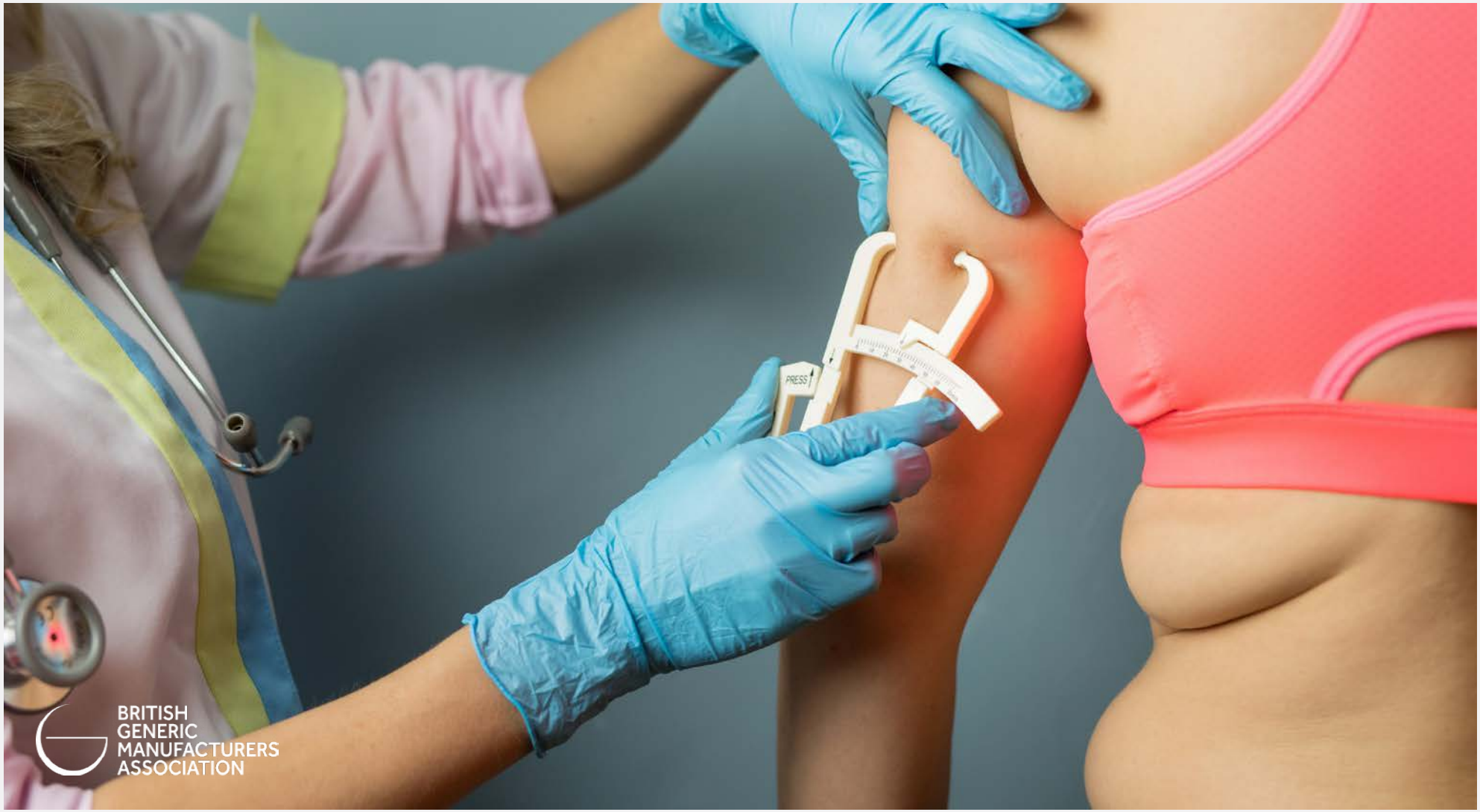
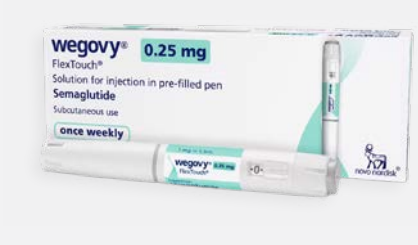
Weight Loss Medicines Policy Paper

By the British Generic Manufacturers Association (BGMA)



Products overview

	Saxenda® [1]	wegovy® [2]	mounjaro® [3]
			
Generic name	Liraglutide	Semaglutide	Tirzepatide
Also used to treat…	Type 2 diabetes	Type 2 diabetes	Type 2 diabetes
Other brand names	Victoza (diabetes)	Ozempic (diabetes)	Zepbound (US name only)
Current NHS price for weight loss, minus discounts[4]	£171-193 (the price prior to Saxenda's patent expiry)	£73-176 (higher strengths cost more for Wegovy and Mounjaro)	Not yet agreed for weight loss, although NICE has noted an NHS List Price of £92-122[5]
Average current private prescription cost[6]	£95 (mostly not available)	£177-288	£189-240
Weight loss impact, if combined with healthy diet and lifestyle	With a 3mg dose, most patients could achieve at least 5% body weight reduction in 56 weeks [7]	With a 2.4mg dose, patients could on average achieve a 15% body weight reduction when used for or 65 weeks [8]	With a 15mg dose, patients could on average achieve a 20.9% body weight reduction when used for 72 weeks [9]
Licensed for weight loss use by whom[10]?	Adults with an initial BMI of at least 30 kg/m2, or from 27 kg/m2 with at least one weight-related co-morbidity	A person with a BMI of at least 35.0 kg/m2, or a BMI from 30.0 kg/m2 if they meet the criteria for referral to specialist weight management services	Adults with an initial BMI of at least 30 kg/m), or from 27 kg/m2 with at least one weight-related co-morbidity
How to take treatment	Pre-filled 6mg pen to be injected once daily	Pre-filled pen, supplied in different strengths, to be injected once weekly	Pre-filled pen, supplied in different strengths, to be injected once weekly
About the treatment	A pen lasts between 6-17 days. Increase dose strength by 0.6mg each week, until week 5, usually when the injection is 3mg	Starting dose is 0.25mg, once a week for 4 weeks. A pen lasts 4 weeks. Increase dose strength every 4 weeks until the injection is usually 2.4mg	Start at 2.5mg, once a week for 4 weeks, increase by intervals of 2.5mg after 4 weeks, maintenance doses are 5mg, 10mg or 15mg
GP review and long-term usage[11]	GP to review up to 4 months after treatment start. Only continue using Saxenda if patient has lost at least 5% of body weight after 12 weeks. Use in consultation with GP for as long as remains effective to reach desired weight	A GP to check if patient has lost at least 5% of body weight after 6 months; consider ending treatment if not. For up to 2 years, use in consultation with GP for as long as remains effective to reach desired weight	A GP to check if patient has lost at least 5% of body weight after 6 months; with risk/benefit analysis on continuing treatment if not. Patient may move up to strengths of 7.5mg, 10mg, 12.5mg and 15mg in consultation with GP. Use in consultation with GP for as long as remains effective to reach desired weight
When is the patent expiry?	November 2024	2031	2037

*Other weight loss treatments available include Orlistat (including under several brand names) and Mysimba.

1. https://www.saxenda.com/
2. https://www.novomedlink.com/obesity/products/treatments/wegovy.html
3. https://www.gov.uk/government/news/mhra-authorises-diabetes-drug-mounjaro-tirzepatide-for-weight-management-and-weight-loss
4. IQVIA, 2024
5. www.nice.org.uk/guidance/GID-TA11156/documents/draft-guidance-2
6. The averages from a basket of pharmacies, taken on 11 November 2024 and featuring: https://onlinedoctor.superdrug.com/weight-loss-treatments.html; https://my.privatedoc.com/; https://onlinedoctor.asda.com; https://www.prescriptiondoctor.com/weight-loss; https://onlinedoctor.boots.com/weight-loss/treatment; https://well.co.uk/shop/online-clinic/weight-loss?srsltid=AfmBOorbiG3vijrVm46WLcp5bSrjoQj-Km8BhjP08D0cH8Bo8zLKHbRM
7. https://www.nejm.org/doi/full/10.1056/NEJMoa1411892
8. https://www.nejm.org/doi/full/10.1056/NEJMoa2032183
9. https://www.nejm.org/doi/full/10.1056/NEJMoa2206038
10. https://cks.nice.org.uk/topics/obesity/management/management/
11. https://cks.nice.org.uk/topics/obesity/management/management/

Overview

> "Demand is far harder to predict than for typical generic or biosimilar markets..."

Liraglutide, marketed under the brand names Victoza and Saxenda by Novo Nordisk, is a glucagon-like peptide-1 (GLP-1) receptor agonist used primarily for the treatment of type 2 diabetes and obesity. Victoza is brand name licensed for treating diabetes and Saxenda the brand name licensed for weight loss. Since its approval by the US FDA in 2010, liraglutide has become a cornerstone in diabetes management, offering significant benefits in blood sugar control and cardiovascular risk reduction.

Its patent protection lifted in the US and Europe in 2023 and ended in the UK in November 2024. This is a significant milestone as it is the first genericisation of a GLP-1 weight loss medicine in the UK and offers enormous potential opportunity for the NHS with regard to public health.

Victoza and Saxenda have been considerable clinical and commercial success stories however, it must be noted that these products are not expected to follow a typical loss of exclusivity model when the patent expires. For a number of reasons, the market and demand dynamics are expected to be different to the vast majority of medicines which lose exclusivity and attract generic[12] competition.

At least four companies are expected to have UK marketing authorisations in place with indications to cover diabetes and obesity when the Victoza / Saxenda patent expires. It is not clear how many will launch immediately and therefore it is harder to predict whether large price erosions will occur straight away.

Usually, a patent expiry would quickly see increased generic competition which would drastically reduce the prices paid by the NHS by as much as 80-90% compared to the originator product.

Demand is far harder to predict than for typical generic or biosimilar markets, which can expect to see a steady rise in demand as the price decline enables the NHS to widen access following loss of exclusivity. In the case of these weight loss treatments, while the level of demand through NHS prescription will undoubtedly be more post-patent, it is not clear how much unmet demand exists.

Unlike most medicines prescribed on the NHS, there is also significant market in private prescriptions, whether available in high street pharmacies or solely online pharmacies. Indeed, the abundance of private prescriptions has also been a significant causal factor in the shortages of products available to diabetes patients via the NHS in the past 12 months.

Alternative patented branded products such as Mounjaro and Wegovy (also known as Ozempic) which require once-a-week jabs compared to daily injections with Saxenda, are also significant market factors. Some patients may prefer the once weekly injections, others may be agnostic, particularly if the price point for the latter is more affordable. Mounjaro and Wegovy also provide on average higher weight loss ranges, as we note earlier.

With all of these issues in mind, it is much more difficult to predict the precise usage levels of generic liraglutide with any immediate certainty, particularly in the private market. We note that the NHS has already launched a tender for generic liraglutide, which will be free to be supplied when Saxenda's / Victoza's patent expires.

However, what these competing versions will bring is greater capacity and choice allowing the NHS to start to treat increased numbers of patients for weight-loss and diabetes with the broader long-term benefits that can deliver.

Generic liraglutide will ensure greater long-term security of supply in a market that under complete patent protection has so far not been able to keep up with demand as the weight loss indication has gained in popularity.

Generic liraglutide, sold at a lower cost, could also provide a way for the NHS to ultimately treat more patients, as well as for people to more easily access and pay for the treatment on private prescription.

So, while the market may take longer to establish than a typical generic loss of exclusivity, the benefits are there to be grasped. It's now up to those marketing weight loss treatments to create compelling offers and for payors in the private sector and NHS to adapt accordingly. In this paper, we outline in more detail some of the factors we expect to influence uptake. We also detail recommendations which we believe can help support safe and sustainable growth.

12. Weight loss treatments like liraglutide and semaglutide are actually biologics and are derived from living organisms. Some follow-on versions launched by other manufacturers when the originator versions are off-patent are actually called biosimilars. Biosimilars are, however, similar in concept to generics, and so, for the sake of ease, we refer to them as generics throughout this document.

Introduction

Mark Samuels

Chief Executive of the British Generic Manufacturers Association (BGMA)

Undoubtedly, the genericisation of the first wave of GLP-1 weight loss medicines is a significant development for the NHS and societal healthcare more broadly in the UK. These products have the potential to deliver important public health benefits in terms of access, cost savings and broader knock-on impacts. The hope is that weight loss medicines can support more Britons to live healthier long-term lifestyles, increasing productivity and saving the billions that obesity costs the NHS annually – quoted between £6.5-19.2bn each year. 'The Nourishing Britain: a political manual for improving the nation's health' report authored by the UK government's former food policy advisor Henry Dimbleby and public health expert Dr Dolly van Tulleken, states that two-thirds of adults in the UK are living with obesity and excess weight. It says unhealthy diets are now a leading cause of disability, disease and early death which are costing the UK £98 billion a year. So the opportunity to widen access to weight loss treatments to those who can benefit from them is clear. So far, however, while they have been used on the NHS, we believe that the market to date has been largely privately driven by patients self-paying for medication.

The cost of the patented medicines can create affordability challenges for the NHS, so not surprisingly, weight loss treatments – with patients maintained on the medicine for many months – have been limited by prescribers and NHS commissioners. However, the onset of generic competition will likely significantly reduce the price in time, and this means the NHS can afford to treat more patients. It should also mean diabetes patients have greater access to treatments which have been in short supply due to the private demand for weight loss treatment. This is important because in a market that has experienced supply interruptions where demand is not yet clear and could be significantly higher, having a plurality of supply will help deliver more resilience. However, we must consider two key aspects for the full potential of these medicines to be realised. For various reasons, we don't expect these products to initially follow a typical off-patent event and therefore the competition, capacity and savings usually expected may take longer to materialise. Prescribers and payors need to be cognisant of this and enact policy and regulation which helps establish a market which won't be automatically made following patent end.

Secondly, these medicines are not a magic bullet and need to be taken as one element of changes to patients' diets and lifestyles that enable lasting and sustainable impact – changes that the Nourishing Britain report details in full. The whole picture needs to be communicated to patients but there also is a responsibility by providers to ensure adequate ongoing care is in place, as befits any other prescription medicine on which a patient is maintained for a period of time.

Over the next five years, more of these products will face generic competition providing the access and competition which are hallmarks of the UK market. This will ensure they reach more patients than ever before while delivering important savings to the NHS.

If deployed correctly and responsibly, there is also an enormous opportunity to make patients less reliant on healthcare services for other comorbidities which are common for patients being treated for diabetes or obesity.

These are potentially transformative medicines from a public health perspective, but their impact will only be delivered by a well-resourced and fully functioning off-patent market.

Liraglutide market factors and dynamics

> "For clinical and safety reasons, it is right patients should access these treatments via a prescription."

There are a number of specific factors surrounding the genericisation of liraglutide which differentiates it from other loss of exclusivity events. We examine these below.

Education for payors, prescribers, and patients

This is a class of medicines which is hard to compare to other loss of exclusivity events before it. The genericisation of Viagra had some comparative elements, by dint of the treatment's popular appeal leading to a booming private prescription market. But there is not much precedent to learn from. This is across the board for payors, prescribers and patients and it is important that all groups fully understand the benefits and how to realise them for the full public health impact to be deployed. NHS England should take a lead with industry and other partners to create materials and public health messaging which support safe and responsible creation of the market.

Prescription market

For clinical and safety reasons, it is right patients should access these treatments via a prescription. For those prescribed on the NHS because obesity is creating or exacerbating health conditions (such as diabetes, hypertension or high blood pressure, and cardiovascular disease), it will allow prescribers to manage resources ensuring the well-being of patients is prioritised and maintained.

The NHS approach

The NHS has tendered for liraglutide to be supplied once the patent protection has expired. The recent NHS tender showed a

far larger emphasis on procuring for weight loss as opposed to for diabetes. This is positive to see the NHS create demand for generic liraglutide. Understandably, however, the NHS will want to ensure that the capacity exists to meet demand and the supply chain is secure.

Separately, there is a consultation looking at the conditions enabling the phased launch of Mounjaro for its use in weight loss, which to date, has not been prescribed on the NHS[13]. According to NICE's final draft guidance in response to the consultation, "the most likely cost-effectiveness estimate for people with an initial BMI of at least 35kg/m2 and at least 1 weight-related comorbidity are within the range that NICE considers an acceptable use of NHS resources".[14]

The NHS is likely to want to put in place prescriber guidance (which may also be useful for patients to access given the public interest) about which treatments should be considered, for whom and in what order.

UK as a test case

Despite the patent ending earlier in Europe, manufacturers are expected to keep a close eye on how the UK market develops and potentially use the learnings to help launch or establish versions across the continent. Therefore, from a broader health perspective it is important that the UK market is successfully established.

Shortages

One of the advantages of generic competition should be greater supply resilience in the market.

Due to high demand - particularly from a private perspective - shortages of these products has been an issue, specifically for NHS diabetes patients. An analysis of the Specialist Pharmacy Service's Medicines Supply Tool shows that presentations covering Liraglutide (both Saxenda and Victoza) and Semaglutide (Ozempic) have had supply problems over the last year[15]. At the time of writing, Saxenda appears out of stock with many pharmacies.

It is important now that the market is created to ensure a good number of generic manufacturers compete to supply. Patients are typically taking these medicines for long periods of time, and it is critical they can fully access all the medicines they need for the full course of treatment.

Private vs NHS

As we have discussed, there is already a significant private market. The extent of demand, and how much the NHS seek to qualify treatment locally, will dictate what proportion of total need is by private prescription.

13. https://www.nice.org.uk/news/articles/consultation-on-nhs-england-proposals-for-a-phased-launch-of-obesity-injection

14. https://www.nice.org.uk/guidance/GID-TA11156/documents/draft-guidance-2

15. Liraglutide (Saxenda) 6mg/ml solution for injection 3ml pre-filled disposable devices; Liraglutide (Victoza) 6mg/ml solution for injection; Semaglutide (Ozempic) solution for injections.

What the NHS spend data tells us?

From September 2022 to August 2023, IQVIA data show that Saxenda sales for weight loss on the NHS cost around £72m, not including any discounts offered. In the following 12 months, from September 2023 to August 2024, this fell to just £7m. For over a year, Saxenda has been in short supply. Demand may have been fulfilled in this time by Wegovy being made available on the NHS for weight loss treatment. According to IQVIA, Wegovy in this time cost the NHS £61m, not counting any sales discounts.

Based on IQVIA data, Saxenda's NHS Tariff price ranges from £171.35 to £192.61. This will cover a patient for between 6-17 days depending on how much he or she uses. Initially, the 6mg pre-filled pen will cover most of the 17 days, because the patient will be taking a lower dosage as their body acclimatises to the treatment. Over time, the patient can take a higher dosage, meaning a pen lasts for fewer days.

> **"Saxenda is a daily injection, whereas Wegovy is a once weekly injection."**

According to IQVIA, Wegovy costs the NHS £73.25 over the first 4 weeks (starting with the 0.68mg pre-filled pen), rising to £175.80 from week 17 with the 3.2mg pre-filled pen. Based on this, the maintenance cost is likely to be £175.80 every 4 weeks, depending on the final strength that the patient and prescriber settles on.

Saxenda is a daily injection, whereas Wegovy is a once weekly injection.

Noted at the beginning of this document, Wegovy appears to be more expensive for patients on private prescription, whereas Saxenda appears less expensive in the limited number of pharmacies where stock is available.

Separately, IQVIA data show us that Eli Lilly's Mounjaro has got over £54m of reimbursed NHS sales from a standing start over the last 12 months. Note that this has been to treat diabetes, with the NHS consulting upon beginning to use it as a weight loss treatment. Mounjaro is currently sold at between £92-122 to the NHS, depending on strength (between 2.5-15mg). It is a once weekly injection.

This tells us that upon patent expiry, generic liraglutide should become increasingly competitive, as off-patent manufacturers are likely to offer a more competitive price.

Our recommendations

The overall focus of policy when it comes to use of weight loss medicines as more competition is introduced via genericisation must be to deliver what is best for NHS patients and increasing access as well as what is most cost effective for already pressured ICB budgets.

There is an opportunity to deliver increased access for both diabetes patients and those needing to lose weight, but it must be done in a responsible way for a set of medicines which due to market demand and dynamics will not necessarily conform to traditional off-patent models from the off.

We outline four key recommendations for policymakers, payors, and regulators to consider as these medicines become more available. We believe this is a potentially fast-moving area and policy, as well as regulation, should be reviewed and updated on an ongoing basis.

1. Weight loss medicines need to be prescription-based and not available as an over-the-counter product. This should be the case whether they are obtained privately through a high street pharmacy, a solely online pharmacy for example or prescribed via the NHS. We urge those selling the medicines to ensure that patients have regular GP consultations and can report any concerns. Patients could be prescribed these medicines for up to two years.

2. The Government and the NHS need to be clear in their communications with patients that these medicines are to be taken as part of a broader focus on improved diet and increased exercise. The medicines alone will not deliver lasting and sustainable weight loss. For these medicines to deliver not only patient benefits but also reduce the need from the broader healthcare system, the Government should follow Nourishing Britain's recommendations, and education must be put in place to encourage patients to use weight loss medicines as part of other changes to their lifestyles and habits.

3. Unlike traditional off-patent models, it will be hard to predict the levels of demand – particularly initially – from liraglutide. There could be substantial patient interest particularly from the private dispensed market or uptake maybe slower as the necessity to inject daily puts some people off. However, it is important that in any scenario there is adequate numbers of medicines available. With patients likely to be prescribed courses which could last as long as two years, it would be a failure of the market if shortages of supply prevented patients from accessing all the medicines they require. Equally, diabetes patients have for more than a year experienced shortages of NHS prescriptions so it is critical their needs are factored in on top of demand from new areas. We support NHS England's liraglutide tender prior to patent expiry. The delivery of weight loss medicines as an NHS service is likely to create more GP consultations and administration, which will need planning for. We expect the increasing use of these treatments to reduce GP and acute NHS workload and resources in due course.

4. Last, with multiple weight loss treatments likely to be available at different price points, it will be important for the NHS to put in place updated prescriber guidance, following liraglutide's loss of exclusivity. This should set out treatment prioritisation for different patient cohorts and it should ensure that NHS funds are used in a cost-effective way. Currently, local ICBs' weight management service funding is not likely to be near meeting demand. Local consistency around prescribing should be encouraged to reduce postcode lottery issues.

For further information about the BGMA, please get in touch by email jeremy.durrant@britishgenerics.co.uk or visit the website www.britishgenerics.co.uk