Generics & Biosimilars: Innovation not Imitation

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Introduction

“Imitation is not just the sincerest form of flattery – it’s the sincerest form of learning.”

George Bernard Shaw might have been thinking about a higher art form than generic medicines when he said those words, but the sentiment applies.

Generic medicines are by definition ‘a pharmaceutical product that is usually intended to be interchangeable with an innovator product, is manufactured without a licence from the innovator company and is marketed after the expiry date of the patent or other exclusive rights’.[1] This definition essentially describes generic as a copy of the original product; but in reality, the generics of today are so much more than that.

This white paper seeks to establish the value that generics bring to the UK, but also show how generics manufacturers have been learning over last 10 years and how their evolution will impact in the future.

The virtuous circle of generics

Around 75% of all medicines in the UK are generic, making the UK one of the highest writers of prescription generic medicines in Europe. Generics are an essential cornerstone of the UK health system as they deliver £13 billion, or a third the total NHS medicines bill, in savings every year, according to NHS figures.[2,3]

In general, once a branded originator medicine loses its patent and becomes generic – the generic price drops by 70% within the first six months from the originator, falling to 80-90% lower over a four-year period.[2] In reality, that drop to 90% usually happens much faster, often only weeks after the initial 70% drop. In fact, on average the cost of a 28-day supply of generic medicines supplied by Accord to the NHS is c£1.15 – that is less than a cup of high street coffee.[4] These steep drops in price can in part be contributed to pharmacists being incentivised by a retained buying margin resulting in cost effective purchasing, and competition amongst generic manufacturers.

Those savings not only allows the NHS to provide newer medicines that have just been approved, but the threat of generic competition acts as a driver to incentivise originators to maximise their R&D efforts to bring new innovative medicines onto the market. It also means best-in-class treatments that had been pushed lower in a treatment pathway due to prohibitive costs become more widely available. This is a critical element of the industries’ role in improving healthcare outcomes.

In general, the UK has the lowest generic prices across Europe when compared the five largest mature generic markets.[2] The value that generics bring to the NHS industry is more than just freeing up resources for new medicines, it also can offer stability to the medicine supply particularly when major events occur without warning.

Whilst the UK was reeling in response to Covid-19, and other UK and global challenges such as Brexit and the Suez Canal crisis, the generics industry has had a pivotal role in ensuring that access to medicines remained constant and consistent.

Whilst, the pandemic caused disruption across all industries, it was particularly urgent to maintain the supply of medicines during this critical period. For the generics industry this was a huge responsibility. Not only do generic medicines take the lion-share of all medicines prescribed on the NHS,[2] but we know they played a critical role in the response to Covid-19.

At Accord, at the outset of the pandemic we built a forecasting model based on what we thought would happen to the demand, particularly for intensive care medicines. We worked hard to fulfil the extra demand from hospitals and community pharmacies to ensure there were fewer potential points of failure in the supply chain.

The fact that the NHS didn’t run out of essential medicines during that tough first wave or subsequent waves against a backdrop of other seismic events is a real testament to the flexibility and resilience of the industry.

Balancing cost and sustainability

There are some long-term commonly misplaced perceptions that generic medicine prices are subject to arbitrary spikes and that there is much disruption.

Accord UK has been monitoring generic medicine reimbursement prices over the last 5 years and as you can see on the chart below, generic medicine reimbursement prices remained stable throughout the pandemic, dropping recently to reflect a well supplied market:

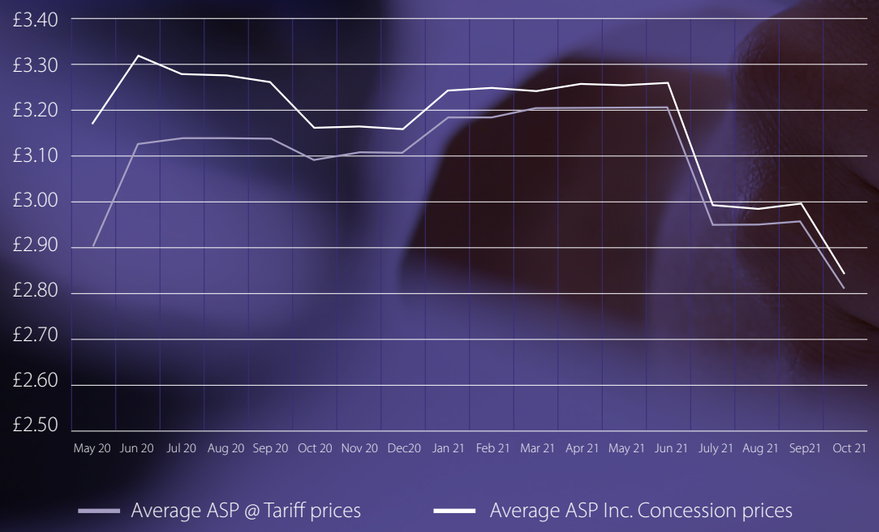


Figure 1: Accord UK Beyond the Headlines November 2021 – Average reimbursement price (inc concession pricing)
***ASP = Average Selling Price**

Given the shifts in currency due to global events, impacts from GMP closures, Brexit and the Covid pandemic, the industry has proved remarkably resilient to these factors, in a very real and challenging environment.

Initiatives that promote the NHS getting better value is a positive step for patients and increasing access to critical medicines.

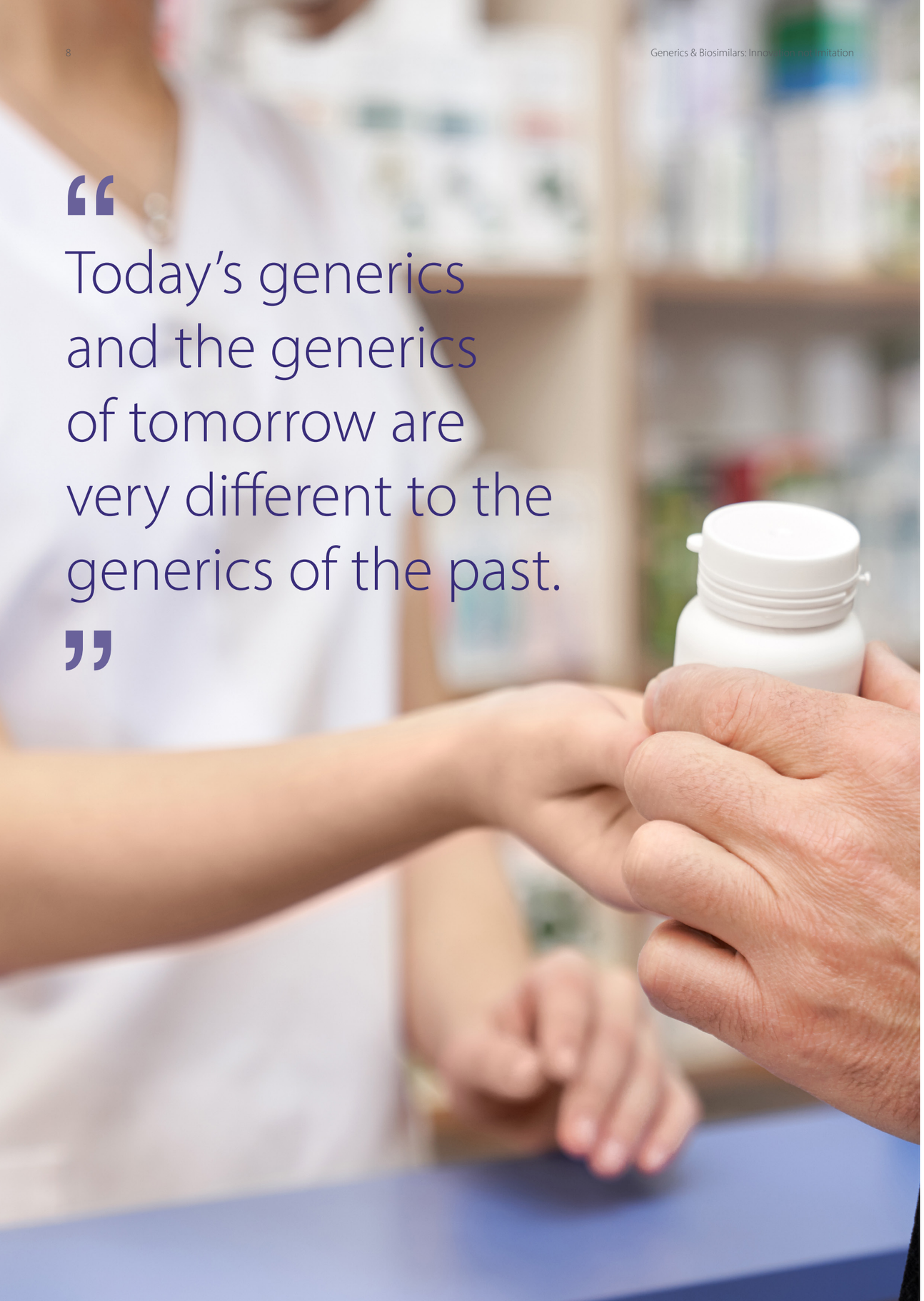
A voluntary pricing scheme VPAS has emerged from what used to be the Pharmaceutical Price Regulation Scheme (PPRS). It puts a 2% a year spending cap on branded medicines for five years and is designed to save the NHS money, while allowing some incentive for innovation.[5] It is a deal between the Department of Health and Social Care (DHSC) and the Association of the British Pharmaceutical Industry (APBI).

Mark Samuels, Chief Executive Officer at the British Generics Manufacturing Association (BGMA) gives his view:

> The NHS, estimate that they save £300 million a year from prescribing biosimilars and these are included in the scheme.[6] This means that although the scheme is meant to cap the spend on new medicines and encourage better value medicines, manufacturers that produce biosimilars with already squeezed margins are being penalised. In the long-term it could undermine the stability of the biosimilar industry.

We have established that overall, the generic industry brings value to the NHS in terms of cost. However, a need for sustainability in the supply of medicines means that focusing just on price can be short-sighted. The crusade to get the lowest cost can create thinly stretched supply chains that are more suspectable to disruption leading to shortages.

If we encourage payers, regardless of whether they are a large pharmacy chain, an independent pharmacy, or the NHS buying for hospitals, to look beyond price and consider other factors such as supply chain resilience, sustainability from both an environmental and production perspective, you can still have a freedom of pricing model that supports the lowest prices in Europe, whilst getting the best outcomes.



“Today’s generics and the generics of tomorrow are very different to the generics of the past.”

Yesterday’s blockbusters – todays generics

In the past generics were traditionally high-volume products, for example 28 tablets, as a brand coming off patent. In today’s market, there’s a lot of different forms of medicine including the evolution of biosimilars, and the therapy areas and patient groups may be smaller. The technology, time, and cost to develop and market these newer products are much higher, but they also mean very often generic companies look to bring improvements to the product in how it may be used, a change of form or device to help either the healthcare professional or indeed patient.

For example, Humira (adalimumab), when it was approved by the European Medicines Agency (EMA) in 2003, was considered a blockbuster drug, e.g., a medicine that reaches the billion-dollar sales mark, and was the most expensive drug used in NHS hospitals.[7] Since its core patent expired in 2016 in the US and in 2017 in the EU there have been eight[8] biosimilars approved for use by the EMA.[9,10] As well as the value reduction due to competition, on June 10th 2021, NICE announced a change to treatment options for up to 25,000 patients with moderate rheumatoid arthritis due to the availability of lower cost biosimilars and supporting treatments.[11] This is a great example of both value in savings but also increased access to best-in-class treatments.

NHS England guidance on biosimilars published in September 2017 says its aim is that at least 90% of new patients will be prescribed the best-value biological medicine within 3 months of launch of a biosimilar medicine, and at least 80% of existing patients within 12 months or sooner if possible.[12]

So, what does this mean for the generics industry?

One of the key current concerns is ensuring we find a way of making sure that the vast majority of the high volume, everyday medicines, that total more than 1.2bn packs a year remains sustainable.[13]

Simply, if you want those specialist medicines launched and developed by generic companies, you also need to have a sustainable base. It is not just a case of levelling-up machinery technology. These more complex medicines often have a greater risk/benefit ratio and therefore it is also about building knowledge and skills to support the additional patient and healthcare materials that are required for the health and safety of the medicine.

As the traditional generics manufacturer model is one of scale, a key challenge for the industry electing to develop expensive biosimilar medicines is being able to realise that investment and forecast the uptake. It is here that the NHS can be a helpful partner, by communicating their benefits and ensuring uptake which ultimately will benefit them through cost savings.

Biosimilars are different from generic medicines. They are medicines that are made or derived from a biological source such as living cells or organisms, whereas generic medicines are identical to the originator, biosimilars are ‘highly similar’. Both contain the same active ingredient as the equivalent original branded medicine and are authorised to the same standards of safety, quality, and efficacy as the original branded medicine.[6]

Patient-centricity is not just for big pharma

Competition is a great driver in the generic medicines market in keeping costs affordable and providing a great saving resource for the NHS, but it also drives innovation. As generic medicine manufacturers have become more focused on meeting patient needs, it has created a natural differentiator for products that benefit both patients and healthcare professionals.[3]

Patient centricity is officially defined as the process of designing a service or solution around the patient.[14] Such improvements could include making a device that delivers the medicine in a more convenient way, makes it easier to use or providing digital information that improves the experience for the patient.

According to Medicines for Europe 'Many stakeholders believe innovation only leads to generating new molecules, while innovation can come from other areas as well'. [15]

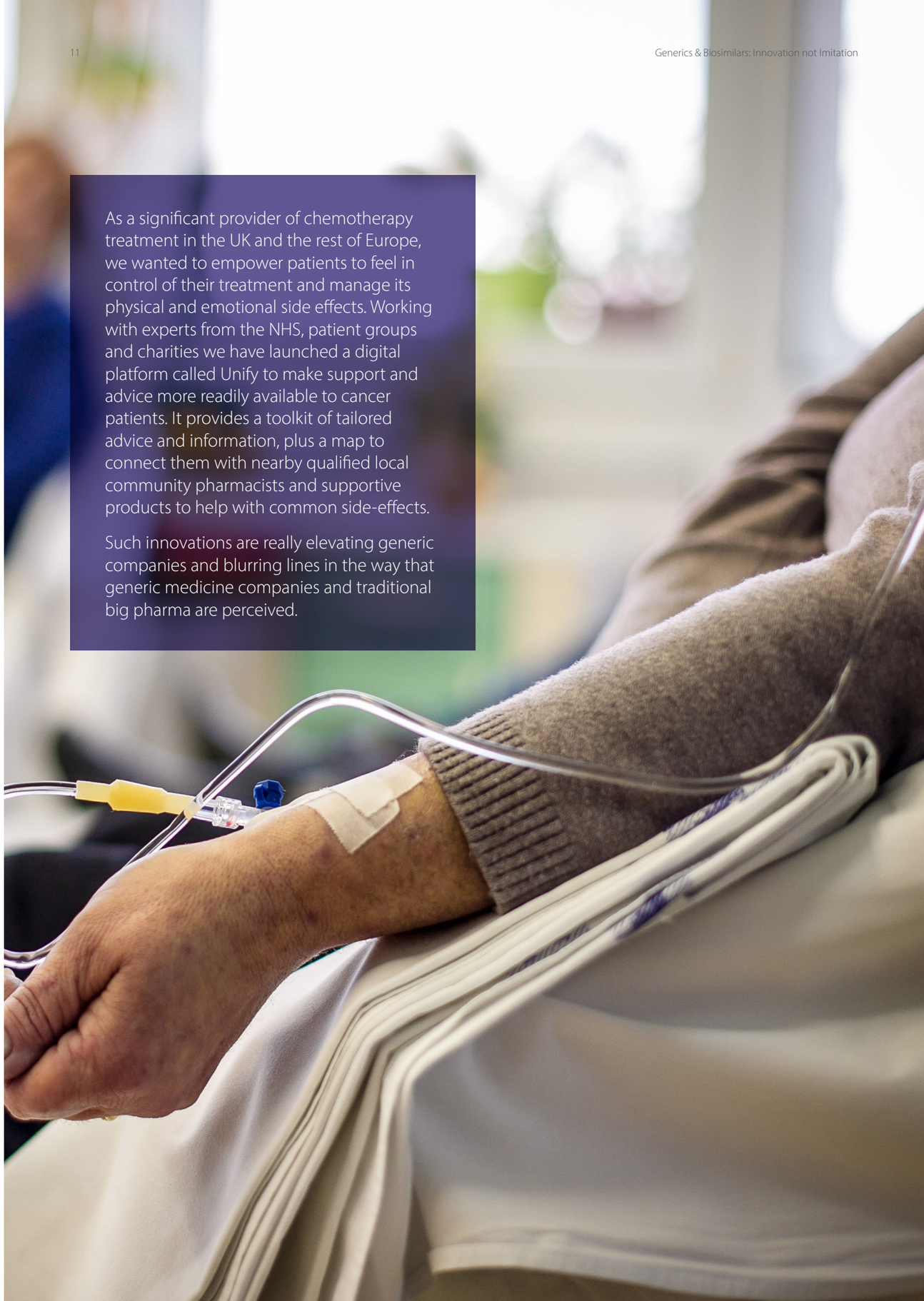
When a medicine patent expires, there are years of R&D and knowledge about that medicine. Often the originator pharmaceutical company has moved on having reaped their investment and are looking ahead to the next advancement. However, this is an opportunity for the generics industry who can build on knowledge accumulated to develop new formulations, new dosage forms or combinations that have the potential to benefit the patient. 'Enhanced customisation of existing therapies to address existing patient or healthcare needs can lead to better outcomes for the entire healthcare community.[14] During the pandemic, reformulations in the way the medicine is administered have allowed patients to take their medicines at home and avoid the need to travel to the hospital.[16]

Patient-centricity is about listening to needs of patients and working with healthcare professionals to deliver solutions that meets both the needs of the patient but also the healthcare professional. Without the latter, the solution is unlikely to reach the patient.

Increasingly, when a medicine patent expires, as a manufacturer we will revaluate how it will be used in the real-world setting and what we can do to make it better.

An example of this approach has been a recent hospital injectable product that was originally developed in a powder form and since it's expiry has been reconstituted into a ready-to-use solution. That might seem a small incremental innovation, but it makes a huge difference to healthcare professionals by reducing the preparation required to use the product. As other manufacturers follow-suit it will produce a cost-saving that will allow more patients to be treated.

It has been well-documented about the rise of patient empowerment and with this comes an appetite for information that helps them, and their healthcare professional better manage their condition. Creating digital innovation platforms for patients used to be the domain of the big originator pharmaceutical companies. Recently, this patient-centric solution has been seized by generic companies keen to find more ways to holistically support patients and healthcare professionals.



As a significant provider of chemotherapy treatment in the UK and the rest of Europe, we wanted to empower patients to feel in control of their treatment and manage its physical and emotional side effects. Working with experts from the NHS, patient groups and charities we have launched a digital platform called Unify to make support and advice more readily available to cancer patients. It provides a toolkit of tailored advice and information, plus a map to connect them with nearby qualified local community pharmacists and supportive products to help with common side-effects.

Such innovations are really elevating generic companies and blurring lines in the way that generic medicine companies and traditional big pharma are perceived.

Conclusion

Generic medicines companies today have come a long way from 20 or even 10 years ago, but the journey is far from over and there are still several bumps in the road that the industry need to overcome to achieve their vision and potential.

What has become clear, is that the balance is shifting and innovation is no longer the mainstay of Big Pharma. The generics medicine industry is undergoing an evolution that is demonstrating innovation on several fronts that benefit both the healthcare professional and the patient.

However, despite the generic medicine industry's track record for stability and resilience, we need to focus on uptake and sustainable policies to ensure companies can continue to invest in the future pipeline, more complex products and patient-centred medicines.

The NHS has a significant role to play in making this work. Six of the top 10 medicines by spend prescribed in NHS hospitals are biological products.[7] and as highlighted earlier they are committed to ensuring that new and existing patients are prescribed the best value biological medicines. It is in their interest to proactively work closely with generic manufacturers to bring more affordable biosimilars onto the marketplace. By working together, everyone benefits – the manufacturer, the NHS and most of all the patients.

Peter Kelly Bio

Pete Kelly is the Managing Director for Accord UK and vice-chair of the BGMA. Accord is one of the largest generic and biosimilar manufacturers in Europe, and in the UK currently supply 1 in 5 of all generic medicines. Pete has worked in the pharmaceutical industry for more than 20 years, the last 15 years being at Accord in a number of senior commercial roles. Alongside his Vice Chair role at the BGMA, Pete has previously chaired the BGMA Economic and Commercial working group.

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