ANONYMOUS v GENUS

Conduct of Apo-go nurse advisor

An anonymous, uncontactable 'concerned pharmacist' complained about the conduct of a local Apo-go (apomorphine hydrochloride) nurse advisor employed by Genus Pharmaceuticals to advise patients about their medicines for Parkinson's disease.

The complainant noted that within the local area there were two extremely good and capable Parkinson's Disease Nurse Specialists (PDNSs) who managed patients with Parkinson's disease. The Apo-go nurse advisor's role was to educate professionals and patients about the use of apomorphine in Parkinson's disease and to support the PDNS with people using apomorphine. It was the role of the consultant and PDNS to advise patients about the dose of all medicines used in Parkinson's disease, including apomorphine.

The complainant was concerned that the Apo-go nurse advisor in question, who was previously a local PDNS, continued to change oral Parkinson's disease medicines and increase the dose of apomorphine. The nurse advisor was not a nurse prescriber and so should not have altered any medicines. She did not tell nurses what she had done, eg how a patient responded to apomorphine. The complainant alleged that, left to her own devices, the nurse advisor posed an immense risk to patients as the clinicians involved did not know why any changes to treatment had been made.

The detailed response from Genus is given below.

The Panel noted that the introduction to the PMCPA Constitution and Procedure stated that it was for the complainant to prove their complaint on the balance of probabilities. Anonymous complaints were accepted and, like all complaints, judged on the evidence provided by the parties.

The Panel noted that the nurse support programme offered by Genus was linked to the use of Apo-go such that the Panel considered that it was, in effect, a package deal as set out in the relevant supplementary information. The Panel noted that in accordance with the terms of the programme agreement, the nurse advisor would provide, *inter alia*, education, audit, clinical support and development, mentorship and patient support. The Panel considered that on the evidence before it the arrangements constituted a *bona fide* package deal and did not constitute 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 contrary to the Code and no breach was thus 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 a medical or educational good or service. The Panel noted its finding above that the arrangements constituted a *bona fide* package deal. It was not covered by the requirements in relation to a medical and educational good or service and thus no breach of the Code was ruled.

The Panel noted that the Nurse Support Programme Agreement provided that the lead consultant retained clinical responsibility for the patient and the PDNS remained the nursing lead in patient management. The Panel noted that this was reflected in the evidence submitted by Genus; anonymized patient notes indicated that the nurse advisor in question consulted the local consultant neurologist before she altered this particular patient's medication, and any change made was documented. The Panel also noted that the consultant neurologist's testimonial, submitted by Genus, stated that the Apo-go nurse advisor had 'without exception consulted me whenever a patient of mine has required any alteration of prescription (Apomorphine or any other aspect of treatment)'.

The complainant had submitted no evidence to support his/her serious complaint about the conduct of a fellow health professional. Evidence submitted by Genus showed that the nurse advisor was well respected by her colleagues. Thus, on the basis of the evidence before it the Panel considered that the nurse advisor had not failed to maintain high standards, and no breach of the Code was ruled. The Panel thus ruled no breach of Clause 2.

An anonymous, uncontactable complainant who described him/herself as a 'concerned pharmacist' complained about the conduct of a local Apo-go (apomorphine hydrochloride) nurse advisor employed by Genus Pharmaceuticals Ltd to advise patients about their medicines for Parkinson's disease.

Apo-go was indicated for the treatment of disabling motor fluctuations ('on-off' phenomena) in patients with Parkinson's disease which persisted despite individually titrated treatment with levodopa (with a peripheral decarboxylase inhibitor) and/or other dopamine agonists.

COMPLAINT

The complainant noted that within the local area there were two extremely good and capable Parkinson's disease nurse specialists (PDNSs) who managed patients with Parkinson's disease. One had worked closely with the medicines management team devising prescribing guidelines for local GPs.

The Apo-go nurse advisor's role was to educate professionals and patients about the use of apomorphine, a subcutaneous dopamine agonist treatment used in Parkinson's disease, and to support the PDNS with people using apomorphine. It was the role of the consultant and PDNS to advise patients about the dose of all medicines used in Parkinson's disease, including apomorphine. Parkinson's disease was complex and needed to be monitored by appropriate people.

The complainant was concerned that the Apo-go nurse advisor in question, who was previously a PDNS at a local health centre, continued to change oral Parkinson's disease medicines and increase the dose of apomorphine. The nurse should have contacted the local Parkinson's disease nurse to report any changes in any patients' condition to enable the consultant or nurse to change their oral medicines as necessary. The nurse advisor was not a nurse prescriber and therefore should not have altered any medicines. She did not write to the nurses to inform them of her actions, eg how a patient responded to apomorphine. She seemed to be a law unto herself and think that as she was previously a PDNS she could continue to work as such. This was not the case as she was, and had been for some time, an Apo-go nurse advisor. The complainant alleged that left to her own devices the nurse advisor posed an immense risk to patients as the clinicians involved did not have the information as to why any changes to treatment had been made.

When writing to Genus, the Authority asked it to consider the requirements of Clauses 2, 9.1, 18.1 and 18.4 of the Code.

RESPONSE

Genus submitted that the Genus Nurse Advisor in Apo-go therapy patient support programme was a successful and respected programme that had worked with NHS partners since September 2008. The programme supported the NHS in its management of people living with Parkinson's and Apo-go therapy. The programme was developed in response to an expressed health professional need, the Department of Health (DoH) Joint Working publication and a gap in healthcare provision as identified by people living with Parkinson's disease and the Parkinson's Disease Society (now Parkinson's UK).

The programme was very strongly focussed on patient benefit and safety and was aligned to best available evidence supporting the value of patient support programmes. It operated independently of the Genus commercial team and adhered to the following codes of practice and principles:

- The Nursing and Midwifery Council (NMC)
- NMC 2005, Guidelines for Records and Record Keeping
- Data Protection Act 1998
- Caldicott Guidelines
- Trust principles, terms and conditions within an honorary contract
- Parkinson's Disease Nurse Association
- Transparent and ethical practice

In terms of 'fitness to practice' each nurse in the patient support programme had Criminal Records Bureau (CRB) clearance, NMC registration, Royal College of Nursing (RCN) membership, occupational health clearance, were identity verified, and had the right to work in the UK. Additionally they had driving licence verification and professional references. Each nurse undertook regular statutory learning, was supported by the company in professional development and if not already achieved, encouraged to undertake the diploma in Parkinson's management.

Apo-go therapy was the only injectable treatment for the management of Parkinson's and so presented a particular challenge for patients and health professionals. The majority of clinical units would have only a few patients using this therapy and frequently struggled to assimilate and retain the skills needed to initiate a successful patient therapy experience. In such circumstances problems of extended hospital stays, sub-therapeutic therapies and poor patient satisfaction were not uncommon. Furthermore, a limitation on community visits from local PDNSs meant the patient and his/her family valued the input of a nurse with specific skills in the community, in this instance, the Genus Nurse Advisor in Apo-go.

The nurse team offered a range of services around Apo-go therapy but also had a significant level of knowledge in Parkinson's disease. It was not the aim of the project to act as PDNSs, nevertheless to enable holistic management each nurse had to have good general Parkinson's disease and general health knowledge. However, any patient interaction was only under the auspices of a programme agreement, trust honorary contract and established health professional relationship. Patients who benefited from the input of a nurse advisor would either already be receiving Apo-go therapy or have been identified by the prescriber as potentially benefitting from such therapy. The nurse advisors never audited or recruited patients for therapy. As stated by the complainant, a large part of the nurse's role was education about Apo-go therapy and Parkinson's disease management. Before any interaction took place between the nurse advisor and the patient, an honorary contract had to be established between the specific nurse involved and the individual trust within which she would operate.

The terms of the programme agreement setting out the parameters and limitations of the project would have been discussed and approved by the relevant health professional and trust's human resources department. On completion of, and in addition to trust contracts, the patient must have given written consent to the input of the Genus nurse advisor in Apo-go; the patient could withdraw from the care package at any time and his/her prescriber would be informed.

Genus provided testimonials to support the value of the nurse advisor in managing people living with Parkinson's disease and their Apo-go therapy. This supported the company's belief that the nurse team and the nurse in question were highly experienced, professional and effective in supporting patients receiving Apo-go therapy. Their sole aim was to improve the quality of care received by patients on Apo-go and to assist the NHS and health professionals to deliver, in a timely fashion, the best possible quality of care for patients. The Genus patient support programme worked with NHS partners to meet NHS and government initiatives to *inter alia*:

- Develop staff skill and performance
- Enhance the patient experience, provide choice and put the patient at the centre of care decisions
- Provide care at home; support family members, share skills and avoid unnecessary hospital admissions
- Effective, successful and cost saving Apo-go therapy initiation
- Promote positive aspects of Joint Working Partnership
- Support therapy guidelines (eg from the National Institute for Health and Clinical Excellence (NICE)) and improved patient care pathways.

Genus submitted that although the nurse in question had extensive experience as a PDNS, she was a nurse advisor within the Genus patient support programme and as such adhered to the scope of the programme agreement, which maintained that the prescriber was responsible for all changes/amendments to medicine and the nurse advisor supported those changes at the patient's home. This included ensuring the patient understood the recommended changes and that they made the change, and where Apo-go was concerned, supervised technical adjustments to the flow rate setting which dictated the amount of medicine delivered each hour. This was particularly important in a vulnerable patient group known to have significant cognitive changes associated with their disorder and where carer strain contributed to a reduction in quality of family life. In each instance regular verbal and written communication was maintained with the prescriber. A patient's medicine would only be changed at the clear instigation of the prescriber. The nurse would also document her practice in both patient and nurse held notes (examples were provided). Other communication included letters, calls to the GP and PDNS, although some patients did not have access to a PDNS or more than one; the primary PDNS would take precedence over any other. All documentation was treated as per NMC guidelines. In every case a patient's medicine would only be changed at the clear instigation of the prescriber who was informed throughout. Genus referred to Case AUTH/2358/9/10 in which it outlined the process by which the nurse advisors would get involved in changing a patient's medication as follows:

- 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 a nurse advisor initiated with a referral form (and often telephone call in addition). The nurse advisor was not involved in the recruitment of patients by any means whatsoever.

- The nurse advisor worked 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, *inter alia*, other possible medicines, social activities, diet and sleep, etc.

- If a change in medicine was indicated and the doctor or PDNS was 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/PDNS 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.

Turning back to Case AUTH/2443/10/11, and given the extensive skill and experience of the nurse advisor at issue, long term health professional relationships and the willingness of the director of neurology at a local health centre to continue a professional working relationship, Genus refuted the complainant's allegation that 'left to her own devices the nurse advisor posed an enormous risk to patients …'. On every occasion and in every circumstance the nurse advisor adhered to the NMC Code of Conduct and fulfilled her duty of care to the patient. It was unthinkable that the Genus nurse advisors and this particular nurse would compromise patient safety given the amount of time, expertise and passion invested in maintaining and upholding the value and professionalism of nursing alongside the NMC Code of Conduct that underpinned excellent patient care provision. Nor would Genus expect its NHS partners to put the safety of their patients in her hands if they had any reason to believe she did not meet their high expectation for patient care. In fact, to demonstrate their commitment to the service they had expressed their support in emails, copies of which were provided. Therefore, Genus strongly refuted the accusation of poor standards and compromised patient safety and questioned the quality and level of evidence to support such a serious accusation. In support of safe professional practice copies of anonymised patient notes and written communication between the consultant and the Genus nurse advisor were provided.

Genus therefore concluded that, given the above evidence and information, Genus and the provision of Apo-go nurse advisors had not brought discredit to, and reduced confidence in, the industry (Clause 2). Conversely Genus had made a significant investment to develop a package of care that greatly enhanced the provision of service and quality of care delivered by the NHS to its Parkinson's disease patients and was, in effect 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 was about quality outcomes and the patient experience.

The Genus patient support programme was a valued service and the nurse in question was very experienced, well qualified and had received a high degree of training on a continuous basis both around the therapy area and Apo-go; this was expected of all the nurses who were ambassadors not only for Genus but also the nursing profession. They upheld the principle of considering the patient first and foremost because they:

- Treated them with care and dignity
- Took ownership for the care they provided and decisions made
- Were vigilant of any potential risk and acted accordingly to maintain patient safety

The nurses ensured that all documentation was in place and shared with all concerned; operated a transparent and open service while recognising the importance of the patient's right to confidentiality. Without exception the patient was at the centre of all care decisions and contributed to their disease management. The nurse advisor team was a significant part of the Genus package of care and continually strove to maintain and improve quality of care in which Genus encouraged patients to participate as aligned to the intent of the White Paper 'Equity and Excellence, Liberating the NHS 2010', which included the principle 'no decisions about me without me'.

Genus agreed that the nurse in question was not a nurse prescriber, had never acted as one and had never allowed patients and health professionals to believe she was qualified to prescribe. However, with many years' experience in the therapeutic management of Parkinson's disease her knowledge and skill was exceptional and greater than that of many prescribers. As a qualified nurse she administered medicines according to a prescription. The NMC's standards for medicines management stated that a nurse must know the therapeutic uses of a medicine, its normal dose, and any side effects and contraindications before it was given to a patient. A spokesperson for the Royal College of Nursing stated: 'Trusts have a shared responsibility with nursing staff to ensure they are competent in drug administration …', 'But it is down to the nurse to ensure competency is maintained and that they work within the scope of their practice to make sure they are safe [to administer medicine]'. The Medicines Act 1968 stated that prescription only medicines might only be administered by or in accordance with the directions of an appropriate practitioner. The Act did not require a written order although both the appropriate practitioner and the administering nurse were accountable for the standard of communication and harmful consequences to the patient of an administration error. Appropriate practitioners were defined as registered medical practitioners, registered dentists and nurses and midwives who complied with conditions specified by Order. Despite recent changes in prescribing law, nurses generally were not appropriate practitioners and must only administer medicines in accordance with directions issued by an appropriate practitioner. Unless instructed, there was no scope to alter the dose or change the form of a medicine by crushing or opening a capsule and to do so would be a breach of the 1968 Act. The Genus nurse advisor assumed this role within the realms of the professional relationship (with the doctor) and the honorary contract. Again, Genus questioned the evidence that postulated this specific nurse advisor was deemed incompetent and submitted there had been no breach of Clause 9.1.

The patient support programme was designed to assist and support patients who had been identified as suitable for treatment with Apo-go due to their oral therapy failing in terms of efficacy. This positioning was supported and recommended by the National Institute for Health and Clinical Excellence (NICE), as per the 2006 guidelines. This decision was made purely on the basis of the patient's condition and the advancing nature of the disease. As there was no benefit in kind to any health professionals directly there was no inducement to prescribe Apo-go. The benefits were focussed on the patients with regard to the nurse advisor support, 24/7 helpline, educational support and, of course, assistance with the dedicated infusion pump and all necessary peripherals. As part of the 'package of care' Genus did not believe this fell within the definition of 'goods and services' as usually interpreted within the Code.

In Case AUTH/2358/9/10 the Panel considered that the service was, in effect, offered as a package deal and 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. In that case the Panel considered 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'.

Genus therefore strongly believed that there had been no breach of Clause 18.1 on this basis and the evidence presented above.

Genus considered that its patient support programme was an integral part of the care package which it offered to support patients who were suitable to receive Apo-go. As such, it did not believe the nurse advisors should be classed as a 'service or goods' as defined within Clause 18.4. With regard to the educational element of the package, again this was support offered to Parkinson's disease patients who were already receiving Apo-go and were specifically around the disease area and the role of Apo-go in their treatment.

In Case AUTH/2358/9/10 the Panel highlighted that 'Clause 18.4 related to the provision of medical and educational goods and services'. 'Given that the service offered by Genus … 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'.

With this in mind, again, Genus did not believe there had been any breach of Clause 18.4.

Genus submitted it had conducted a thorough review of the comments raised and had supplied supportive data and logical arguments where it believed there to be no breach of the Code.

PANEL RULING

The Panel noted that the complainant, who described him/herself as 'a concerned pharmacist' was anonymous and non contactable. The introduction to the PMCPA Constitution and Procedure stated that it was for the complainant to prove their complaint on the balance of probabilities. Anonymous complaints were accepted and, like all complaints, judged on the evidence provided by the parties.

The Nurse Support Programme Agreement stated that the programme was a non-promotional programme offered as a service to medicine by Genus. The Panel was unsure what was meant by the term 'non-promotional'. The service was linked to the use of Apo-go such that the Panel considered that it was, in effect, a package deal as set out in the supplementary information to Clause 18.1 Package Deals. The Panel noted that the relevant supplementary information provided 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 noted that the Nurse Support Programme Agreement stated that the nurse advisor would provide *inter alia* education, audit, clinical support and development, mentorship and patient support. The Panel considered that on the evidence before it the arrangements constituted a *bona fide* package deal and did not constitute 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 contrary to Clause 18.1. No breach of Clause 18.1 was thus ruled.

Clause 18.4 referred to the provision of medical and educational goods and services. The supplementary information to that clause stated that goods or services 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 a medical or educational good or service. The Panel noted its finding above that the arrangements constituted a *bona fide* package deal. It was not covered by Clause 18.4 and thus no breach of that clause was ruled.

The Panel noted its rulings above and the submissions made by Genus in relation to the conduct of the Apo-go nurse advisor in question. The Panel noted that the Nurse Support Programme Agreement provided that the lead consultant retained clinical responsibility for the patient and the PDNS remained the nursing lead in patient management. The Panel noted that this was

reflected in the evidence submitted by Genus. The Panel noted that the anonymized patient notes submitted by Genus indicated that the Apo-go nurse advisor in question consulted the local consultant neurologist before she altered this particular patient's medication, and any change made was documented. The Panel also noted that the consultant neurologist's testimonial, submitted by Genus, stated that the Apo-go nurse advisor had 'without exception consulted me whenever a patient of mine has required any alteration of prescription (Apomorphine or any other aspect of treatment)'.

The Panel noted that the complainant had submitted no evidence to support his/her serious complaint about the conduct of a fellow health professional. Evidence submitted by Genus showed that the nurse advisor was well respected by her colleagues. Thus, on the basis of the evidence before it the Panel considered that the nurse advisor had not failed to maintain high standards, and no breach of Clause 9.1 was ruled. The Panel thus ruled no breach of Clause 2.

Complaint received **14 October 2011**

Case completed **23 November 2011**