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 (EU).[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 15 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 September 2024, 76% of patients in receipt of adalimumab 40 mg and 77% 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)[i] [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. The EMA and the Heads of Medicines Agencies (HMA), in a joint statement issued on 19 September 2022, have confirmed that biosimilar medicines approved in the EU are interchangeable with their reference medicine or with an equivalent biosimilar. Interchangeability in this context means that the reference medicine can be replaced by a biosimilar without a patient experiencing any changes in the clinical effect.[4] A clinician, in consultation with their patient, may switch a reference biological medicine to a biosimilar medicine (or vice versa).[5] Pharmacist-led substitution of biological medicines is not permitted under the Health (Pricing and Supply of Medical Goods) Act 2013.[6]

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

[i] 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).

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.

As part of the evaluation process, the MMP will undertake a formal consultation phase where submissions are invited from relevant stakeholders. Engagement with clinicians will also be carried out to support the prescribing of BVB medicines. The MMP will monitor the utilisation of and expenditure on BVB medicines and consider key performance indicators for the adoption of same.

Work Plan

The MMP has identified the following biological medicines for which it may initiate a BVB medicine or best-value medicine (BVM) process in 2024:

- 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).

References

1. Health Products Regulatory Authority. Guide to Biosimilars for Healthcare Professionals. 5 August 2020.
2. HSE-Medicines Management Programme: Biosimilar Medicines in the Irish Healthcare setting. January 2016.
3. Framework Agreement on the Supply and Pricing of Medicines 2021.
4. European Medicines Agency and the Heads of Medicines Agencies. Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU. 19 September 2022. Last updated 26 April 2023.
5. European Medicines Agency and European Commission. Biosimilars in the EU: Information guide for healthcare professionals. October 2019.
6. Government of Ireland. Health (Pricing and Supply of Medical Goods) Act 2013. S.I. No 14/2013.