With global healthcare budgets increasingly under pressure due to escalating costs, the spend on pharmaceuticals is a prime target for healthcare planners as it is the second largest budget item after staffing expenditure. Against this financial pressure, payers are, understandably, looking at any avenue to save costs and a method that looks increasingly attractive to healthcare planners is boosting prescribing of alternatives to branded medicines via generics and biosimilars. Although generic substitution has largely been accepted as desirable, the prescribing of biosimilars remains contentious. This article looks at the various issues and policies affecting the uptake of non-branded medicines in the UK and across the globe, and highlights the most important issues associated with the topic to assist policy-making going forward. The UK has managed to achieve a high level of generic prescribing without implementing a policy of mandatory prescribing; and the key to the success of this policy is physician advocacy, a concept that must form the bedrock of any policy seeking to expand biosimilar market penetration, both in this country and abroad.

Key Words: Prescribing • Biosimilars • Branded • Generic • Healthcare spend
on definitions regarding generic and biosimilar medicines (see Table 1). Likewise, there is often confusion surrounding the definitions of the policies employed by payers regarding the substitution of branded medicines, which is clarified in Table 2.

The UK experience with generics and biosimilars

Generic medicines

The UK has a very high level of generic prescribing, with 83.9% of prescriptions written generically in 2013 (IMS, 2015). However, it is important to realise that the UK market does not mandatorily enforce international non-proprietary name (INN) prescribing and generic substitution by pharmacists is not permitted. The UK has a number of key policies in place, such as encouraging trainee doctors to prescribe by INN and prescribing software such as ScripSwitch.

Despite the comparatively high number of medicines being prescribed generically in the UK, Duerden and Hughes argue that there are still cost savings that could be made if generic medicines were substituted against prescriptions written by the branded name or by getting prescribers to adhere to advice to prescribe generically (Duerden and Hughes, 2010). On the other hand, the OHE believes that medicine spend is well under control in the UK and that in the period between 2012 and 2015, nine of the current top 20 selling brands in the NHS will lose or have lost their patent exclusivity, delivering significant savings to the NHS (OHE, 2012). Table 3 shows the OHE estimates for the UK medicine bill from 2012–2015.

The issue of ‘space for innovation’ remains a key element in any policy or proposal seeking expansion of generic prescribing in the UK and beyond. Pharmaceutical manufacturers receive patent exclusivity for a set period of time from molecule discovery and a limited amount of time to recoup this once a product is marketed. It seems logical that once patent exclusivity has expired on particular medicines, this money should be reinvested to ensure patients gain access to new innovations from the pharmaceutical field as long as the overall spend on medicine remains roughly constant and in line with inflation. However, with the recent introduction to market of high-cost medicines, such as eculizumab for atypical haemolytic uraemic syndrome (aHUS), which is expected to cost the NHS between £57.8 million and £82 million over the next 5 years (National Institute for Health and Care Excellence (NICE), 2015a), it is unclear if generic prescribing and loss of

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<th>Table 1. Definition of generic medicines and biosimilars</th>
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<td><strong>Item</strong></td>
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<td><strong>Small molecule</strong></td>
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<td>Generic Medicine</td>
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<td><strong>Biological products</strong></td>
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<td>Biosimilar</td>
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<th>Table 2. Definition of branded medicine substitution policies</th>
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<tr>
<td><strong>Policy name</strong></td>
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<tr>
<td>Generic substitution</td>
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<td>Therapeutic substitution</td>
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<tr>
<td>International non-proprietary name (INN) prescribing</td>
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products should be prescribed by brand name under MHRA policy (MHRA, 2008) to prevent accidental pharmacist substitution. Pharmacist substitution of biosimilars is not permitted in the UK.

In terms of reimbursement, NICE has issued a statement that it will only consider biosimilars within the context of multiple technology appraisals (MTA) (NICE, 2015b). Therefore, in England a biosimilar is reimbursed at 100% until the MTA occurs. However, unlike conventional generics, biosimilars as branded medicines fall under the Pharmaceutical Price Regulation Scheme (PPRS) regulation, meaning that there is a cap on the spending.

Before NICE performs an MTA, the outcome of which is also adopted in Scotland and Wales, the Scottish Medicines Consortium (SMC) and the All Wales Medicines Strategy Group (AWMSG) appraise all new biosimilars. They have a pragmatic approach to HTA, where if equivalence is demonstrated in clinical studies, then a cost minimisation approach can be taken as long as the reference product is recommended (SMC, 2015; AWMSG, 2015). The differential treatment of biosimilars by different HTA agencies could lead to inequality in access to biosimilars across the UK, although such a case has not yet occurred.

NICE has recently considered the infliximab biosimilars within the context of the ankylosing spondylarthritis MTA. Interestingly, even when the lower acquisition price of the biosimilar was considered within the model, the incremental patent exclusivity alone will be sufficient to raise the funds to pay for the latest innovations.

**Biosimilars**

Unlike conventional generic medicines, the uptake of which has been high in the UK compared to many European countries, the prescribing of biosimilars is currently low, and lags far behind countries such as Germany and Sweden. Compared to the 84% of prescriptions overall that are written for generics, biosimilar prescribing makes up less than 30% of the volume market share of the reference biological products (IMS Health, 2012).

This reluctance to prescribe biosimilars may be due to physician and patient concerns over the equivalence of the safety, quality and efficacy of biosimilars to the reference product, which are not molecularly identical. It could also come from the Medicines and Healthcare products Regulatory Agency (MHRA) position that ‘products (biosimilar and reference) that have the same INN are not to be presumed identical’ due to the fact that ‘biological products are fundamentally different from standard chemical products in terms of their complexity, and it is unlikely that the biosimilar product will have an identical structure to that of the reference product’ (MHRA, 2008).

The slow uptake of biosimilars may also be due to the lack of nationwide policies to increase awareness of biosimilars and the fact that, unlike conventional generics where INN prescribing is encouraged, biosimilars and their reference products should be prescribed by brand name under MHRA policy (MHRA, 2008) to prevent accidental pharmacist substitution. Pharmacist substitution of biosimilars is not permitted in the UK.

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**Table 3. Total UK medicines bill**

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<tr>
<td>Generics</td>
<td>2,405</td>
<td>2,257</td>
<td>2,414</td>
<td>2,618</td>
<td>2,679</td>
<td>3,099</td>
<td>3,296</td>
<td>3,599</td>
<td>3,945</td>
<td></td>
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<tr>
<td>Biosimilars</td>
<td>37</td>
<td>46</td>
<td>58</td>
<td>77</td>
<td>92</td>
<td>105</td>
<td>134</td>
<td>236</td>
<td>328</td>
<td></td>
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<tr>
<td>Brands</td>
<td>9,231</td>
<td>9,792</td>
<td>10,192</td>
<td>10,513</td>
<td>10,810</td>
<td>10,514</td>
<td>10,807</td>
<td>11,070</td>
<td>11,310</td>
<td></td>
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<tr>
<td>Total UK medicines bill (gross)</td>
<td>11,673</td>
<td>12,095</td>
<td>12,664</td>
<td>13,208</td>
<td>13,581</td>
<td>13,718</td>
<td>14,237</td>
<td>14,905</td>
<td>15,583</td>
<td></td>
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<tr>
<td>Value of adjustments</td>
<td>508</td>
<td>577</td>
<td>649</td>
<td>718</td>
<td>775</td>
<td>808</td>
<td>800</td>
<td>753</td>
<td>749</td>
<td></td>
</tr>
<tr>
<td>Total UK medicines bill (net)</td>
<td>11,165</td>
<td>11,518</td>
<td>12,015</td>
<td>12,490</td>
<td>12,806</td>
<td>12,910</td>
<td>13,437</td>
<td>14,152</td>
<td>14,834</td>
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cost-effectiveness ratios (ICERs) for infliximab at the biosimilar price (£36,751–£60,222 per QALY under different scenarios) were still above the threshold below which drugs are normally considered cost-effective (~£30,000 per QALY) (NICE, 2015b). The list price of the biosimilar Remsima® in the UK is £377.66 per 100 mg vial (equating to between £15,106 and £12,085 for an average patient, depending on dosing schedule), which is only 10% cheaper than the originator Remicade®, despite a previous press release from manufacturer Celltrion stating that the price reduction would be over 30% (UK Medicines Information, 2015; NICE, 2015b).

NHS England spent £164 million on Remicade® alone in 2013 (Pharmafile, 2015); therefore, the introduction of biosimilars at even a 10% discount could lead to substantial savings. The British Generic Manufacturers Association (BGMA) has said that the onset of competition in the UK for infliximab biosimilars is a significant milestone in the development of the biologic market (BGMA, 2015). However, the case study in ankylosing spondyloarthritis demonstrates how biosimilars can still have a large price tag and may not be considered a cost-effective use of NHS resources. Thus, although policy should incentivise the prescription of biosimilars over original brands for patients and physicians who are well informed of the potential differences, the cost-effectiveness of these expensive biosimilars should still be ascertained.

MTAs conducted by NICE would be required immediately when a biosimilar is launched, especially if other comparators have become available since the recommendation by NICE of the originator brand. It was highlighted at a roundtable run by the OHE in 2014 that if the originator brand was rejected by NICE, the need for an HTA assessment of the biosimilar becomes greater (Mestre-Ferrandiz and Towe, 2014).

**International experience with generics and biosimilars**

The issues affecting the uptake of generics and biosimilars are part of a global phenomenon and, as with the complexity and heterogeneity observed between markets, policies and approaches differ significantly between countries.

The global generics sector reached $269.8 billion in 2012 and is expected to reach $518.5 billion in 2018, with a compound annual growth rate of 11.5% (BCC Research, 2014). This high penetration of generic medicines is due to various incentives being offered to clinicians, patients and payers; although mandatory INN prescribing in international markets is rare. Biosimilars and non-original biologics reached only $2.48 billion in 2012, but are expected to represent 4-10% of the $250 billion global biologics market by 2020, although growth rates are still subject to considerable uncertainty and will largely be driven by the US market over the coming years (Rickwood and Di Biase, 2013).

**United States**

The US is the world’s largest generic market, with sales accounting for just over $100 billion in 2013 (IMS Institute for Healthcare Informatics, 2014). Generic substitution is thus very common, with pharmacists playing a key role, although regulations may vary from state to state (Hassali et al, 2014b). Although mandatory generic prescribing is not universally adopted, there are a number of incentives within the healthcare system to explain the high generic drug volume observed in the US.

The first set of incentives focuses on the patient; most public and private insurance plans offer financial benefits to patients who choose the generic medicine over the branded one, usually through tiered formularies that offer a lower co-pay to select the non-branded medicine.

Second, generic substitution is permitted across all states in the US. In some states, pharmacists have to mandatorily switch to a generic medicine if it is available, while in others, patient consensus is required to make the switch. States in which patient choice is required have a 25% lower rate of generic substitution compared to states in which it is mandatory (Hassali et al, 2014b). This figure raises the issue of patient choice in that branded medicines may be preferred to generic medicines, despite a Food and Drug Administration (FDA) requirement for a generic medicine to have the same active substance, strength, route of administration,
identity, quality, purity and efficacy as the branded product (see Table 1). In the US, the FDA lists approved drug products and therapeutically equivalent generic medicines in the ‘orange book’ (FDA, 2015a). Other incentives in the US healthcare system to incentivise non-branded prescriptions include federal subsidies of generic drugs dispensed to Medicare Part D beneficiaries; prescribing controls by insurers (e.g. adjusting formularies to reflect patent expiry and new generic launches); and ‘4/10’ programmes where large suppliers (such as Walmart) are able to offer 30- and 90-day supplies of certain generic drugs for $4 and $10 respectively (IMS Health, 2015).

Unlike in Europe, where the European Medicines Agency (EMA) first approved a biosimilar in 2006, the FDA has only recently approved its first biosimilar, named filgrastim-sndz (Zarxio®), on 6 March 2015, following years of finalising the abbreviated licensure process for biosimilars (FDA, 2015b). Under the Biologicals Price Competition and Innovation (BPCI) Act, the FDA has the power to approve a biological product to be ‘interchangeable’ with its reference product, which would allow pharmacist substitution. However, Zarxio® has been approved as a biosimilar that is not interchangeable, and substitution at the pharmacist level is not permitted. It remains to be seen whether any follow-on biological product can achieve the level of evidence required by the FDA to be categorised as interchangeable.

Interestingly, the FDA has created a new placeholder non-proprietary name for Zarxio®, ‘filgrastim-sndz’ to differentiate it from its originator product ‘filgrastim’, preventing accidental substitution of one biosimilar for another if the physician uses the non-proprietary name on the prescription. The FDA will soon be issuing guidance on how current and future biological products should be named in the US (FDA, 2015b).

Although the biosimilar market in the US is in its infancy, it is thought that payers will seek to build on their experience with generics, and employ incentives for patients to choose the cheaper biosimilar products, such as higher cost sharing for originator products and lower cost sharing for biosimilars (Cohen et al, 2014).

Figure 1. Biosimilar uptake across Europe (source: IMS Health, 2012)
Europe

In Europe there has been a great deal of variation in the uptake of biosimilars since 2006 (Figure 1) (IMS Health, 2012). Sweden, along with Germany, Austria, Greece and Romania, has one of the highest prescriptions of biosimilars by volume. The high uptake in Sweden, however, has not been due to mandatory pharmacist substitution, which is not permitted for biosimilars, as it is for conventional generics. The high use must instead be due to physician awareness and comfort with these biosimilar drugs, which may explain the large differences in uptake seen across different indications in Sweden (for example, biosimilar HGH has an 18% share of the volume while biosimilar G-CSF has an 81% share (IMS Institute for Healthcare Informatics, 2014)).

A study carried out by Duke University in the United States assessed the experience of biosimilars in France, Germany, Italy and the UK, and concluded that Germany had the most favourable market for biosimilars (Haustein et al, 2012). Whereas countries like France have specifically banned substitution of biosimilars at pharmacist level, the picture in Germany is a little less clear, as substitution might be possible under the German generic substitution policy (‘Aut-idem-Regelung’), although this has not been sanctioned explicitly (Vogler and Schmickl, 2010).

The success of biosimilars in Germany, where there is around 50% volume uptake (IMS Health, 2012; Figure 1), has largely been attributed to specific reimbursement policies introduced by the country’s sickness funds, rather than to substitution. These include physician prescription quotas, education sessions for clinicians on biosimilars and publication of data supporting biosimilars’ safety and efficacy. Quotas have been highly successful in Bremen, where biosimilars now make up 70% of the available market, which is in stark contrast to Saarland where no such quotas were introduced and where biosimilars account for only 16% of the erythropoietin market (GaBI Online, 2013). Just as Sweden is one of the European countries leading the way with biosimilar uptake, it also has a similar record with conventional generic medicines, largely due to the introduction of mandatory generic prescribing in 2002. Pharmacies are obliged to substitute the cheapest available product, generic or parallel import, containing the same active substance and considered to be medically equivalent according to a list produced by the Swedish Medical Products Agency (MPA) (Andersson et al, 2005). However, since 1 January 2015, pharmacists have been able to oppose a switch if they feel it will significantly inconvenience the patient. The system also incentivises patients to comply with generic substitution and those who reject substitution must pay the difference between the cheapest alternative and the product they request (IMS Health, 2015). Physicians in Sweden are able to prohibit substitution on medical grounds (e.g. anti-epileptic medication) and patients do not have to pay the difference in this case (IMS Health, 2015).

Like the UK, the other four EU-5 markets (Germany, Italy, France and Spain) do not have mandatory prescribing for generic medicines as in Sweden, but have initiated a number of other policies to assist with the uptake of generic medicines. For example, in France, generic substitution targets have been set for pharmacists since 2006. A national target (85% in 2014) is established annually by agreement between the pharmacists’ associations and the national union of health insurers Union Nationale des Caisses d’Assurance Maladie (UNCAM).

INN prescribing become mandatory in France from 1 January 2015 (IMS Health, 2015). In Spain, INN prescribing is not mandatory, but since April 2012 doctors have only been allowed to write prescriptions for branded medicines if the treatment is chronic and the drug is included in the reference pricing system, or if there is no generic alternative on the market (IMS Health, 2015).

Japan

The Japanese market has low generic uptake compared to the US and western European markets (IMS Health, 2015). One of the suggested reasons for this is a cultural preference for branded products (IMS Health, 2015).
although a study by Kobayashi et al suggested that public understanding of generic medicines was poor, and there was a critical need to get timely and correct information to patients via physicians and pharmacists to assist generic uptake (Kobayashi et al, 2011).

The Japanese government fully understands the budgetary burden of having low generic uptake and has embarked on a number of policies to boost generic prescribing, including dispensing fees, physician incentives and tightening generic substitution criteria. Generic substitution is not mandatory in Japan, although doctors now have to opt out of substitution rather than the previous situation of opting in. Doctors can also claim a 20 yen fee for INN prescribing, which is dispensed by a pharmacist, who since April 2014 have to provide a written explanation to the Ministry of Health, Labour and Welfare (‘Korosho’) if they decide to prescribe a branded version (IMS Health, 2015).

Pharmacists can claim fees for dispensing generics, ranging from 180 yen (55–64% generic dispensing rate) to 200 yen (>65% generic dispensing rate) per item (IMS Health, 2015). The Japanese government is clearly trying hard to bring generic prescribing in line with western markets; however, whether this will be enough to achieve its target of 60% generic uptake (prescription volume) by 2017 and overcome cultural barriers remains to be seen.

Japan has tried to follow in the footsteps of Europe, rather than the US, when it comes to biosimilars, in line with the Japanese government’s campaign in recent years to increase the use of conventional generics. They have a regulatory system that is less stringent than in the US when it comes to demonstrating similarity to an existing biological product, which has allowed biosimilars to be available in Japan since 2009. The first biosimilar to be approved in Japan, epoetin kappa, had reached 74% market share by 2014, and indicates that biosimilar uptake in Japan may be faster than generic uptake (GaBI Online, 2014).

The popularity of epoetin kappa in Japan is not due to substitution with its originator, epoetin alpha, which is not permitted and is actually prevented by the Japanese adopted naming (JAN) system. The JAN system does not follow INN but, as in the US, creates a new non-proprietary name for the biosimilar. Instead, the uptake could be due to the Japanese company that market epoetin kappa, Japan Chemical Research Pharmaceuticals, who have ensured that clinicians are educated on biosimilars and who emphasise their reputation for quality within the Japanese pharmaceutical market.

The phenomenon of ‘brand loyalty’, which is perceived to be strong in Japan and has hampered the penetration of conventional generics in the country, may not be such an insurmountable problem for the branded biosimilars, especially if they are a Japanese-owned brand.

‘Placebo’ effect and brand loyalty
One of the key barriers associated with the uptake of generics and biosimilars is the concept that physicians and patients do not believe the drug they are prescribing or have switched to is as good as the branded alternative. Joan Costa-Font and his collaborators heavily attribute the sluggish development of the European generic drug market to patient and physician loyalty to branded products (Costa-Font et al, 2014). They estimate that at least 13% of the population would not accept generics as substitutes to the original brand and this situation is made worse by the ‘generics paradox’ – a phenomenon where on the entry of a generic product, manufacturers increase the branded product’s price to exploit patient brand loyalty (Costa-Font et al, 2014).

The existence of brand loyalty and the generics paradox will be a worry to healthcare planners who are trying to save costs by encouraging generic substitution. The concept of brand loyalty is important because the belief that the generic medicine is inferior to the branded medicine can lead to issues with poor adherence or removal of the ‘placebo effect’, resulting in sub-optimal medical outcomes.

Krska et al looked at patients’ views and experiences in a statin switching programme across seven GP practices in East Lancashire, UK (Krska et al, 2012). The study found that over half of patients (52.9%) did not understand the reason for the switch and 17.7% of respondents
experienced increased side-effects (compared to 3.4% who experienced fewer side-effects). Likewise, a study analysing GP beliefs, perceptions and behaviours towards generic medicines in Ireland found that although 30 of the 34 GPs in the study actively promoted generic medicines, a third reported complaints of increased or altered side-effects (Dunne et al, 2014).

The concept of brand loyalty is likely to be even stronger for biosimilars, where the molecule is not identical to the originator and there may be more uncertainty and fear over equivalence. There is great variation across countries as to whether physicians have the perception of lower efficacy with biosimilars. One study of stakeholders in Germany, France and Italy found that, although physicians in Germany and France thought biosimilars would have similar efficacy, those in Italy more often suspected that biosimilars would have lower efficacy than the originator brand (Sewak and Jones, 2014).

In terms of patients, it is likely that there is also a certain degree of variation over whether they would be willing to switch to or initiate a biosimilar. A study of 3,214 diabetic patients reported that 66% of patients would ‘definitely’ or ‘likely’ be willing to use a biosimilar insulin when they become available in the US, while 17% reported that they were ‘unlikely’ to use or would ‘definitely not use’ such an agent (Wilkins et al, 2014). The most common concerns of patients included whether the biosimilar would be as effective as the originator product (~650 respondents) and whether side-effects would be different (~220 respondents). This study does indicate, at least, that the majority of patients would consider switching to a biosimilar, so the notion of brand loyalty may not be an unsurmountable one.

Policy implications
This review has provided an overview and international insight into current issues surrounding the uptake of generic and biological medicines. There are three key implications for policy-makers from our findings.

First, there is a mandate for governments to provide accurate and clear information on what a ‘generic’ and a ‘biosimilar’ product is to physicians, pharmacists and, crucially, patients. This is vital for ensuring that switching decisions are made in a transparent and consensual manner, and that myths associated with generics and biosimilars are dispelled based upon the latest factual information.

Second, it is clear that biosimilars should not be considered as ‘generic’ biological medicines and will require different approaches from policy-makers to boost uptake. In markets where there are higher levels of out-of-pocket payments (OPPs), financial incentives to the patient will assist with the uptake of biosimilars. However, in markets such as the UK, where the OPP is fixed, different strategies to encourage uptake will be required. Given that substitution of biosimilars is not permitted, we would advocate that education should be given on biosimilars as a mandatory part of physician training. Updates when HTA agencies (e.g. NICE/SMC/AWMSG) approve or reject biosimilar products and when the latest evidence surrounding biosimilars is released would also be useful and could be incorporated into electronic prescribing systems.

Finally, although the savings with generics and biosimilars are substantial, it is important to recognise that the current level of generic prescribing compared to branded products in the UK is not matched by biosimilars. Also, while generic prescribing is universally accepted as being cost-effective, the current NICE MTA in ankylosing spondylarthropathy has shown that despite being cheaper, the cost-effectiveness of biosimilars is not guaranteed.

The savings made by generic medicine uptake have been impressive, but whether biosimilar penetration will ever achieve the same level of uptake at present remains uncertain. However, it is important to recognise that a lot of the current scepticism surrounding the uptake of biosimilars was previously directed at generic medicines upon market entry and only time will tell if biosimilars are able to achieve similar levels of success. As new high-cost, branded therapies come to market, the ‘space for innovation’ for these new therapies is unlikely to be funded exclusively from savings made to the pharmaceutical budget via generics and...
biosimilar uptake – policy makers will have to look for other ways to optimise the medicines budget while retaining a positive research and development environment for life science companies.

Conclusions

Despite being alternatives to branded medicines, generics and biosimilars are clearly very different, and attitudes towards them here in the UK and abroad reflect this notion. Sweden leads the way in both the biosimilar and generic markets in terms of uptake; and it seems a paradox that the US has the largest generics market in the world but only approved its first biosimilar this year. Japan is the polar opposite, with cultural traditions hampering the generic markets – yet a relaxed regulatory framework and company loyalty are contributing to an expansion in the branded biosimilar market.

The dichotomy observed between markets reflects the fact that the perception of biosimilars by prescribers and patients, in terms of their safety and efficacy, differs markedly from country to country. Although evidence surrounding the ‘placebo effect’ and brand loyalty is demonstrable with generic medication, this is likely to be exacerbated in the biosimilar market, which will inevitably also affect uptake.

Potential savings with both generics and biosimilars are enormous, but the discount for biosimilars (~10–30%) compared to the originator product is less than for generics (~70–80%), and the competition on the market for these branded products will be very different and cost savings may be harder to realise.

Despite the universal acceptance of the benefits of generic prescribing, the UK has managed to achieve a high level of generic prescribing without implementing a policy of mandatory prescribing. The key to the success of this policy is physician advocacy; and, although achieving the same levels as generic uptake seems unlikely for biosimilars at present, this surely must form the bedrock of any policy seeking to expand biosimilar penetration in the UK and abroad.

References


Haustein R, de Millas C, Hoer A, Haussler B (2012) Saving money in the European healthcare systems...
with biosimilars. Generics and Biosimilars Initiative Journal 1(3-4): 120–6


Scottish Medicines Consortium (2015) infliximab (Remsima). Available at: https://www.scottishmedicines.org.uk/SMC_Advice/Advice/1006_14_infliximab_Remssima/infliximab_Remssima (accessed 24.3.15)

Sewak NPS, Jones C (2014) Anti-TNF biosimilars indicated for rheumatoid arthritis are increasingly available in Europe: How do payers and key stakeholders perceive them? Value in Health 17(7): A388


