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Enhancing Prescribing Efficiency Through Increased Utilisation of Generics at Low Prices

Pharmaceutical expenditure is increasingly scrutinised across all sectors due to its rapid growth outstripping other components of healthcare. This growth has been driven by well-known factors. These include changing demographics, strict clinical outcome targets, rising patient expectations, continued pressure from pharmaceutical companies and the continued launch of new expensive drugs.

Unsustainable growth has resulted in greater urgency among governments, professional medical organisations, health authorities and health insurance companies to introduce additional reforms to conserve resources. These are typically centred on generics to improve prescribing efficiency of existing products in a class or related classes, and include both supply and demand side initiatives (Table 1). The objective is to take advantage of the increasing availability of generics, with estimated global sales of products likely to lose their patents between 2008 and 2013 at $50bn to $100bn/year.

The reforms and initiatives also include measures to address concerns with the effectiveness and safety of generics when they occur. The result is enhanced savings with the increasing availability of generics to help maintain comprehensive and equitable healthcare in Europe.

Ongoing Initiatives to Lower the Prices of Generics

Each European country has introduced different measures to lower the price of generics. However, they can be categorised into three distinct approaches: Prescriptive pricing, market forces, or a combination of the two (mixed approach). Table 2 (page 30) contains the definitions and examples. Typically across Europe, patients have to pay the price difference for a more expensive molecule than the reference price themselves, which helps drive down generic prices where countries use market forces or mixed approaches.

The various measures helped reduce reimbursed expenditure for generic simvastatin by between 53% to 97% in 2007 versus 2001 originator prices among a range of European countries. Price reductions were typically less for generic omeprazole, i.e. in 2007 between 52% to 82% below 2001 originator prices.

However, there is still considerable variation in reimbursed prices for both generic omeprazole and generic simvastatin across Europe despite these reductions (Figure 1, page 31). This confirms earlier studies, which showed generic prices could vary up to 36 fold in the ambulatory care sector depending on the molecule. There are also considerable differences in drug prices among hospitals, with discounts and rebates up to 100% for certain products.

Addressing Concerns Regarding Generics

There have been concerns regarding the effectiveness and safety of generics among some physicians and patients, exacerbated by some originator companies questioning the quality of generics as part of their marketing strategies to reduce sales erosion post patent loss. These issues are being addressed by health authorities and health insurance agencies to fully capitalise financially from the availability of generics.

Activities include:

- **Physicians – Medical product agencies and health authorities/health insurance agencies only licensing and approving generics where there are no concerns with their bioequivalence or therapeutic equivalence; encouraging INN prescribing from the outset; encouraging physicians to speak with patients where there is the potential for substitution to help allay fears; helping develop and adhere to an agreed list of non-substitutable product including for instance long acting opiods, digoxin, ciclosporin and warfarin.**

- **Pharmacists** – encouraging pharmacists financially to speak with patients when substituting products, limiting the number of times products can be substituted where concerns and instigating databases in pharmacies. The latter to help avoid duplication if different branded generics are dispensed each time potentially causing confusion among patients.
- **Patients** – Promotional campaigns to allay fears regarding the effectiveness and safety of generics; information and other campaigns encouraging patients to accept INN prescribing; databases in pharmacies to check previous prescribing history to avoid duplication.
- **Regulators** – Only authorising substitution where no concerns with bioequivalence or therapeutic equivalence as well as acting quickly to recall generics from the market place where concerns with their quality, e.g. the recent recall of certain generic clopidogrel preparations.
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Overall, concerns with the effectiveness and safety of generics typically only apply in a minority of situations, with physicians rarely forbidding substitution in practice if safeguards are in place. As a result, helping health authorities and health insurance agencies realise appreciable savings from the availability of generics. For instance in France, the recent measures to enhance the prescribing and dispensing of generics, coupled with their prescriptive pricing policy for generics (Table 2) and price cuts, led to estimated annual savings of one billion euro in 2007, up from 500 million euro in 2005.
Some European countries also look at the environmental aspects of drugs, including generics, in their decision making; however, currently this only applies to a very limited number.

Conclusion

The various initiatives have lowered the price of generics throughout Europe. This includes countries with smaller populations such as Lithuania, Norway and Sweden, dispelling the myth that such countries cannot obtain low prices for drugs. These initiatives, coupled with measures to enhance generic utilisation, have also resulted in stabilisation of reimbursed expenditure for the PPIs and statins in recent years among the majority of Western European countries. This is despite appreciable increases in utilisation. These efficiency gains have been achieved without compromising care.

However, there has been increased expenditure among European countries with currently limited intensity of demand side measures to counteract pharmaceutical company activities such as France, Ireland and Portugal. These differences in the extent of both supply and demand side reforms led to over tenfold difference in reimbursed expenditure for the PPIs and statins in 2007 among European countries when adjusted for populations. However, there was greater morbidity among the Irish population studied. These savings have been enhanced by reducing concerns with generics among all key stakeholder groups.

There are still, however, considerable opportunities for all European countries to improve their prescribing efficiency with existing drugs. This includes additional measures to lower generic prices. In Germany for instance it is estimated there were potential savings of over one billon euro/year in 2007 alone just from lowering prices of generic PPIs and statins to those seen in Sweden and UK (Figure 1). France, Ireland and Portugal could benefit from initiatives to enhance the prescribing of generics in a class. European countries could also be more proactive where permitted with anticipating generic launches to maximise savings rather than waiting to their launch before instigating initiatives. Greater proactivity is envisaged to save over one billion pounds/ year in the UK (1.1 billion euro) alone.

It is likely that the pace of reforms will accelerate, especially given the current financial concerns in Europe coupled with ongoing pressures. As a result, countries will increasingly need to learn from each other when considering future measures. This is already happening.

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