

# ANONYMOUS v GENUS

## Role of nurse advisors

An anonymous and non-contactable complainant provided a copy of a journal advertisement for APO-go (apomorphine hydrochloride) issued by Genus. The complainant had highlighted the claim 'Pd [Parkinson's disease] specialist Nurse Advisors in APO-go (NAAs)' and alleged that this implied that the support offered by Genus was a team of Parkinson's disease specialist nurses which was not so. The majority of this team were undoubtedly APO-go nurse advisors but they were not Parkinson's disease nurse specialists and this terminology was wholly misleading.

The complainant noted from experience that team members frequently referred to their role as that of a Parkinson's disease nurse specialist. This was inappropriate, misleading and could confuse patients. That some of the team also changed patients' medicines – other than apomorphine – was a total scandal. Documentation from this team was scant and seldom appeared in patients' notes, communication was poor and overall the behaviour of this group created significant risk for patients.

The complainant requested that the Authority ensured that these nurses stopped referring to themselves as 'Parkinson's disease specialist nurse advisors'. The complainant also asked the Authority to review their business cards.

The detailed response from Genus is given below.

The Panel noted that the advertisement referred to 'Pd [Parkinson's disease] specialist Nurse Advisors in APO-GO (NAAs) – dedicated Pd trained nurse support'. The nurses fulfilling that role had various levels of expertise and experience with regard to Parkinson's disease from four who were NHS Parkinson's disease nurse specialists (PDNSs) to one who was a lead nurse in the blood service with a parent who had Parkinson's disease. Some already had, and others were working towards, the diploma in Parkinson's disease. Given that a PDNS was a recognised qualification and role in the NHS the Panel considered that it was misleading to refer to the APO-go nurse advisor team as Parkinson's disease specialist nurse advisors. Some readers might assume, not unreasonably, that all of the nurse advisors were PDNSs which was not so. The advertisement was misleading in that regard and the Panel ruled a breach of the Code. The Panel noted the submission from Genus that 'specialist' had only been used in the advertisement and that it would stop using that term when referring to the nurse team. In that regard the Panel noted that the business cards referred to 'Nurse Advisor in APO-go Therapy'.

The Panel noted that the business cards were headed with the product name, APO-go followed by 'Senior nurse advisor in APO-go therapy' or 'Nurse advisor in APO-go therapy' followed by the relevant name and contact details and the web address details. The reverse side included details of the APO-go helpline, an out-of-hours telephone number and the company name, address and contact details. The Panel did not consider that the business cards were misleading as to the status of the nurse advisors. No breach of the Code was ruled.

The Summary of Services booklet stated that the programme was non promotional and offered as a service to medicine. The Panel was unsure what was meant by the use of the term 'non promotional'. The service was linked to the use of APO-go such that the Panel considered that it was, in effect, offered as a package deal. The Panel noted that the Code did not prevent the offer of package deals. The Panel considered that there was no information before it to suggest that the package of care offered by Genus was a gift, benefit in kind or a pecuniary advantage given or offered to a health professional as an inducement to prescribe, supply, administer, recommend, buy or sell APO-go. No breach of the Code was ruled.

Given that the service offered by Genus bore the name of APO-go and was inextricably linked with the product, it could not be considered to be a medical or educational good or service and thus no breach was ruled in that regard.

The Panel noted that the Summary of Services booklet detailed the nurse support programme. The double page centre spread referred, *inter alia*, to the Parkinson disease guidelines issued by NICE. Extracts from those guidelines were quoted in the booklet and referred to PDNSs and the essential skills of a PDNS. The booklet stated that the initiation of apomorphine should be restricted to expert units with the availability of a home monitoring system by a suitably trained health professional such as a PDNS. Under the heading 'Nurse Advisor in APO-go' it was stated that in order to assist the NHS to implement the NICE guidelines, Genus had established a network of nurse advisors to assist in various aspects of APO-go therapy. The stated skill set of a PDNS was referred to. In the Panel's view it was not unreasonable that some readers might assume that all of the nurse advisors provided by Genus were PDNSs which was not so. Under the same heading, a bulletin from the Royal College of Nurses entitled 'Specialist Nurses "targeted" to cut costs' was referred to which strengthened the impression that

**the nurse advisors in APO-go were specialist nurses ie PDNSs. The Panel considered that the booklet was not sufficiently clear with regard to the qualifications and status of the APO-go nurse advisors and a breach of the Code was ruled.**

**The Panel noted its rulings above and considered that high standards had not been maintained. A breach of the Code was ruled. The Panel, however, did not consider that the matter was such as to bring discredit upon or reduce confidence in the pharmaceutical industry. No breach of Clause 2 was ruled.**

An anonymous and non-contactable complainant provided a copy of a journal advertisement (ref APG.API.V11) for APO-go (apomorphine hydrochloride) issued by Genus Pharmaceuticals Ltd. The complainant had highlighted the claim 'Pd [Parkinson's disease] specialist Nurse Advisors in APO-go (NAAs)'.

## **COMPLAINT**

The complainant stated that the advertisement implied that the support offered by Genus was a team of Parkinson's disease specialist nurses and this was not the case. The majority of this team were undoubtedly APO-go nurse advisors but they were not Parkinson's disease nurse specialists and this terminology was wholly misleading.

The complainant noted from experience that this impression was further reinforced by their behaviour 'in the field' where this team frequently referred to their role as that of a Parkinson's disease nurse specialist. This was inappropriate, misleading and could confuse patients. That some of the team also changed patients' medicines – other than apomorphine – was a total scandal. Documentation from this team was scant and seldom appeared in patients' notes, communication was poor and overall the behaviour of this group created significant risk for patients.

The complainant requested that the Authority ensured that these nurses stopped referring to themselves as 'Parkinson's disease specialist nurse advisors'. The complainant also asked the Authority to review their business cards.

When writing to Genus, the Authority asked it to respond in relation to Clauses 2, 7.2, 9.1, 18.1 and 18.4 of the Code.

## **RESPONSE**

Genus explained that APO-go was administered subcutaneously either as an intermittent injection, using a pen device, which was useful for patients on oral therapies, who needed to boost their medicine when they experienced 'wearing-off' or 'off' periods (as they were referred to by health professionals) or by continuous infusion administered via the APO-go pump device. The latter method of administration was suitable for more complex (and usually later

stage) Parkinson's patients. Both regimes required the patients to receive a 'challenge' which identified that they were suitable to receive APO-go, determined their response in terms of efficacy and allowed dose titration. The challenge in the majority of cases required the patient to go into hospital, either as a day-case or longer for more complex cases, which in itself caused issues in terms of availability of beds and medical staff qualified to administer the challenge. There could often be a delay of several months before patients received an effective treatment, during which time their condition might deteriorate significantly.

The package of care that Genus offered, once it had been decided to treat appropriate patients with APO-go, was for the sole purpose of improving the quality of healthcare provided to patients with complex Parkinson's disease and who were going to receive APO-go. Through the advertisement, Genus offered a number of support services within the package of care to help health professionals deliver the highest quality of care to patients with complex Parkinson's disease, but only after it had been decided to use APO-go in the management of their disease.

Genus submitted that this aligned perfectly with the government's drive to improve patient choice and patient experience and become a part of the decision making process about their treatment. The package of care and in particular the nurse advisors team also helped to deliver quality of care when patients had been discharged which again fitted perfectly with the 30 day post discharge responsibility that now fell to secondary care trusts. Patients were fully involved in the decision to use the nurse advisors in APO-go at the outset of their treatment. The nurse advisor input would not proceed without the patient's agreement. As such the patients were part of the decision making process, which aligned very closely with the White Paper 'Equity and Excellence, Liberating the NHS'.

The registered nurses employed to work with health professionals and patients had strong backgrounds in neurology. Four were NHS Parkinson's disease nurse specialists, three worked in neurology alongside patients with Parkinson's disease and were involved in APO-go therapy management, two were multiple sclerosis nurse advisors, and one a lead nurse in the blood service with a parent who had Parkinson's disease. All had, or were working towards, the diploma in Parkinson's disease. All provided Parkinson's disease teaching, education and mentorship for NHS staff and some taught on the junior doctor training schemes with national coverage.

The nurses had all undergone a comprehensive and intensive training programme when they joined the company on all aspects of APO-go and the management of patients with Parkinson's disease. In addition to the experience and training each nurse worked within the constraints of an honorary contract which had to be approved by the trust

personnel department and the appropriate consultants. It could not be approved by any other person including specialist Parkinson's disease nurse specialists. A copy of the honorary contract was provided.

In support of the excellent work done over the last two years, Genus provided several testimonials to demonstrate the high degree of value that health professionals placed on the package of care but in particular on the support nurse advisors delivered to patients and the NHS. Genus also provided an example of their business cards and name badges as there was a suggestion within the complaint that these were also misleading.

In conclusion, Genus considered that the nurse advisor team was highly experienced and effective in supporting patients who were receiving APO-go treatment. Their sole aim was to improve the quality of care that APO-go patients received and to assist the NHS and health professionals to deliver, in a timely fashion, the best possible quality of care for patients. Given their level of experience, qualifications and training it was fair to describe them as Parkinson's disease specialist nurse advisors in APO-go as the emphasis was on being specialists in APO-go not Parkinson's disease in general. However, in order to avoid any ambiguity, Genus had withdrawn any reference to 'specialist' when referring to the nurse team. In fact the only reference made to 'specialist' was in the advertisement. This had now been withdrawn. There was never any intent to mislead or deceive.

With regard to the allegation that some of the nurses changed patients' medicines – other than apomorphine, Genus submitted that the team provided medical support relating to the use of APO-go therapy under the auspices of an honorary contract, issued/signed by trust personnel ie consultant and personnel department (a Parkinson's disease nurse specialist signature was not acceptable). Medicines were changed upon instruction only. A nurse advisor would never work independently without the instruction of the lead consultant. However APO-go therapy might be discontinued if this was deemed best for the patient. The emphasis was on optimal/best practice therapy for each individual patient, which might no longer include treatment with APO-go. The patient was always consulted and contributed to the process, the nurse acted as the patient's advocate, and the patient was Genus' primary concern.

On every occasion and in every circumstance, the nurse advisors adhered to the Nursing and Midwifery Council code of conduct and fulfilled their duty of care to the patient.

Genus therefore concluded that the provision of its nurse advisors could not bring discredit to or reduce confidence in, the industry (Clause 2). Conversely, Genus had invested a great deal of time in developing a package of care that greatly enhanced the provision of service and quality of

care the NHS delivered to its Parkinson's disease patients and was an excellent example of the industry and the NHS working in partnership to deliver the highest level of service possible to its patients. This was in line with the aims and ambitions set out in the White Paper 'Equity and Excellence, Liberating the NHS' and very much about quality outcomes and the patient experience.

As demonstrated above, the nurse advisor team was very experienced, well qualified and received a high degree of training on a continuous basis about the therapy area and APO-go. The matter in question depended on the definition of 'specialist'. One such definition would be a medical practitioner who devoted attention to a particular class of diseases or patients. Using this definition Genus considered that the term Parkinson's disease specialist nurse advisor in APO-go was justified, taking account of their role, experience, training and qualifications as outlined above. However as mentioned above, the term 'specialist' had only appeared in the advertisement and did not appear on business cards or name badges. Genus therefore denied a breach of Clause 7.2.

The aim of the advertisement had been to inform health professionals of the new 'APO-go homecare delivery' service that had been added to the package of care support from Genus. The aim was to improve the convenience for patients with complex Parkinson's disease, many of whom found walking to the local pharmacy quite difficult and inconvenient. The service, which included regular telephone calls to check patients' medicine supply, helped monitor adherence and avoid stock piling (a significant cost to the NHS) and arranged the efficient and effective disposal of sharps boxes. Genus believed the advertisement was informative and accurate and of a high quality and standard; it denied a breach of Clause 9.1.

The package of care was designed to assist and support patients who had been identified as suitable for treatment with APO-go due to the efficacy of their oral medicine failing. This positioning was supported and recommended by the National Institute for health and Clinical Excellence (NICE), as per its guidelines of 2006. This decision was made purely on the basis of the patient's condition and the advancing nature of the disease. There was no benefit in kind to any health professional directly and therefore there was no inducement to prescribe APO-go. The benefits were totally focused on the patients with regards to the nurse advisor's support, 24/7 helpline, educational support and assistance with the dedicated infusion pump and all necessary peripherals. As a 'package of care' Genus did not believe this was a 'good and service' as usually interpreted within the Code. Genus therefore strongly believed that there had been no breach of Clause 18.1.

Genus believed that the nurse advisors were an integral part of the package of care offered by Genus to support patients who had been identified

as being suitable to receive APO-go therapy. As such Genus did not believe they should be classed as a 'service or goods' as defined within Clause 18.4. With reference to the educational element of the package of care offered to patients, this was a support that was offered to patients who were already receiving APO-go for their Parkinson's disease, and was specific to the disease area and the role of APO-go in their treatment. Genus thus denied a breach of Clause 18.4.

In response to a request for further information Genus outlined the process by which the nurse advisors would get involved in changing a patient's medication:

- The patient, responsible clinician and trust agreed to use the services of the nurse advisor as demonstrated by a signed patient consent form, programme agreement and honorary contract.
- Only when the patient had been identified and/or started on APO-go therapy was the service of the nurse advisor initiated with a referral form (and often telephone call in addition). At no point was the nurse advisor involved in the recruitment of patients by any means whatsoever.
- The nurse advisor would work with the doctor and/or specialist nurse in an educational capacity to learn about and identify the nature of the parkinsonian symptoms specific to the patient in relation to APO-go therapy. Inevitably, the patient was reviewed as a 'whole' and this included, but was not limited to, other possible medicines, social activities, diet and sleep etc.
- If a change in medicine was indicated and the doctor or Parkinson's disease nurse specialist were unable to make the changes personally eg when the patient was at home with no access to primary care Parkinson's disease services, the following steps would be taken:
  - The nurse advisor would visit the patient – as agreed in consultation with relevant health professionals.
  - Conduct a clinical assessment using accepted Parkinson's disease documentation, such as the Unified Parkinson's Disease Rating Scale Part III.
  - Speak to the doctor and/or nurse and complete nursing notes about the patient's condition.
  - The doctor/Parkinson's disease nurse specialist would instruct the nurse advisor to make the relevant changes, taking into account the patient's condition.
  - This was recorded in the nursing/patient notes and shared with all NHS health professionals.
  - The nurse advisor would conduct the follow up visits as agreed by the relevant health professional to ensure the changes had not caused any untoward effect and the anticipated benefit was realised. Each visit was recorded and the record sent back to the responsible health professional immediately.

- The only change that the nurse advisor would initiate without prior consultation was if an emergency arose, eg if the patient experienced severely low blood pressure, whereupon the APO-go infusion was stopped, patient's safety stabilised, emergency services called if necessary, and the responsible NHS health professional contacted immediately.
- At all times the patient was consulted and included in the care plan and could ask the nurse advisor to leave at any time.

## PANEL RULING

The Panel noted that the complainant had commented in general about the role of the APO-go nurse advisor team but had requested that 'for the moment' the Authority ensure that the nurses stop referring to themselves as 'Parkinson disease specialist nurse advisors'. The Panel noted that the advertisement at issue referred to 'Pd [Parkinson's disease] specialist Nurse Advisors in APO-GO (NAAs) – dedicated Pd trained nurse support'. The nurses fulfilling that role had various levels of expertise and experience with regard to Parkinson's disease from four who were NHS Parkinson's disease nurse specialists (PDNSs) to one who was a lead nurse in the blood service with a parent who had Parkinson's disease. Some already had, and others were working towards, the diploma in Parkinson's disease. Given that a PDNS was a recognised qualification and role in the NHS the Panel considered that it was misleading to refer to the APO-go nurse advisor team as Parkinson's disease specialist nurse advisors. Some readers might assume, not unreasonably, that all of the nurse advisors were PDNSs which was not so. The advertisement was misleading in that regard and the Panel ruled a breach of Clause 7.2. The Panel noted the submission from Genus that 'specialist' had only been used in the advertisement and that it would stop using that term when referring to the nurse team. In that regard the Panel noted that the business cards referred to 'Nurse Advisor in APO-go Therapy'.

The Panel noted that the business cards were headed with the product name, APO-go followed by 'Senior nurse advisor in APO-go therapy' or 'Nurse advisor in APO-go therapy' followed by the relevant name and contact details and the web address details. The reverse side included details of the APO-go helpline, an out-of-hours telephone number and the company name, address and contact details. The Panel did not consider that the business cards were misleading as to the status of the nurse advisors. No breach of Clause 7.2 was ruled.

The Summary of Services booklet stated that the programme was non promotional and offered as a service to medicine. The Panel was unsure what was meant by the use of the term 'non promotional'. The service was linked to the use of APO-go such that the Panel considered that it was, in effect, offered as a package deal. The Panel noted

that Clause 18.1 did not prevent the offer of package deals whereby the purchaser of particular medicines received with them other associated benefits provided that the transaction as a whole was fair and reasonable and the associated benefits were relevant to the medicines involved. The Panel considered that there was no information before it to suggest that the package of care offered by Genus was a gift, benefit in kind or a pecuniary advantage given or offered to a health professional as an inducement to prescribe, supply, administer, recommend, buy or sell APO-go. No breach of Clause 18.1 was ruled.

Clause 18.4 related to the provision of medical and educational goods and services. The supplementary information to that clause stated that the goods or service must not bear the name of any medicine. Given that the service offered by Genus bore the name of APO-go and was inextricably linked with the product, it could not be considered to be a medical or educational good or service. It was not covered by Clause 18.4 and thus no breach of Clause 18.4 was ruled.

The Panel noted that the Summary of Services booklet detailed the nurse support programme. The double page centre spread headed 'Background' referred, *inter alia*, to the Parkinson disease guidelines issued by NICE. Extracts from those guidelines were quoted in the booklet and referred to PDNSs and the essential skills of a PDNS. The booklet stated that the initiation of apomorphine should be restricted to expert units with the

availability of a home monitoring system by a suitably trained health professional such as a PDNS. Under the heading 'Nurse Advisor in APO-go' it was stated that in order to assist the NHS to implement the NICE guidelines, Genus had established a network of nurse advisors to assist in various aspects of APO-go therapy. The stated skill set of a PDNS was referred to. In the Panel's view it was not unreasonable that some readers might assume that all of the nurse advisors provided by Genus were PDNSs which was not so. Under the same heading, a bulletin from the Royal College of Nurses entitled 'Specialist Nurses "targeted" to cut costs' was referred to which strengthened the impression that the nurse advisors in APO-go were specialist nurses ie PDNSs. The Panel considered that the booklet was not sufficiently clear with regard to the qualifications and status of the APO-go nurse advisors. The Panel ruled a breach of Clause 7.2.

The Panel noted its rulings above and considered that high standards had not been maintained. A breach of Clause 9.1 was ruled. The Panel, however, did not consider that the matter was such as to bring discredit upon or reduce confidence in the pharmaceutical industry. No breach of Clause 2 was ruled.

**Complaint received**                      **22 September 2010**

**Case completed**                              **26 January 2011**

---