COMPLAINANT v NAPP

Asthma review service

A complaint was received about the activities of Napp Pharmaceuticals in relation to its asthma review service.

Napp's product Flutiform (fluticasone and formoterol) was indicated in the regular treatment of asthma where use of combination product (an inhaled corticosteroid (ICS) and a long-acting beta 2 agonist (LABA)) was appropriate.

The complainant was concerned about the conflict of interest in the offering of pharmacists for asthma/ diabetes reviews for quality outcome framework (QOF). The complainant alleged that he/she had heard from a number of customers that companies such as Napp doing this favoured its products and put patients on these without taking into consideration the preferences of the nurses or patients. In one particular case, a nurse noted that the Napp pharmacist had moved the majority of her patients on to Flutiform and the patients were not happy.

The detailed response from Napp appears below.

The Panel noted that therapy review services were permitted and their acceptability as far as the Code was concerned depended on a number of factors including the arrangements, how and to whom the service was offered.

The Panel noted Napp's submission that whilst it funded the pharmacist-led service, the choice of therapy remained the decision of the GP, and offering of the service was not conditional on the prescribing of any Napp product.

The Panel noted that there were a number of ICS/ LABA combinations on the market. The Panel had some concerns about how the services were offered and whether all the features of the services amounted to a clinical assessment of patients. With regard to the complainant's view that a 'Napp pharmacist' had moved the majority of patients to Napp's product Flutiform without taking into consideration the preferences of the nurses or patients, the Panel noted that it was not necessarily a breach of the Code not to take into account the nurses or patients preferences if the GP or other prescriber considered otherwise. The Panel noted that the complainant bore the burden of proof and had provided no evidence to support his/her allegation. The Panel therefore ruled no breaches of the Code based on the narrow allegation including Clause 2.

A complaint was received about views of asthma patients referring to the activities of Napp Pharmaceuticals Limited.

Napp's product Flutiform (fluticasone and formoterol) was indicated in the regular treatment of asthma where the use of combination product (an inhaled corticosteroid (ICS) and a long-acting beta 2 agonist (LABA)) was appropriate.

COMPLAINT

The complainant stated that he/she wanted to raise concerns for the conflict of interest going on currently in the pharmaceutical industry – specifically in the offering of pharmacists in practice to aid with asthma/diabetes reviews for quality outcome framework (QOF). Whilst this used to be a practice happily provided by the pharmaceutical industry, the complainant alleged it now presented a significant conflict of interest with the companies putting patients on to their products. The complainant stated he/she had heard from a number of customers that companies such as Napp doing this favoured Napp products and put patients on these, and did not take in to consideration the preferences of the nurses or patients. In one particular case, a nurse noted that the Napp pharmacist had moved the majority of her patients on to Flutiform and the patients were not happy.

The complainant queried how this practice was allowed in the industry? If all were being held accountable for their actions, surely this was a conflict of interest?

In writing to Napp attention was drawn to the requirements of Clauses 2, 9.1, and 19.2 of the Code.

RESPONSE

Napp submitted that it took the Code very seriously and conducted its business in a responsible, ethical and professional manner at all times. Napp submitted that its pharmacist led asthma therapy review service was entirely consistent with Clause 19 of the Code. The reviews were not switch services and importantly it had received two previous complaints about the conduct of the therapy review services, neither of which were upheld by the Panel – Case AUTH/2808/12/15 and Case AUTH/2956/5/17.

Napp contracted three third-party providers of therapy review services and details were provided. The reason why Napp had two pharmacist-led services and a nurse-led service was as a result of health professional feedback that some GP practices preferred a therapy review to be undertaken by nurses whilst others preferred this to be led by a pharmacist. The Napp asthma therapy review services were both designed, organised and conducted in the same way, differing only by the use of either pharmacists or nurses to deliver the service.

Napp absolutely refuted that its therapy review services constituted a medicine switch as it was not conducting the reviews to put patients on Napp products as suggested by the complainant. The majority of the patient reviews did not result in a new medicine being prescribed. Instead the patient had a structured review, including the following:

- asthma assessment
- taught optimal asthma inhaler technique
- clinical examination, or their existing inhaler dose optimised
- compliance/education on non-adherence
- stop existing medicine
- lifestyle advice (triggers etc).

Clause 19 medical and educational goods and services (MEGS) clearly explained that a therapeutic review 'is a legitimate activity for a pharmaceutical company to support and/or assist'. Thus, the complainant was incorrect that this was a 'conflict of interest'. Napp was not involved in the reviews either directly or indirectly and did not stipulate that its product should be recommended. The briefing documents for the service providers stated:

> 'pharmacists will only implement therapeutic review services and will not:
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> - Recommend a specific pharmaceutical product
> - Write prescriptions
> - Recommend or take any action that does not comply with the practice treatment protocol.'

Napp submitted that whilst it funded the service, therapy choice arising from the patient clinical review process remained the decision of the GP, and offering of the service was not conditional on the prescribing of any Napp product.

The comprehensive reviews were not primarily conducted for QOF. Rather they were primarily to enhance patient care and benefit the NHS. The reviews ensured that patients were receiving optimal treatment, both non-medicinal and/or medicinal. This was made clear in the certified protocols, briefing documents and training materials.

With regard to the complainant's view that 'I have heard from a number of my customers that companies such as Napp doing this favour Napp products and put patients on these, and do not take in to consideration the nurses preference or the patients', Napp submitted that the complainant was correct that several pharmaceutical companies provided asthma therapy review services to the NHS. The pharmacists were employed by Napp's providers, so were not 'Napp pharmacists'. The complainant did not make it clear who specifically were his/her 'customers', were they GP practices, doctors, nurses or other? A therapy review service could not favour any medicine (ie a Napp product) and the prescribing decision remained clearly with the patient's prescriber, which was usually a GP, or could be a qualified nurse-prescriber. The protocol documents made this clear, and were aligned to Clause 19. The protocol stated '… pharmacists do not suggest and will not implement switch services which simply change a patient from one medication to another without a full clinical assessment'.

Napp submitted that the service model (details provided) clearly indicated that all decisions and signatures were made by the lead GP:

The introduction to the service stated:

> 'The clinician responsible for the care of his/her patients retains full control over the entire process. NAPP supports this non-promotional service in full accordance with the ABPI Code of Practice for the Pharmaceutical Industry. The arrangements for a therapy review must enhance patient care, or benefit the NHS and maintain patient care.
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> Whilst the service is funded and organised on behalf of Napp Pharmaceuticals Limited, therapy choice arising from the patient review process remains the choice and sole decision of the lead GP, and offering of the service will not be conditional on the prescribing of any Napp products or services.'

The service model for the second service provider (details provided) highlighted that the GP decided on any patient interventions:

The introduction to the service stated:

> '… pharmacists will only engage in the provision of services which enhance patient care or benefit the NHS and maintain patient care. Whilst the service is funded and organised on behalf of Napp Pharmaceuticals, therapy choice arising from the patient review process remains the choice and sole decision of the GP, and offering of the service will not be conditional on the prescribing of any Napp products or services.'

Therefore, Napp submitted it was clear that a 'Napp pharmacist' (they were employees of Napp's third party providers, and not Napp) could not make a prescribing decision (as clearly stated in the therapy review protocols) and so could not, as the complainant suggested, move the 'majority of her patients on to flutiform'. The 'one particular case' was not supported by any evidence as part of the allegation and Napp was unable to comment further unless more detail was provided. This practice was clearly not allowed in the pharmaceutical industry as it would be against Clause 19, and by association would not maintain high standards (Clause 9.1), and ultimately bring the industry into disrepute (Clause 2). Napp again refuted that it had conducted a switch programme disguised as a therapy review service.

Napp had received confirmation from both providers that they had received no complaints from any practices or patients about a change to their medicine following an asthma therapy review.

Napp provided details of the pharmacist-led asthma therapy review services.

There were 11 certified documents (through ZINC) detailing the asthma therapy review service by one provider on behalf of Napp. There were 10 certified documents (through ZINC) detailing the asthma therapy review service by the other provider.

The pharmacist-led asthma therapy review services were offered to GP practices which were selected based upon clear criteria, (identical for both providers).

Practice selection criteria

In order to deliver the maximum patient and practice benefit the following practices may benefit most from the service:

1. Practices in high areas of asthma prevalence or where high levels of variation in care exist in comparison to other CCGs/practices within their own locality.
2. Practices lacking a trained respiratory nurse specialist.
3. Practices requiring additional resource to effectively review their asthma population.'

Napp submitted that as its therapy review service was not a switch programme, it did not therefore collect data on the 'proportion of patients at each practice who have been switched to flutiform/other Napp products'.

Details of when the service commenced and the number of practices were provided.

Napp did not monitor any uplift in sales in areas where the therapy review services had been conducted. Neither were representatives' bonuses based on this service to the NHS. The company did not include any planned or future asthma therapeutic reviews in the calculations used to determine the sales targets, did not incentivise staff based on these reviews and no individual sales person's target was affected by the asthma reviews. A respiratory senior scientific advisor oversaw the service as this was a non-promotional role within the Napp medical department and he/she had regular contact with the service provider, along with provision of a management report to discuss any operational issues. The report was discussed within Napp's medical and code compliance department which allowed the company to ensure that the service providers were offering the service in accordance to the provision of MEGS as set out in Clause 19.2.

The briefing document specified the dos and don'ts for account managers in terms of non-promotional vs promotional calls as represented by a flow diagram. The Q&A section of this document specified that once a therapeutic review was in progress in a practice, account managers were not allowed to discuss the asthma review service with any of the health professionals in that practice. It also detailed the requirements of the therapeutic review service in accordance with the Code.

Napp account business managers (ABMs) and healthcare development managers (HDMs) were the only people allowed to discuss the therapeutic review service in detail in a non-promotional call once a practice had expressed interest following the brief introduction.

The ABMS and HDMs were all trained face to face according to the detailed information in the training slides including a specific briefing document for the ABMs/HDMs which included:

> 'You may introduce the service by giving a brief description of the service during the promotional call but may not instigate a detailed description about the service at the same time as a call when products are being promoted, this should be done in a non-promotional call.
>
> **You should ensure the following is adhered to:**
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> - Napp support of this review must **NOT** be dependent on the customer prescribing a Napp product. This must be neither the fact in practice nor the impression given either verbally or in any documents connected with the project, internal or external
> - The prescribing of specific products must **NOT** be linked to the service either in conversation, or in writing, with any customer
> - Detailed discussion about the service must **NOT** be initiated at the same time as a call at which products are promoted.'

In addition, following the comprehensive training, the ABMs/HDMs received a validation test before any introduction of this service to practices and they had to score 100%.

Napp submitted that the service providers' pharmacists were all trained in asthma management and associated national asthma guidelines. The pharmacists were given a comprehensive briefing document on the conduct of the asthma therapy reviews, including compliance and pharmacovigilance.

All pharmacists involved in the therapy review delivery were qualified, registered, members of the relevant governing body (the General Pharmaceutical Council (GPhC) for England, Scotland and Wales and the Pharmaceutical Society of Northern Ireland (PSNI) and as such bound by their own standards of conduct, ethics and performance. The standards helped to ensure patients using pharmacy services received safe and effective care.

In conclusion, Napp strongly refuted all allegations about the provision of a pharmacist-led asthma therapy review service as a 'conflict of interest'. It submitted that it had provided comprehensive evidence that it had robust and compliant processes and training to implement a genuine high quality non-promotional therapeutic review service via its third party suppliers. Two previous Napp cases had been scrutinised and no breaches of the Code were ruled in relation to the nurse-led (Case AUTH/2808/12/15) or pharmacist-led (Case AUTH/2956/5/17) services. Integral to this non-promotional service to the NHS, the company submitted it had continued to pay particular focus on Clauses 19.1 and 19.2. It had continued to