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Novo Nordisk Broke UK Rules By 'Disparaging' Rival Eli Lilly

Accused Of 'Cynical' Ploy By Diabetes Competitor

by Andrew McConaghie

The Danish company has once again broken UK industry rules, this time by looking to get the upper hand on its GLP-1 receptor agonist market rival Eli Lilly.

Novo Nordisk has broken the UK industry code of practice once again, having been found to have 'disparaged' its competitor *Eli Lilly* in relation to a shortage of its GLP-1 receptor agonist diabetes medicine Trulicity (dulaglutide).

Novo Nordisk is already suspended from the UK industry association the ABPI for two years, after it was found to have paid pharmacists in 2021 to conduct what was effectively a promotional campaign for weight loss treatment Saxenda (liraglutide injection 3mg) disguised as an educational program. It was recently reprimanded for a similar second incident. (Also see "*Novo Nordisk's Obesity Drug Activities Break UK Rules Again*" - Scrip, 22 May, 2023.)

The new case dates from early 2022 and once again concerns the burgeoning multi-billion dollar GLP-1 receptor agonist (GLP-1 RA) market, which spans both diabetes and obesity treatment, and where Novo Nordisk and Lilly are fierce rivals.

Demand for the drugs is such that both companies are experiencing shortages globally, and in January last year, Lilly alerted England's National Health Service (NHS) that the two higher doses of Trulicity (3mg and 4.5 mg weekly) would not be available at least until April.

Apparently spotting an opportunity, Novo swiftly sent out its own emails, informing healthcare professionals that it had 'no stock-out issues' relating to its own diabetes treatments, Ozempic and Rybelsus (the injectable and oral versions of semaglutide). Local NHS organizations

generally recommended patients switch to lower doses of Trulicity on a temporary basis, but patients were allowed to switch to other treatments, such as those from Novo, if deemed necessary.

Lilly responded to Novo's emails by raising a complaint with the Prescription Medicines Code of Practice Authority (PMCPA), accusing its rival of a "cynical attempt to take commercial advantage" of the stock outage, with the "disguised goal of switching patients" from Trulicity higher doses to Ozempic or Rybelsus.

The PMCPA issued its ruling on 1 June, finding that the wording and tone of Novo Nordisk's emails implied that maintaining supplies of medicines was viewed as a priority for it but not for Lilly. Consequently, it ruled that Novo had disparaged its competitor, a breach of Clause 6.6.

This was based on the email passages which stated: 'Novo Nordisk's priority is maintaining supply of treatment to support adults living with type 2 diabetes' followed by 'We can reassure you as an HCP, that we have supply available of all doses of both Ozempic and Rybelsus, should you be seeking a GLP-1 RA to prescribe for adults with type 2 diabetes at this time', which directly followed reference to Lilly's supply issues.

Escaped More Serious Censure

Lilly also accused Novo of a number of other misdeeds. These included allegedly misleading healthcare professionals regarding Department of Health and Social Care (DHSC) guidance to Novo about the duration of Lilly's supply issues, and of not making clear that switching to a Novo Nordisk GLP-1 RA was not the DHSC's preferred option,but these and other allegations were dismissed by the watchdog.

That meant Novo was not found in breach of two of the most important rules: Clause 2, the requirement that activities or material must not bring discredit upon, or reduce confidence in, the pharmaceutical industry; and Clause 5.1, requirement to maintain high standards.

The dismissal of those claims will be cause for relief at Novo Nordisk UK, which is currently under audit by the ABPI, a condition attached to its suspension. Any further lapses in corporate governance could see stronger punishment, including expulsion from the association, although the ABPI cannot impose fines or marketing restrictions on firms.

Asked to comment, Novo Nordisk UK said the latest case pre-dated its suspension from the ABPI announced in March this year. It added that it was continuing to strengthen its compliance framework in the UK, including a review of its processes, and remained committed to following the ABPI Code of Practice.

Rivalry Will Only Ramp Up

Regardless of Lilly's victory in the case, the rivalry between the firms is likely to intensify in the UK and worldwide, as they compete to serve fast-growing demand for the products in diabetes and obesity.

For now, Novo Nordisk is on top, as its share of the global GLP-1 RA market in diabetes rose to nearly 55% in 2022, up by more than 2% in two years. Its dominance is based on sales of Rybelsus, Ozempic and older drug Victoza (liraglutide) which rose by 42% last year to DKK 83bn ($11bn), while Lilly's Trulicity trailed somewhat on $7.43bn, up by 15% in the same period.

However, Lilly's new Mounjaro (a GLP-1 and GIP dual agonist) has shown best-in-class glycemic control and weight loss, and has broken records since its US launch in diabetes just over 12 months ago. Its anticipated US Food and Drug Administration approval in obesity later this year will pit it directly against Novo's Wegovy (also semaglutide). (Also see "*Lilly's Mounjaro Shows Strong Sales And Data As Firm Eyes Obesity Market*" - Scrip, 27 Apr, 2023.)

Wegovy is already licensed and recommended by the UK's cost effectiveness watchdog the National Institute for Health and Care Excellence (NICE). However Wegovy has not been launched in the UK because of its own struggles to raise manufacturing output to meet demand, which have also created shortages for existing diabetes patients.

Lilly declined to comment on the PMPCA ruling. It did confirm, however, that it was currently seeking regulatory approval and NICE approval for Mounjaro in the UK.

The UK government has just announced a pilot scheme aimed at making access to obesity treatments easier on the NHS to eligible patients, although Saxenda is the only GLP-1 RA treatment currently available.

This article was updated on 8 June to include a response from Novo Nordisk UK.