BVB medicine (i.e. Enbrel®, Humira®) be switched to a BVB medicine, where possible.
- Inform you of a recent enhancement to the High Tech Hub so as to enable clinical teams to identify patients who remain on Enbrel® or Humira®.

Primary Care Reimbursement Service High Tech Co-ordination Unit at PCRS.HiTech@hse.ie.

Non-BVB Medicines

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Medicines Management Programme

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High Tech Hub Enhancement

The High Tech Hub has been enhanced to support clinical teams to identify patients who remain on non-BVB medicines (i.e. Enbrel®, Humira®). A search function has been added to the *My Patients* tab; this allows clinical teams to search for prescriptions generated on the High Tech Hub by INN or medicinal product within a specified timeframe. This will facilitate timely identification of patients who remain on a non-BVB medicine.

The extension of the gainshare until 30 June 2023 provides clinical teams with an opportunity to use this

High Tech Hub Enhancement

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BVB medicines is optimised. I would ask that you continue to support this important initiative, which helps to secure ongoing access for patients to new and innovative medicines.

With best wishes,

Michael Barry.

Professor Michael Barry,
National Clinical Lead,
HSE-Medicines Management Programme.

Medicines Management Programme

BVB Medicines: Implementation

- High Tech Hub
- Gainshare arrangement
- Policy for new patients
- Site visits to provide information sessions
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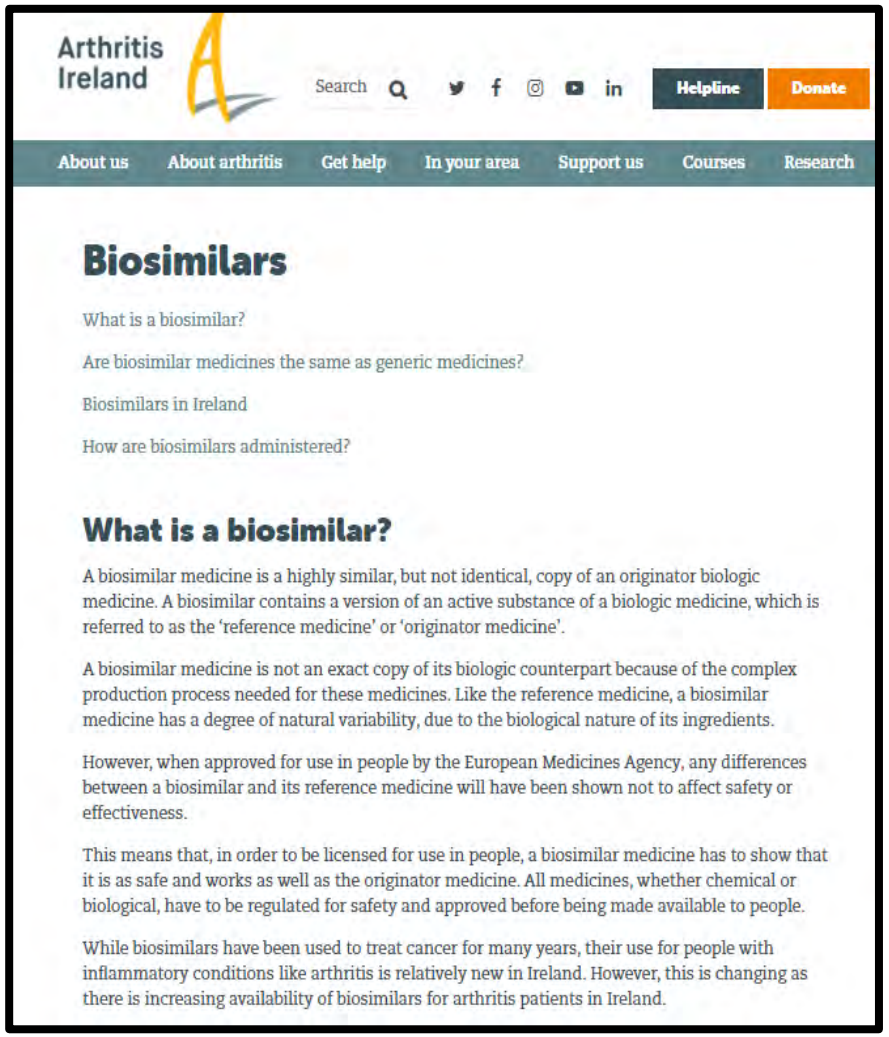
- **Collaboration with stakeholders**
  - **National Clinical Programmes**
  - **Patient Support Groups**

Medicines Management Programme



Medicines Management Programme

International Journal of Clinical Pharmacy
https://doi.org/10.1007/s11096-021-01243-0

RESEARCH ARTICLE

Uptake of biosimilars for TNF-α inhibitors adalimumab and etanercept following the best-value biological medicine initiative in Ireland

B. Duggan[1,2] · Amelia Smith[1] · M. Barry[1]

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Abstract

Background There is over 10 years of clinical experience and evidence to show that biosimilar medicines can be used as safely and effectively in approved therapeutic indications as their originator biological medicines. In Ireland, biosimilar medicine uptake has been very slow, and savings to the health service will only be realised through fostering a competitive biological medicine market. *Objective* The objective of this study was to investigate the utilisation of biosimilars following a 'best-value biological' medicine initiative for adalimumab and etanercept in the Irish healthcare setting. *Methods* Data was extracted from the National High Tech claims database and High Tech ordering and management hub for the following drugs; adalimumab (Humira®, Amgevita®, Hulio®, Idacio®, and Imraldi®) and etanercept (Enbrel® and Benepali®). Main outcome measure: uptake of the best-value biological medicines. *Results* In June 2019, just over 90 patients had been initiated on, or switched to a best-value biological for adalimumab or etanercept. Over the next 12 months this increased to over 8500 patients. With the best-value biologicals accounting for approximately 50 % of market share in June 2020, the combined estimated savings and avoided costs are €22.7 million to date. The gain-share prescribing incentive has raised over €3.6 million for the specialties to invest back into patient care. *Conclusion* Against the background of a finite healthcare budget, this study shows that increasing use of biosimilars can create the financial savings and space to invest in new innovative therapies for the benefit of many patients.

Medicines Management Programme

Best-value biological (BVB) medicines / Best-value medicines (BVM) 2024

The HSE-Medicines Management Programme has identified the following medicines for which it may conduct a best-value biological (BVB) medicine or best-value medicine (BVM) process in 2024:

Biological Medicines

- Adalimumab (L04AB04)
- Eculizumab (L04AA25)
- Etanercept (L04AB01)
- Filgrastim (L03AA02)
- Follitropin alfa (G03GA05)
- Lipegfilgrastim (L03AA14)
- Liraglutide (A10BJ02)
- Natalizumab (L04AA23)
- Pegfilgrastim (L03AA13)
- Somatropin (H01AC01)
- Somatrogon (H01AC08)
- Teriparatide (H05AA02)
- Tocilizumab (L04AC07)
- Ustekinumab (L04AC05)

Non-Biological Medicines

- Abiraterone (L02BX03)
- Bicalutamide (L02BB03)
- Cinacalet (H05BX01)
- Deferasirox (V03AC03)
- Fulvestrant (L02BA03)
- Glatiramer (L03AX13)
- Icatibant (B06AC02)
- Lenalidomide (L04AX04)
- Pirfenidone (L04AX05)
- Pomalidomide (L04AX06)
- Posaconazole (J02AC04)
- Sildenafil (G04BE03)
- Sunitinib (L01EX01)
- Voriconazole (J02AC03)

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