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 developed to be highly similar to an existing biological medicine in physicochemical and biological terms.[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 2016 Framework Agreement on the Supply and Pricing of Medicines provides for an automatic price reduction of 20% for patent-expired, non-exclusive biological medicines. In addition to this price reduction, a rebate of 12.5% is applied. 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 originator 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 originator biological medicines. To date the utilisation of biosimilars in Ireland is significantly lower when compared with other European countries e.g. the market share of biosimilars for tumour necrosis factor-alpha (TNF-α) inhibitors was 5% in Ireland compared with 90% in Denmark and 82% in Norway in 2016.[3]

The MMP aims to identify the best-value biological (BVB) medicine(s) [using the criteria outlined below] within various therapeutic classes/indications. Prescribing and Cost Guidance will be published to support clinicians in the prescribing of these medicines. A collaborative approach involving clinicians, pharmacists, nurses, patients and the health service is required to implement utilisation of the 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. Interchangeability[†] of biological medicines is permitted in Ireland at prescriber level, whereas pharmacist-led substitution is not allowed under the Health (Pricing and Supply of Medical Goods) Act 2013.[4]

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 Prescribing and Cost Guidance for the relevant therapeutic areas to include prescriber and patient support materials.

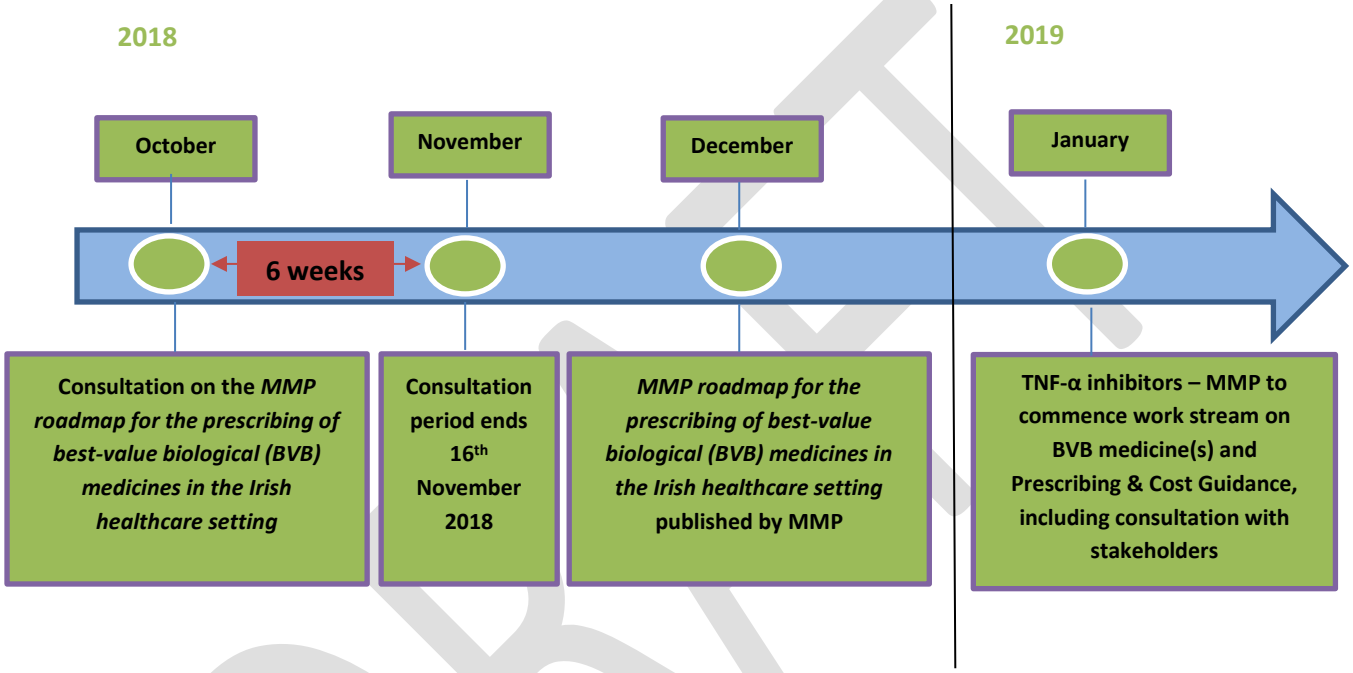
A number of criteria will be considered by the MMP in identifying the BVB medicine(s), including:

1. Reimbursement price
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 savings
9. National clinical guidelines
10. Robustness of supply to the Irish Market
11. Department of Health National Biosimilar Medicine Policy (awaiting publication)
12. Utilisation and clinical experience with the biological medicine
13. Any other relevant factors.

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

Work Plan

The MMP will initially review the use of TNF-α inhibitors reimbursable on the High Tech Drug (HTD) scheme (January 2019 - see indicative timeline below). Total expenditure‡ on these biological medicines accounted for approximately €220.9 million in 2016, representing the highest expenditure category on the HTD scheme. The Humira® patent expiry and associated loss of exclusivity is recognised as mid-October 2018. There were approximately 10,400 patients in receipt of Humira® 40 mg and 80 mg in the pre-filled pen and syringe presentations on the HTD scheme in 2017, accounting for total expenditure‡ of approximately €124 million.



Other therapeutic areas the MMP may consider at a future date include: colony-stimulating factors, erythropoietins and fertility medicines.

Definitions

†**Interchangeability** refers to the possibility of exchanging one medicine for another medicine that is expected to have the same clinical effect. This could mean replacing a reference product with a biosimilar (or vice versa) or replacing one biosimilar with another. Replacement can be done by:

- Switching, which is when the prescriber decides to exchange one medicine for another medicine with the same therapeutic intent
- Substitution (automatic), which is the practice of dispensing one medicine instead of another equivalent and interchangeable medicine at pharmacy level without consulting the prescriber.[5]

‡**Total expenditure** includes ingredient cost and VAT where applicable based on claims submitted by pharmacists.

References

1. National Institute for Health and Care Excellence. Introducing biosimilar versions of infliximab: Inflectra® and Remsima®. February 2015.
2. HSE-Medicines Management Programme: Biosimilar Medicines in the Irish Healthcare setting. January 2016.
3. Quintiles IMS. The Impact of Biosimilar Competition in Europe. May 2017.
4. Government of Ireland. Health (Pricing and Supply of Medical Goods) Act 2013. S.I. No 14/2013.
5. European Medicines Agency and European Commission. Biosimilars in the EU: Information guide for healthcare professionals. April 2017.