Since 2010, the Irish health service has spent over €1 billion on two medicines alone: adalimumab (brand name: Humira) and etanercept (brand name: Enbrel). Both are complex biological medicines that are licensed to treat a variety of conditions ranging from rheumatoid arthritis and psoriatic arthropathy to inflammatory bowel disease including Crohn's disease and ulcerative colitis.

The beneficial effects of these drugs are experienced by over 16,000 patients today, but this comes at a large price. In 2017, expenditure on adalimumab (Humira) exceeded €111 million, while expenditure on etanercept (Enbrel) exceeded €45 million.

Despite spending approximately €2.3 billion (including hospitals) on drugs we are struggling to afford the standard of care - and fund new medicines - in some therapeutic areas.

The availability of biosimilar medicines may, in part, provide the solution to our funding challenge. A biosimilar medicine is a biological medicine that is developed to be highly similar to an existing biological medicine in physicochemical and biological terms.

Due to the complex manufacturing process for all biological medicines, biosimilars are not absolutely identical versions of the original reference product, so they are not considered to be generics.

This means that they are not designated interchangeable under the Health Act 2013 and pharmacists cannot dispense a cheaper biosimilar in lieu of a prescription for the original biological medicine.

However, they have been assessed by the European Medicines Agency (EMA) and designated as highly similar to already approved biological medicines in terms of structure, activity, efficacy and safety. Therefore, biosimilars can be used in place of the reference medicine, achieving the same beneficial outcomes for patients.

The recent availability of lower-priced biosimilar medicines to adalimumab and etanercept provides a real opportunity to reduce costs associated with these very expensive drugs.

For a variety of reasons, the uptake of cheaper alternative medicines is a slow process in the Irish healthcare setting.

We have seen this in the past with very low generic prescribing rates, where some prescribers preferred more expensive branded products despite the opportunity to reduce expenditure on medicines by opting for much cheaper generics.

It was not until the introduction of legislation on reference pricing and generic substitution (in November 2013) that the HSE obtained the real benefits of generic medicines.

We started with the cholesterol-lowering drug atorvastatin, or Lipitor. There were lots of generics on the market. We set a common reimbursement price, or reference price, for a group of interchangeable medicines.

If a patient wanted a particular brand that cost more than the reference price, then the patient must pay the additional cost of that product. It has delivered huge savings. These savings have enabled us to fund new, innovative drugs.

We could deliver substantial savings on biologic medicines. The prescribing of these occurs predominantly in the hospital setting. Prescriber behaviour appears to have changed little in recent years, with doctors ignoring the availability of much cheaper biosimilar alternatives.

Take Benepali, the lower-priced and only biosimilar product for etanercept. Benepali was introduced to the Irish market in September 2016, but accounted for just 2 per cent of all

etanercept use by volume two years later. Corresponding figures for countries like Norway, Denmark and Britain were in the region of 80 per cent. The contrast is stark indeed.

Lower-priced biosimilar products to adalimumab, the only drug on which we spend more than €100 million per annum, have been available to Irish prescribers since 2018.

The early evidence indicates that the uptake of these lower-cost alternatives has been negligible. This is a real concern and represents an opportunity lost. It simply has to be addressed.

The HSE Medicines Management Programme (MMP) was established in 2013 with the aim of promoting safe, effective and cost-effective prescribing.

In October 2018, we began identifying best-value biological medicines in the Irish healthcare setting. This programme of work began with the group of medications used to treat inflammatory conditions (called TNF inhibitors) including adalimumab and etanercept.

In the coming weeks, the Medicines Management Programme will announce the best-value biological (BVB) medicine for adalimumab and etanercept. Prescribing the identified BVB will have the potential to save millions of euro each year.

The first two months of 2019 have seen a significant investment in medicines by the HSE, with 18 new approvals including 15 new drugs and licensed extensions for three products.

It is interesting to note that 11 approvals were for drugs used to treat rare diseases (including translarna for Duchenne muscular dystrophy, kuvan for phenylketonuria) and seven approvals were for cancer drugs. This represents an investment by the HSE of €150 million over the next five years.

Not surprisingly, available expenditure for new drugs in 2019 is almost exhausted at this point in time.

Therefore, it is essential that our hospital doctors, mainly from the disciplines of rheumatology, gastroenterology and dermatology, embrace and support the uptake of lower-priced biosimilars for adalimumab and etanercept to enable the HSE to afford the new innovative high-cost therapies that are coming our way.

History tells us that attempting to change prescribing behaviour takes time and is not always successful. And yet we need to deliver change almost immediately, as many of the 2019 new approvals are dependent on savings being realised from increased biosimilar uptake.

One option under consideration is to only reimburse at the pricing point of the BVB and the introduction of a reimbursement application system which would require prescribers to justify their therapeutic choice if prescribing more expensive alternatives to the BVB.

One way or another, biosimilar use will need to increase dramatically if Irish patients are to have any chance of gaining access to new, costly, innovative therapies.

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