

CHIEF PHARMACIST v SHIRE

Lack of transparency of role in commissioning materials

A chief pharmacist/director of pharmacy services at an NHS foundation trust alleged that Shire had commissioned an agency to develop materials in a way which failed to reveal the company's involvement and that it would use them for promotional purposes.

The complainant explained that a consultant colleague had been approached by the agency to discuss her work with ADHD (attention deficit hyperactivity disorder) Services. Whilst the emails from Shire's agent referred to its work 'receiving sponsorship' from Shire, it did not disclose that Shire would use the material promotionally before it gained consent to speak to the colleague. As the extent of Shire's involvement was not made clear in advance and only emerged at the interview stage, this process was alleged to be unacceptable and did not meet the transparency requirements of the Code.

The detailed response from Shire is given below.

The Panel noted that the complaint concerned the transparency of Shire's role in relation to its initiation and funding of the activity and intended use of the material when its agency invited the health professional to act as a consultant. The health professional was concerned that she had not been fully informed at the outset of the extent of Shire's role in relation to the material. The health professional had raised the matter with a senior pharmacist colleague who in turn had submitted the complaint.

The Panel noted Shire's submission that it had intended to interview the health professional to assist in the compilation of a new module for its existing ADHD Service toolkit. The new module would include case studies and tools relating to patients transitioning from child/adolescent services to adult mental health services. According to Shire the toolkit was used as a service to medicine and would not refer to or promote Shire products or any other medicines. It was used by Shire's health development managers. The Panel had no detail about their role nor did it have a copy of the current toolkit.

The Panel noted that the initial email sent by Shire's agency to the health professional was headed 'Invitation – share your example of good local practice in ADHD Transition Services' and stated that 'We are collecting examples of good practice in transition services ...' but did not state who 'We' referred to. At the end of the second paragraph the email stated that the initiative had 'been supported by funding from Shire Pharmaceuticals' and that the health professional would be reimbursed for her time. During a subsequent telephone conversation

with the agency the health professional declined further involvement when Shire's role was made clear.

The Panel noted that on instructing the agency Shire had discussed disclosure of its role at a meeting and subsequently by email. The project was described in these communications as 'an initiative by Shire,' a service 'supported by Shire' and 'non-promotional, sponsored/funded by Shire'. The Panel was concerned that contrary to Shire's email instruction to its agency it appeared that the health professional had not been sent a contract by Shire on receipt of a positive response to the initial invitation.

The Panel considered that the company's explanation of its role including the intended use of the material should have been unambiguous such that the health professional would fully understand the extent of Shire's involvement and influence on the material at the outset. In the Panel's view, given that the initial email from a third party began with 'We are collecting together examples ...' (emphasis added) and stated that the initiative had been 'supported by funding from Shire Pharmaceuticals', it was not unreasonable that the recipient would assume that the activity in question was an independently run project which had received some finance from Shire. The description of Shire's role was not clear. The Panel considered that high standards had not been maintained and it ruled a breach of the Code. In addition, and on balance, the Panel considered that the failure to make the company's role clear at the outset when contacting the consultant was such that the health professional could not make a fully informed decision about whether to accept the invitation to become a consultant. Shire had failed to recognise the professional standing of the health professional concerned. A breach of the Code was ruled.

Shire had been asked to respond in relation to sponsorship of material relating to medicines and their uses and information relating to human health and diseases. The Panel noted that the complaint did not relate to a declaration of sponsorship on the toolkit but rather transparency of the company's role in relation to initiation, funding and use of the material when the health professional was first contacted ie the nature and terms of the consultancy. The Panel therefore ruled no breach of the Code.

The Panel noted its comments above on the nature of the complaint and also the company's submission that the material was non-promotional. In that regard the material could not be disguised promotion and the Panel ruled no breach of the Code.

Shire had also been asked to respond in relation to joint working and the Panel noted Shire's submission that the project was not 'joint working' as defined in the Code. No breach of the Code was ruled.

The Panel noted its rulings above and did not consider that the circumstances were such as to warrant a ruling of a breach of Clause 2 which was reserved as a sign of particular censure. No breach of Clause 2 was ruled.

A chief pharmacist complained that Shire Pharmaceuticals Limited had commissioned a communications agency to develop materials on its behalf in a manner which failed to reveal that Shire had commissioned the materials and would use them for promotional purposes.

COMPLAINT

The complainant alleged that Shire and its communications agency had failed to act openly and transparently when they contacted a local clinician in order to produce materials for Shire as part of its promotional activities. Further, Shire and its agent failed to follow the Code in relation to the development of a joint initiative namely the production of a good practice guide in the management of transition services.

The complainant explained that in December 2014 a consultant colleague had contacted him concerned that she had been approached by the communications agency to discuss her work with ADHD [attention deficit hyperactivity disorder] Services. Whilst the emails from Shire's agent referred to its work 'receiving sponsorship' from Shire, it did not disclose that Shire would use this material promotionally before it gained consent to speak to the colleague. As the extent of Shire's involvement was not made clear in advance and only emerged during the interview stage, this process was unacceptable and not in line with the Code in relation to transparency. Copies of various materials were supplied.

In writing to Shire attention was drawn to Clauses 2, 9.1, 9.2, 9.10 and 12.1 of the 2014 Code. The company was also asked to consider the requirements of Clause 18.5 if the project at issue was 'joint working' as defined the supplementary information to that Clause. The 2015 Constitution and Procedure applied to this complaint.

RESPONSE

Shire stated that it was disappointed to receive this complaint and set out its response below.

1 The development of the 'ADHD Service toolkit'

Shire submitted that it had initiated and funded the ADHD Service toolkit with no other pharmaceutical company involvement. It was developed as a service to medicine for use by its healthcare development managers (HDMs) with health service commissioners and health professionals involved in the development of ADHD services. The current

iPad version was first certified for use as a digital non-promotional tool in October 2014. The HDMs demonstrated the toolkit to health professionals and then emailed specific toolkit content requested by the health professional for use within their own organisation.

The toolkit did not refer to or promote Shire products, or indeed any other medicines. It contained a wide range of tools intended to help NHS health professionals identify gaps in local ADHD service delivery, as well as proposing and implementing improvements to enhance patient care.

2 Shire's relationship with its communications agency

Shire commissioned a marketing and communications agency to develop an additional module for the ADHD Service toolkit. This additional module was to contain case studies and tools relating to ADHD patients transitioning from child/adolescent to adult mental health services (the Transition Service update). This project was performed under a Master Services Agreement with an agreed Statement of Work for the Transition Service update (copies provided).

The project required the agency to research and compile an update for the ADHD Service toolkit on the subject of Transition Services relating to children and adults with ADHD. This included using public domain information to identify key centres and individuals who could be approached to act as consultants in completing the update.

This update was still in development and the Transition Service update had not yet been approved or used as part of the ADHD Service toolkit or otherwise. There were therefore no certified materials relating to it. The existing, approved ADHD Service toolkit was not shared with health professionals as part of this engagement.

3 The engagement of the health professionals in regard to the 'ADHD Service toolkit update'

a) Meeting and communications between Shire and its communications agency regarding transparency and declarations

Staff from the marketing and communications agency and Shire met in November 2014 to discuss the Transition Service update. The meeting minutes recorded the requirement for full transparency in relation to engaging health professionals to work on the project.

'[agency] to make an initial approach to these options. Explain how we will want to work with them to write something up and it's an initiative by Shire. An official letter then needs to be written to outline what we are asking them to sign up to, it needs to state it is non-promotional activity; it's a service which is supported by Shire. We will need to make sure to get permissions that it can be put in the tool, that it can be printable; we can use their names, etc.'

A subsequent email sent between agency colleagues in November 2014 reinforced the commitment to be fully transparent with health professionals engaged in the development of this ADHD Service toolkit update.

‘Thoughts on what we need to cover in the email:

- About the initiative / service
- Non-promotional, sponsored / funded by Shire
- What we would need them to do – have a telephone call and then review documents / tools (the plan is that these would ultimately be made available and be printable) and agree for us to use their name
- Next steps – a contract would be sent by Shire, and once this is agreed, we’d like to set up a call w/c 8 December.’

b) Identification of the health professional as a potential provider of consultancy services in relation to the Transition Service update

The agency identified the health professional as a potential contact through two key publicly available documents. Shire submitted that had the health professional decided to proceed, a written agreement in accordance with Clause 20 would have been used.

c) Initial communication with the health professional by the agency

The agency emailed the health professional in December 2014 to outline the project and reason for contact. This included the following statement:

‘This initiative has been supported by funding from Shire Pharmaceuticals and we will be able to re-imburse you for your time.’

The email explained the need for a telephone discussion to discuss details of the engagement further:

‘We are keen to carry out the telephone discussions before the Christmas break so would be very grateful if you could advise if you would be interested in participating and we can arrange a convenient time to speak to provide more details.’

d) Subsequent communications led to a telephone call to discuss the proposed engagement in more depth

Following the initial email, the health professional agreed to a follow up telephone discussion with the agency. During this telephone call the health professional declined further involvement when Shire’s involvement was highlighted. The call was then brought to a close by the agency. A narrative of the telephone call was provided. Shire submitted that there had been no further contact with the health professional. All other emails were provided.

e) Shire’s review of the correspondence regarding engagement of the health professional

Shire recognised that the health professional did not appear to know that the engagement proposed by the agency was for a project commissioned solely by Shire. However, Shire’s involvement was clearly stated in the initial email from the agency and subsequently during the telephone call to explain the nature of the engagement before any consultant contract was agreed and work initiated. Shire submitted that it had sought to comply with Clause 9.10.

4 Matters concerning the allegation of disguised promotion

In consideration of Clause 12.1 and the allegation of disguised promotion by the complainant that:

‘[The agency] did not disclose that this material would be used for promotional purposes by Shire Pharmaceuticals prior to gaining consent to speak to my colleague.’

As stated above, the material was not intended for promotional use as the ADHD Service toolkit was a non-promotional item for use by health professionals. Shire submitted that no evidence of disguised promotion has been provided. There had been no circulation of materials or activities mentioning Shire products to the health professional. Both the engagement with the health professional and the development of the ADHD Service toolkit were non-promotional in nature and intent. Shire therefore submitted that there was no evidence to support a breach of Clause 12.1.

On the matter of the visibility of Shire’s role in this engagement, Shire noted that it had discussed the declaration of its funding via email and verbally during a telephone call to discuss the proposed engagement above.

5 The alleged engagement in the conduct of joint working

Shire noted that the complainant had stated:

‘Shire pharmaceuticals and its agent failed to follow the Code in relation to the development of a ‘joint initiative’ namely the production of a good practice guide in the management of transition services.’

Shire submitted that the complainant’s phrase ‘joint initiative’ should be interpreted as meaning Joint Working as defined in the supplementary information of Clause 18.5 of the 2014 Code.

Shire submitted that the ADHD Service toolkit was a non-promotional tool provided by Shire for use by health professionals as a ‘Service to Medicine’ item intended to enhance patient care and benefit the NHS (Clause 18.4). There was no element of pooled resources and it did not represent joint development/ implementation of an agreed project. This was not joint working as defined by the Code and in this regard, Shire considered that there had been no breach of Clause 18.5.

Conclusion

Shire's submitted that there was no evidence that the agency intended to gain advice by subterfuge. The evidence provided showed the intent for full transparency in working with the health professional concerned. There was no evidence (or intent) of disguised promotion. The project did not meet the criteria for joint working.

Shire believed that it and the agency had upheld high standards as demonstrated within all communications by being courteous and respectful of the health professional's time and expertise, there was no intention to cause offence in any written or verbal communications. Shire denied a breach of Clause 9.1 or 9.2.

In addition, there was no evidence that Shire employees/agents fell short of competent care or conducted other activities as listed in the supplementary information to Clause 2 that brought discredit upon, or reduced confidence in, the pharmaceutical industry. Therefore Shire denied a breach of Clause 2.

PANEL RULING

The Panel noted that the complaint concerned the transparency of Shire's role in relation to its initiation and funding of the activity and intended use of the material when its agency invited the health professional to act as a consultant. The health professional was concerned that she had not been fully informed at the outset of the extent of Shire's role in relation to the material. The health professional had raised the matter with a senior pharmacist colleague who in turn had submitted the complaint.

The Panel noted Shire's submission that it had intended to interview the health professional to assist in the compilation of an update for its existing ADHD Service toolkit. The additional module for the toolkit would include case studies and tools relating to ADHD patients transitioning from child/adolescent services to adult mental health services. According to Shire the toolkit was used as a service to medicine and would not refer to or promote Shire products or any other medicines. It was used by Shire's health development managers. The Panel had no detail about their role nor did it have a copy of the current toolkit.

The Panel considered that it was important that when companies engaged health professionals as consultants they were, *inter alia*, transparent about the arrangements and the extent of their role. The Panel noted that the initial email sent in December 2014 by an account director from Shire's agency to the health professional was headed 'Invitation – share your example of good local practice in ADHD Transition Services' and stated that 'We are collecting examples of good practice in transition services ...' but did not state who 'We' referred to. The email referred to the health professional's local model on which 'We' would like to compile a short case study to guide her colleagues. The

email further explained that the examples would sit within an ADHD Service toolkit which would help local areas assess their services, identify gaps and implement plans for local improvement. At the end of the second paragraph the email stated that the initiative had 'been supported by funding from Shire Pharmaceuticals' and that the health professional would be reimbursed for his/her time. During a subsequent telephone conversation with the agency's medical writer, the health professional declined further involvement when Shire's role was made clear.

The Panel noted that on instructing the agency Shire had discussed disclosure of its role at a meeting and subsequently by email. The project was described in these communications as 'an initiative by Shire,' a service 'supported by Shire' and 'non-promotional, sponsored/funded by Shire'. The Panel was concerned that contrary to Shire's email instruction to its agency in November, it appeared that the health professional had not been sent a contract by Shire on receipt of a positive response to the initial invitation.

The Panel considered that the company's explanation of its role including the intended use of the material should have been unambiguous such that the health professional would fully understand the extent of Shire's involvement and influence on the material at the outset. In the Panel's view, given that the initial email was sent from a third party and began with 'We are collecting together examples ...' (emphasis added) and stated that the initiative had been 'supported by funding from Shire Pharmaceuticals', it was not unreasonable that the recipient would assume that the activity in question was an independently run project which had received some finance from Shire. The description of Shire's role in the initial invitation email was not clear. The Panel considered that high standards had not been maintained in this regard and ruled a breach of Clause 9.1. In addition, and on balance, the Panel considered that the failure to make the company's role clear at the outset when contacting the consultant was such that the health professional could not make a fully informed decision about whether to accept the invitation to become a consultant. Shire had failed to recognise the professional standing of the health professional concerned. A breach of Clause 9.2 was ruled.

Shire had been asked to respond to Clause 9.10 of the Code which referred to sponsorship of material relating to medicines and their uses and information relating to human health and diseases. The Panel noted that the complaint did not relate to a declaration of sponsorship on the toolkit but rather transparency of the company's role in relation to initiation, funding and use of the material when the health professional was first contacted ie the nature and terms of the consultancy. The Panel therefore considered that Clause 9.10 did not apply. No breach of Clause 9.10 was ruled.

The Panel noted its comments above on the nature of the complaint and also the company's submission about the non-promotional nature of the material.

The Panel thus considered that Clause 12.1 which related to disguised promotion did not apply. No breach of Clause 12.1 was ruled.

The Panel noted that Shire had been asked to respond to Clause 18.5 in relation to joint working only if the activity was a joint working project as defined in the supplementary information to that clause. The Panel noted Shire's submission that the project was not 'joint working' as defined in the Code. No breach of Clause 18.5 was ruled.

The Panel noted its rulings above and did not consider that the circumstances were such that they warranted a ruling of a breach of Clause 2 which indicated particular censure and was reserved for such use. No breach of Clause 2 was ruled.

Complaint received **9 January 2015**

Case completed **13 March 2015**
