ANONYMOUS, NON CONTACTABLE v BRISTOL-MYERS SQUIBB

Orencia patient support service

An anonymous non-contactable member of public alleged that his/her mother had a distressing experience when a nurse from a third party paid for by Bristol-Myers Squibb allegedly attempted to call at her house unannounced.

The complainant explained that his/her mother had severe rheumatoid arthritis and was prescribed Orencia (abatacept) in 2014. The complainant stated that the situation had upset his/her mother and another patient who was too scared to say anything.

The complainant stated that after being started on Orencia in 2014, his/her mother suddenly had someone calling at her house to show her how to use the injection. She refused to open the door as no one had warned her that anyone was going to visit. The person explained she was from a named third party and that the doctor had sent her.

Upon enquiry to the hospital, the complainant was told that this was part of the service from the NHS and he/she wondered why no one had communicated this and why his/her permission had not been sought to visit his/her mother at home.

The complainant usually attended most of his/her mother's hospital appointments and was puzzled when the nurse showed him/her a blank form and stated that the doctor would have signed the consent form on his/her mother's behalf. The complainant was shocked as he/she was not aware that doctors could make decisions for patients without their relatives being informed.

The situation caused the complainant's mother distress especially seeing as she had not asked for the visits. The complainant did not trust pharmaceutical companies and was upset to find that Bristol-Myers Squibb was paying for the nurse.

The complainant queried how it was possible that someone could visit an old woman's house without any permission and without telling him/her. The complainant stated that according to the citizens advice bureau it was not a legal action for the doctor to sign for his/her mother to be visited by Bristol-Myers Squibb or its third party.

The detailed response from Bristol-Myers Squibb is given below.

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. The Panel noted that extreme dissatisfaction was usually required on the part of an individual before he or she was moved to complain. All complaints were judged on the evidence provided by the parties. The complainant had not provided sufficient information so that the particular circumstances could be identified. The complainant could not be contacted for more information.

Notwithstanding its comments about the consent forms the Panel did not consider that the complainant had provided sufficient information to demonstrate on the balance of probabilities that Bristol-Myers Squibb's arrangements were inadequate in relation to the complaint's mother or had not been followed. No breach of the Code including Clause 2 was ruled.

An anonymous non-contactable member of the public alleged that his/her mother had a distressing experience when a nurse from a third party allegedly attempted to call at her house unannounced.

The complainant explained that his/her mother had severe rheumatoid arthritis and was prescribed Orencia in 2014. The complainant stated that his/her mother's doctors and nurses were generally very nice but this situation upset her and another patient who was too scared to say anything. The complainant wished to remain anonymous due to fear that his/her mother would be victimised and treated badly.

Bristol-Myers Squibb Pharmaceuticals Limited's product Orencia (abatacept) in combination with methotrexate was indicated for use in rheumatoid arthritis.

COMPLAINT

The complainant stated that after being started on Orencia in 2014, his/her mother suddenly had someone calling at her house to show her how to use the injection. She refused to open the door as no one had warned her that anyone was going to visit and there had recently been burglaries in the area. The person explained that she was from the third party and that the doctor had sent her. The patient called the complainant but by the time he/she arrived at his/her mother's house the caller had gone.

Upon enquiry to the hospital, the complainant was told that this was part of the service from the NHS and he/she wondered why no one had communicated this and why his/her permission had not been sought to visit his/her mother at home.

The complainant knew how frightened his/her mother was of visitors and he/she had been advised to apply for power of attorney to manager her affairs as she was getting older.

The complainant usually attended most of his/her mother's hospital appointments and was puzzled when the nurse showed him/her a blank form and stated that the doctor would have signed the consent form on his/her mother's behalf. The complainant was shocked as he/she was not aware that doctors could make decisions for patients without their relatives being informed.

The situation caused the complainant's mother distress especially seeing as she had not asked for visits. The complainant did not trust pharmaceutical companies and was upset to find that Bristol-Myers Squibb was paying for the nurse.

The complainant queried how it was possible that someone could visit an old woman's house without any permission and without telling him/her. The complainant stated that according to the citizens advice bureau it was not a legal action for the doctor to sign for his/her mother to be visited by Bristol-Myers Squibb or the third party.

The complainant decided to submit this complaint after all that time as he/she has heard that it happened to another lady at the same hospital. The complainant stated that the nurses and doctors at the hospital were very nice to his/her mother and hoped that it could be looked into to stop other patients from having the same experience.

When writing to Bristol-Myers Squibb the Authority asked it to consider the requirements of Clauses 2, 9.1, 18.1 and 18.4 of the 2014 Code.

RESPONSE

Bristol-Myers Squibb submitted that it strove to ensure that the homecare service provided for patients treated with Orencia (abatacept), was of a high quality and met the needs of its health professionals and patients. Bristol-Myers Squibb was therefore concerned to hear of the alleged incident.

Bristol-Myers Squibb submitted that the anonymous nature of the complaint made it difficult to provide specific commentary and response, however it provided details of the standard operating procedure followed once a patient had been prescribed subcutaneous Orencia and had consented to receive the service.

Given the comprehensive procedures and protocols which were in place, Bristol-Myers Squibb was confident that prior consent to receive the homecare service would have been obtained from the patient and that this alleged nurse visit could only have taken place by directly booking an appointment with the patient.

Bristol-Myers Squibb therefore refuted the allegations and breaches of Clauses 2, 9.1, 18.1 and 18.4.

Bristol-Myers Squibb explained that Orencia was a biologic Disease Modifying Anti Rheumatic Drug (bDMARD) and as with most other bDMARDs, Orencia was administered via infusion and/or subcutaneously. Orencia was marketed subcutaneously via a pre-filled syringe and since June 2015 as a pre-filled pen device (ClickJect). It was also available as an intravenous formulation which was outside the scope of the homecare service. Orencia required cold chain storage and distribution between 2°C and 8°C.

As the complaint related to the 2014 period Bristol-Myers Squibb included the relevant summary of product characteristics (SPC) for the pre-filled syringe as it was the only formulation in scope of the homecare service.

Rheumatoid arthritis (RA) was an autoimmune disease which impacted the joints of patients who commonly presented with swollen or tender joints in the hands, wrists and feet. Patients could become severely disabled by rheumatoid arthritis in its advanced stages and many patients had effects on the hands where there were deformities of the digits, including deviation of metacarpophalangeal joints and swan-neck deformity of the fingers. This could lead to some patients with rheumatoid arthritis being unable to grasp objects properly and made it difficult for them to carry out daily tasks of living, such as impacting their ability to use a pen or to administer injections properly.

As these medicines could be administered subcutaneously at home without the support of a health professional, there was a requirement to provide training to patients on how to safely administer their medication. For that reason, it was common practice for suppliers of subcutaneous biologic therapies, within the rheumatology field, to offer homecare services to their patients due to the long term nature of the condition and the requirement for regular treatment.

Bristol-Myers Squibb engaged a named third party to provide cold chain medicine delivery as well as nurse training and support to patients prescribed subcutaneous Orencia. The third party worked in partnership with the NHS, the pharmaceutical industry and private medical insurers to support patients with a range of conditions.

The purpose of the homecare service for Orencia was:

- To ensure that the patient received a continual supply of the cold chain medicine, without interruption, except when specifically requested by their clinician.

- To provide patients with nurse training in their own home once they had received delivery of Orencia. The training was provided to ensure that the patient was familiar with their medication and understood how to safely administer the injection. The nurse also educated the patient on when it might not be safe to administer and how to report any issues they might have with their treatment. In some instances where the patient was unable to safely administer their own medication the nurse might be required to do this on their behalf. Additionally the nurse would ensure that the patient understood the requirements for storage of their treatment and sharps disposal.

The nurse visit would only take place once the delivery of Orencia had been arranged with and delivered to the patient.

Bristol-Myers Squibb submitted that the service was part of a package deal made available to patients who had been prescribed Orencia and who consented to the homecare service. Only NHS trusts that entered into a service level agreement with the third party could take advantage of the service.

When a health professional, in conjunction with the patient/carer, made a decision to prescribe subcutaneous Orencia a number of steps were required before patients could receive the homecare service.

Following the initial discussion with the health professional there were multiple processes and safeguards in place to ensure that patients had consented to the homecare service and were able to safely receive, store and administer their medication. Details were provided.

If the health professional believed that the patient/carer would also benefit from receiving the homecare service, a discussion took place between the health professional and the patient/carer. At the end of this conversation if, and only if, the patient consented to receive the service, the health professional was required to complete the 'Abatacept SC Patient Registration' form.

Both the health professional and the patient/carer must sign the form to confirm that consent had taken place. If, for any reason the patient was unable to sign the consent section, (eg where a patient had rheumatoid arthritis related complications of the hand joints and had difficulty in using a pen), it was possible that the health professional could sign on the patient's behalf to confirm that the service had been discussed and that consent had been obtained from the patient to receive this service.

The 'Patient Registration' form was updated in 2014. As the complaint letter did not refer to a specific date within 2014 when the alleged event took place, Bristol-Myers Squibb provided the two versions of the form that spanned that period, Version 1 available from January 2013 and Version 2 available from June 2014.

Bristol-Myers Squibb noted that there were some differences between the two versions of the form. Mainly, these were minor text changes in the initial sections. There were also changes made to the 'patient consent' and 'referring physician' sections, further details were provided below.

Both forms required the following information to be completed:

- Patient details
- Referring trust
- GP details
- Patient adverse event reporting consent
- Invoicing details
  Prescriber adverse event reporting consent
  Information required prior to dispensing
  Patient consent
  Referring clinician declaration.

Bristol-Myers Squibb noted that there was one NHS trust that used a slightly different patient registration form. However, the core content and declarations were similar to the main registration form provided.

Bristol-Myers Squibb drew attention to the section 'Information required prior to dispensing' on both versions of the forms. In that section there was a requirement for the clinician to tick whether the patient required training by the nursing service. This should only be ticked after the clinician had had a detailed discussion with the patient to determine if they required the nurse training service and were in agreement to provide their consent for the training to be delivered by nurses from the third party.

The two versions of the forms had relevant declarations in the 'Patient consent' sections for the patient to receive the service. Version 1 required the patient/parent/guardian to sign to give consent. The declaration had wording pertaining to the provision of the … Service:

> 'I confirm my agreement for … to hold, update and use my information for the purpose of providing, monitoring and improving a home delivery service.'

Additionally, the 'referring clinician' had to sign the document which had the following declaration:

> 'I have fully explained and discussed the homecare service with the patient and he/she has given their explicit informed consent to receive this service from …. The patient understands and consents to his/her personal and health information being passed to and processed by …, under the provisions of the Data Protection Act 1998, in order for the homecare service to be provided to them.'

Version 1 could be signed by the patient, parent or guardian. Version 2, made available in June 2014, had slightly different declarations. Version 2 was amended to remove the option for the parent/guardian to sign on the patient's behalf. There was an accompanying amendment to the 'referring physician' section also such that consent was 'to be completed by the referring clinician/Trust representative (if the patient is unable to sign)'.

Version 2 was introduced in response to clinician feedback that patients often had physical difficulty in signing the document due to their disease. To support the patient the form was therefore modified so that the onus was on the referring physician/trust representative to obtain explicit consent before signing the form and thus confirming that such consent had been obtained from the patient. It had been, and still was, a requirement that the patient should be able to comprehend and consent to the service before either version of the form was signed. Both forms had clear information stating: 'This registration form will not be processed … unless it is completed in full and accompanied by a valid prescription'.

Once the form had all relevant sections completed, it was faxed to the third party. In order to initiate

the service, the third party had multiple processes and safeguards in place to ensure that patients had consented to the service and were able to safely receive, store and administer their medication.

Once the registration form and a valid prescription had been received a patient services co-ordinator was required to telephone the patient (installation call) to confirm, *inter alia*, whether the patient had been informed of and consented to the service. There would be an additional explanation of the service and the patient would be given the opportunity to ask questions throughout the call. A script was provided.

- If a patient did not consent to receiving the service in the installation call, they would stop the call and refer the patient back to the hospital.
- If the patient had consented to receive the service the co-ordinator would organise a delivery slot for the patient to receive their medicine and sharps bin.

If the 'training required' tick box had been selected on the 'patient registration' form, an additional telephone call to the patient was made by a nurse co-ordinator to organise a nurse visit. The purpose of the nurse training visit was to teach the patient and/or carer how to administer their medicine safely. As mentioned previously the nurse also educated the patient on when it might not be safe to administer their medication and how to report any issues they might have with their treatment. This visit was always scheduled post-delivery of their medication.

The details of the call made by the nurse co-ordinator was summarised in work instruction. A 'Patient Information Form and Environmental Risk Assessment – Injections' form – SP-NUR-508** was filled in to record vital information needed for the nurse to carry out the visit.

Once the visit date and time had been agreed, one of the team would contact the referring hospital via telephone to inform them of the appointment so that any follow up appointments required could be arranged by the trust.

Following the initial call, if a patient had consented to receiving the service, information packs would be sent to the patient. The information packs provided further details about the service, what to expect and the planned nurse visit (if applicable). This pack was posted to ensure it arrived prior to the first scheduled delivery of the medicine. The welcome information packs included the following documents:

- Patient Information Guide: Sometimes home is the best place to be.
- There was an insert included with this 'Information For Patients Receiving Subcutaneous Orencia (Abatacep)'.

Bristol-Myers Squibb noted the relevant content of the documents were as follows:

a) 'Patient Information Guide: Sometimes home is the best place to be'

Bristol-Myers Squibb stated that the purpose of the 'Patient Information Guide' document was to inform the patient about the patient services co-ordinator as well as information on the service, practical information about packaging and sharps bin, nursing and clinical services available, holiday information, data protection and information about how to complain if the services were not of a good standard. The third party confirmed that it had received no related complaints.

The document provided the following information about what the service entailed:

Why is … providing a service to me at home?

> 'The clinical team responsible for your care in hospital has arranged for us to continue to support your healthcare needs while you are at home. Depending upon your requirements and the service agreed with your consultant, we may provide you with: medicines delivered at regular scheduled intervals, all necessary equipment and ancillaries, comprehensive nursing training, nursing care and support from fully qualified professionals, if required, clinical waste collection (at point of delivery) and disposal.'

The document made it clear that a patient services co-ordinator would have already contacted the patient to make arrangements for the first and subsequent deliveries.

The document stated that the third party took patient security and confidentiality very seriously. All delivery drivers wore a uniform and carried photo ID which could be produced upon request.

The nursing service was also highlighted in this document. It gave information about how the service was set up and delivered to the patient. The document stated that the nursing care was provided in accordance with the procedures and protocols approved by the referring unit (ie the patient's hospital).

The document stated that all nurses were qualified and registered with the Nursing and Midwifery Council and adhered to their code of professional conduct.

The Patient Information Guide gave the following additional information about the nurse visit:

> 'Nursing requests are normally co-ordinated during office hours, Monday to Friday, with nursing care being delivered at the designated time and date arranged on an individual basis.'

There were details of the complaints process. The third party was registered and regulated by the Care Quality Commission (CQC) and the Social Care and Social Work Improvement Scotland (SCSWIS). The Patient Information Guide provided information on what the patient could do if they were unhappy with the service - in the first instance to contact the patient services co-ordinator, customer services manager and lastly the CQC.

b) Information For Patients Receiving Subcutaneous Orencia (Abatacept))

This document provided the patient with further information about abatacept treatment and the nurse visit:

> 'Your consultant or GP may decide that a nurse training visit is necessary for you to be able to self-administer. If this is the case, your co-ordinator will schedule the nurse training visit(s) in conjunction with your first homecare delivery. This training can also be provided to anyone who will help you with your injections. You should not attempt to inject your medication until you have received this training and feel confident about the procedure.'

In addition to the protocols and work instructions in place, the third party explicitly confirmed to Bristol-Myers Squibb, via email, that it would never send a nurse to an address without prior consent or arrangement with the patient or carer or if the patient had not received their first delivery of Orencia. This was to avoid any confusion or distress to the patient, to ensure the security of the patient, avoid wasted/ failed visits for the nurse and even more importantly to ensure that it was honouring its health & safety at work obligations to its nurses. This ensured that the safety and welfare of its nurses was maintained.

The nurses wore a company logo, as well and carried photo ID.

Additionally, there was a service level agreement with every hospital which included a summary of the service to be provided to patients who required the delivery and nursing service.

The relevant sections with regard to patient consent, communication and visits included:

Section 1 Patient Consent/Registration:

> 'Patient consent must be received from all patients/carers prior to the patient record being created and treatment supplied. At the commencement of the service, patients will be registered on the Provider's system and patient consent will be received in the form of a signed patient registration form. This will be the responsibility of the Referrer.'

Section 4 Communication:

> 'The patient co-ordinator will contact the patient prior to their first delivery to explain the service and to ensure that all the information/ requirements are correct. A maximum of 3 attempts will be made to contact new patients. If no contact has been made after this time, a letter will be sent to the patient and the Referrer will be notified. The Provider's patient co-ordinator will await further instructions from the Referrer.'
>
> 'All new patients will receive a letter of introduction and a patient information pack (attachments 10, 11, 12); this will provide an outline of the Provider's service together with details of the patient's delivery schedule in the form of a delivery calendar and all relevant contact details.'

Section 7 Nursing Services:

> 'At all times the Provider's nurses will work and be managed in strict accordance with the established protocols and procedures of the Referrer. The Provider's nurses are employed by the Provider, and may work in a full or part-time capacity.'
>
> 'Where the Referrer is training the patient in medication administration it is necessary to provide the Referrer's scheduled date of training on the registration form. The provision of this information will allow the Provider's patient co-ordinator to ensure that the patient receives the delivery of medications prior to this planned training.
>
> The Provider's nurse will visit the patient at an agreed, convenient time to train the patient (and/ or carer if required) to administer the drug.
>
> The Provider's nurse will contact patients prior to their visit. This allows the nurse to:
>
> - Confirm that the patient has received their installation delivery
> - Agree a convenient date and time for the training.
>
> Training will be initiated within the appropriate timescale of the installation delivery being made, provided this is acceptable to the patient.'

Consent during a nurse visit at a patient's home

In addition to the consent sought in the 'Patient Registration' Form and verbal consent during the installation call, when the nurse visited the patient's home, the nurse would also gain further written consent from the patient. This consent confirmed that the patient had understood and accepted the terms of the service and wanted to receive nursing support prior to commencing the administration training.

The nurse went through all of the documentation provided to the patient in relation to the service. The nurse would also carry out an environmental check to ensure that the patient had all relevant facilities required, in order to successfully store and administer their medicine, and would then train the patient on how to administer the medicine safely. In some instances where the patient was unable to safely administer their own medication the homecare service nurse might be required to do this on their behalf.

Documentation that was relevant for the referring trust to retain would be sent back to the trust following a nurse visit to the patient's home.

Bristol-Myers Squibb submitted that there were multiple steps and layers of processes and procedures in place to speak to and inform the patient about the service and to gain and confirm consent.

- Patient Registration form: The prescribing physician explained the service and gained consent from the patient. The patient and the physician had to sign the form, unless the patient could not physically sign the form. In this instance, the patient was still required to consent and the physician would sign the declaration stating that the patient consented to receiving the service.
- Installation call: A co-ordinator would telephone every patient before initiating any elements of the service. At the beginning of the call the patient was required to provide consent to the service or the call was closed and the patient referred back to the trust.
- Patient Information Packs were sent to the patient prior to the initial first visit with the nurse. As described above, information was provided within the pack about the service and also about nurse visits ie any such visit (if required) would be organised on a designated date and time which was agreed with the patient on an individual basis.
- Nurse co-ordinator call: If a patient had also consented to the nurse training element of the service then a second call would be placed to the patient by the nurse co-ordinator. This was to organise a suitable time for the nurse to visit, as well as to elicit relevant information for the nurse to have prior to the visit.
- In addition to the patient consent to receive the service obtained by the health professional after the health professional had decided to prescribe Orencia in agreement with the patient, further written patient consent was obtained by the nurse at the initial nurse visit: prior to initiation of the service by the nurse.

Given the above, and in addition to the documentation provided to the patient, Bristol-Myers Squibb submitted that it was extremely unlikely, if not impossible, that a nurse would visit a patient without their prior knowledge or arrangement.

The process required the nurse to arrange a time slot with the patient/carer prior to the nurse visit. Bristol-Myers Squibb therefore refuted any breaches of the Code.

In summary, Bristol-Myers Squibb submitted that there were multiple processes and safeguards in place to ensure that a nurse could not call on the patient unsolicited, or without gaining appropriate and relevant consent.

Bristol-Myers Squibb provided screenshots of the approvals/certificates and copies of the relevant material and the list of Bristol-Myers Squibb signatories and their qualifications.

To summarise Bristol-Myers Squibb submitted that it strove to ensure that the service that it provided for patients treated with Orencia, was of high quality and met the needs of its health professionals and patients. Bristol-Myers Squibb worked closely with the NHS and the third party to ensure that patients were appropriately trained to administer injections safely.

Given the comprehensive procedures and protocols which were in place both in the hospital and within the third party, Bristol-Myers Squibb was confident that prior consent to receive the service would have been obtained and that the alleged nurse visit could only have taken place by directly booking an appointment with the patient or their carer.

Based on the information provided Bristol-Myers Squibb submitted that it was unable to find a way that the events described and alleged by the complainant in the anonymous letter to the PMCPA, could have occurred.

Bristol-Myers Squibb was confident that there had not been any breaches of Clause 18.4, Cause 18.1, Clause 9.1 or Clause 2 and it therefore refuted the allegations.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. The Panel noted that extreme dissatisfaction was usually required on the part of an individual before he or she was moved to complain. All complaints were judged on the evidence provided by the parties. The complainant had not provided sufficient information so that the particular circumstances could be identified. The complainant could not be contacted for more information.

The Panel noted that Bristol-Myers Squibb had provided information about the general arrangements for the provision of the homecare service and the procedures in place to ensure consent was obtained prior to delivery of the service. In that regard the Panel noted that the Patient Registration forms provided by Bristol-Myers Squibb were Versions 1 and 3 not Versions 1 and 2 as submitted by the company. Version 2 had not been provided. The section to be signed by the patient/parent/guardian on Version 1 was headed 'patient consent' and referred to the provisions of the Data Protection Act and consent to keep patient details on the third party computer system. It was consent to hold the data rather than consent to receive the service. The referring clinician section contained two elements: firstly a statement that the clinician had fully explained and discussed the homecare service with the patient and that the patient had given explicit informed consent to receive the homecare service and secondly that the patient understood and consented to his/her information being passed to and processed by the third party under the provisions of the Data Protection Act in order for the homecare service to be provided. Version 3 of the form had different wording for the patient section but still referred to the use of information and the Data Protection Act and this section was no longer to be signed by the 'parent/guardian'. The second part was also different, it was now headed 'to be completed by the referring clinician/Trust representative (if the patient is unable to sign)'. The content which followed this heading was similar to Version 1 other than amendments to reflect that it could be signed by either the clinician or a trust representative. The Panel considered it could have been clearer on Version 1 and

Version 3 that the patient when signing (or the parent/guardian on Version 1) was consenting to the provision of the service. The option for the parent/guardian to sign on the patient's behalf had been removed. In the Panel's view it was preferable for either the patient or someone on their behalf (other than the referring clinician or trust representative) to also sign the form.

Notwithstanding its comments above the Panel did not consider that the complainant had provided sufficient information to demonstrate on the balance of probabilities that Bristol-Myers Squibb's arrangements were inadequate in relation to the complainant's mother or had not been followed. No breach of Clauses 18.1, 18.4, 9.1 and 2 were ruled.

Complaint received **11 October 2016**

Case completed **4 January 2017**