CASE AUTH/3044/6/18

ANONYMOUS v ROCHE

Failure to publish joint working executive summary

An anonymous, contactable complainant considered that a cancer data project, operating in a named Scottish region, appeared to be a joint working project although it had not been declared as such by the four companies involved including Roche. The complainant stated that the ABPI had, *inter alia*, published news of the collaboration. The complainant had not seen relevant details published on Roche's website, noting that an executive summary should be published before such projects start. If such details were on the website they were not visible and hence transparent – the project was not listed alongside Roche's other joint working projects.

The complainant acknowledged that it might be a very positive joint working project but queried whether, as long as their project was endorsed by the ABPI, member companies did not have to comply with the Code. The complainant queried whether the ABPI was leading companies to flagrantly bypass the Code.

The detailed response from Roche is given below.

The Panel noted that joint working between the NHS and others and the pharmaceutical industry was defined by the Department of Health as situations where, for the benefit of patients, one or more pharmaceutical companies and the NHS pooled skills, experience and/or resources for the joint development and implementation of patient centred projects and shared a commitment to successful delivery. The relevant supplementary information to the Code described the features of joint working including that it must be for the benefit of patients, but it was expected that the arrangements would also benefit the NHS and the pharmaceutical company or companies involved. The Code required a formal written agreement to be in place and an executive summary of the joint working agreement to be made publicly available before arrangements were implemented.

The first issue that the Panel had to decide was whether the arrangements referred to by the complainant constituted joint working.

To determine whether an arrangement was joint working one had to consider whether the project was for the benefit of patients. The Panel noted the benefits for all stakeholders listed in the protocol and considered that these were primarily, although not exclusively, for the benefit of patients. In the Panel's view, that there were ancillary benefits to pharmaceutical companies did not preclude the overall arrangements being considered a joint working project even if such benefits primarily influenced a company's decision to participate.

The Panel noted that Roche had not explained why the contract at issue was between the ABPI and the NHS region and not directly with the companies in question. The ABPI and the companies had discussed the classification of the project. Ultimately, and irrespective of such discussions, companies had to take responsibility for the project classification under the Code. In the Panel's view it was clear from an overall evaluation of the contract between the NHS region and the ABPI that the ABPI was contracting on behalf of the four companies and the use of a third party did not, in the Panel's view, mean that the companies could circumvent the requirements of the Code. In the Panel's view, the role of the ABPI did not preclude the arrangements being joint working.

The Panel noted that the four companies had each paid £32,480.50 and that the ABPI Scottish Collaborations Group had paid £10,000 towards the project giving a total of £139,922. The NHS had contributed £118,309.50. The Contribution Agreement and Trade Mark Licence referred to the four companies. In the Panel's view, the role of the ABPI did not preclude the arrangements being joint working.

The Panel noted Roche's submission that the NHS was acting as a service provider however the project included features of joint working, namely; industry and NHS resources had been pooled to implement a project for the benefit of patients; outcomes that would also benefit the NHS and the four companies involved; both the health board and the four companies had made a significant financial contribution towards the project; and defined project outcomes were to be measured and documented. However, not all of the benefits for stakeholders as set out in the protocol were for the benefit of patients. The Panel noted its comments above in this regard and considered that the benefits as listed in the protocol in relation to Phase 1 of the project could be predominantly characterized as for the benefit of patients. The Panel considered that the arrangements at Phase 1 of the project in relation to the NHS region were a joint working project and thus an executive summary of the written agreement ought to have been published before the arrangements were implemented. The Panel ruled breaches of the Code including that high standards had not been maintained. In the Panel's view the circumstances did not warrant a ruling of a breach of Clause 2 which was reserved to indicate particular disapproval of a company's activities and reserved for such use. No breach of Clause 2 was ruled.

The four pharmaceutical companies involved in the above project were each subject to a complaint. Novartis (Case AUTH/3043/6/18) and Roche (Case AUTH/3044/6/18) accepted the Panel's rulings

of breaches of the Code. AstraZeneca (Case AUTH/3046/6/18) and Pfizer (Case AUTH/3045/6/18) appealed those rulings.

At the appeals of Case AUTH/3045/6/18 and Case AUTH/3046/6/18 on 17 January the Appeal Board noted that although the whole project (Phases 1-3) included features of joint working the protocol of agreement between the four companies and the NHS region was limited to completing Phase 1. The outcomes of Phase 1 were data centred rather than patient centred. The Appeal Board considered that the arrangements at Phase 1 of the project in relation to the NHS region were not a joint working project and thus no executive summary of the written agreement needed to have been published before the arrangements were implemented. The Appeal Board ruled no breaches of the Code.

After the consideration of the appeals by AstraZeneca and Pfizer the Appeal Board agreed that Novartis and Roche should be contacted and informed of the outcome. The PMCPA Constitution and Procedure did not cover this unusual situation where more than one company was involved in the same set of circumstances and the Appeal Board had taken a different view to the Panel. Novartis and Roche were each offered the opportunity to appeal out of time. The complainant was also informed. Roche declined the opportunity to appeal. Novartis appealed and the Appeal Board subsequently ruled no breaches of the Code.

An anonymous, contactable complainant considered that a cancer data project operating in a named Scottish region appeared to be a joint working project although it had not been declared as such by the four companies involved including Roche Products Limited.

The complaint was taken up with all four companies including Roche.

COMPLAINT

The complainant stated that in May 2018, the ABPI had, *inter alia*, published news of the project in question.

The complainant queried whether the project was a joint working project with the NHS. If that was the case, the complainant had not seen details published on Roche's website and noted in that regard that an executive summary should be published before such projects started. If details were on the website they were not very visible and hence transparent – the project certainly was not listed alongside Roche's other joint working projects.

The complainant noted that the news alert from the ABPI stated 'Funding of the project from the Scottish region was being matched and queried whether matched funding was one of the principles of joint working.

The complainant acknowledged that it sounded like good news and it might be a very positive joint working project but queried whether, as long as their project was endorsed by the ABPI, member companies did not have to comply with the Code.

The complainant queried whether the ABPI was leading companies to flagrantly bypass the Code.

When writing to Roche, the Authority asked it to respond in relation to the requirements of Clauses 2, 9.1 and 20.

RESPONSE

Roche explained that the ABPI Scotland Collaborations Group (SCG), one of three main strategic groups in ABPI Scotland, was a working group of ABPI member companies. The objective of the working group was to allow the sharing of project ideas and inputs from customers about potential projects, and if a project was accepted by members of ABPI SCG then the project could be progressed under appropriate governance. Budget was held by the ABPI not the group.

The collaborative project in question was the first project to be accepted by the ABPI SGP and it was agreed that the group would invest in it along with four companies including Roche. The project was initially proposed by a consultant physician and now operated through the ABPI in collaboration with the local cancer centre.

Because of the need to link data to health technology appraisals (HTAs) the proposal had been worked-up in conjunction with other groups in the ABPI. The project's aims and objectives were developed and agreed at a joint stakeholder workshop in January 2017. Focusing on the breast cancer patient pathway, from the point of diagnosis onwards, the objectives of the project were to:

- better define the gap between what was on offer from data and what could be delivered, with the aim of informing HTA data process for Scottish Medicine Consortium (the economic modelling)
- describe the data completeness, data quality and scope of a comprehensive linked regional cancer dataset
- build an analytical framework for the quantification of population size, population characteristics, clinical and patient outcomes, tolerability, healthcare costs and value of recently adopted new technologies for cancer.

The project would also:

- develop appropriate governance by which industry and others could apply for access to the dataset
- test the robustness and validity of the dataset.

The ABPI entered into a contract with the NHS region in March 2018. Roche reviewed the contract in December 2017.

Roche did not consider that the project was joint working covered by Clause 20 because:

- the primary benefit was to the industry in terms of insight gathering to inform future activities such as HTA submission
- the ABPI was a leading partner in the project and ABPI Scotland verified during the scoping process

that it was unable to conduct joint working
- whilst there might be a subsequent patient benefit from the project this collaboration was not focussed primarily on benefit of patients which was a key requirement for a joint working project.

In Roche's view the NHS was a service provider in the project and thus when considering applicability of the Code Roche considered that the arrangements fell under Clause 21, Relationships and Contracts with Certain Organisation which stated:

> 'Contracts between companies and institutions, organisations or associations of health professionals under which such institutions, organisations or associations provide any type of services on behalf of companies (or any other type of funding by the company not otherwise covered by the Code) are only allowed if such services (or other funding):
>
> - comply with Clause 19.1 or are provided for the purpose of supporting research
> - do not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.'

In summary, Roche did not consider that the project fell under the scope of Clause 20 and therefore it denied any breach of Clauses 20, 9.1 or 2.

In response to a request for further information Roche stated that the project's aims and objectives, which had been agreed and ratified in January 2017, were as documented in the protocol for the Data Intelligence for the Value Appraisal of Personalised Healthcare Technologies for Cancer within [a named] Cancer Network (as provided). Roche's financial contribution towards the project was paid directly to the ABPI.

The Project had a Steering Committee on which the four industry collaborators plus the ABPI were represented alongside numerous other third-party organisations. They offered oversight, experiential comment and suggestions about progress with the project. The day-to-day running of the project was managed by a team comprised of employees from the NHS region in question, often with dual academic roles. This group was responsible for delivering as per the project outline and timelines as well as making final decisions on governance. Additional clinical/academic input came from senior personnel in the field of oncology across Scotland (represented by various organisations including, but not limited to the NHS region in question).

According to Roche, the aim of the project was to test the validity of the real-world dataset for a number of purposes including possible use in future health technology appraisal submissions. Some example questions to test the validity of the data for those purposes were stated in the project report, which had been drafted by the clinical lead. The Project Team would assess the robustness of the data in answering these questions. Any reporting of the outcome would be included in the final report of the Project Team and conclusions of the project. This would be of a reporting level suitable for the public domain. Roche had no part in delivering this work by the project team and would only see the results when compiled for publication. As a member of the Steering Group, Roche would be informed of progress of the work against the milestones agreed in the project plan.

PANEL RULING

The Panel noted that joint working between the NHS and others and the pharmaceutical industry was defined by the Department of Health as situations where, for the benefit of patients, one or more pharmaceutical companies and the NHS pooled skills, experience and/or resources for the joint development and implementation of patient centred projects and shared a commitment to successful delivery. This definition was reproduced in the supplementary information to Clause 20 Joint Working. The relevant supplementary information to Clause 20 then described the features of joint working including that it must be for the benefit of patients, but it is expected that the arrangements will also benefit the NHS and the pharmaceutical company or companies involved. Clause 20 required a formal written agreement to be in place and an executive summary of the joint working agreement to be made publicly available before arrangements were implemented.

Thus, in the Panel's view, it was clear that joint working would produce benefits to the NHS and pharmaceutical companies in addition to outcomes for the benefit of patients. That a joint working arrangement produced other benefits including in relation to a company's commercial interests would not necessarily preclude the overall arrangement being classified as a *bona fide* joint working project.

The complainant alleged that certain companies had failed to publish an executive summary of joint working arrangements. The first issue that the Panel had to decide was whether the arrangements constituted joint working.

The Panel noted that the complaint concerned four pharmaceutical companies including Roche. All four companies were members of the ABPI Scotland Collaboration Group. The Panel noted that although the complaint concerned the same project the companies gave differing accounts about some aspects of the project including its internal classification. Not all companies had provided all relevant documentation.

The Panel noted that the project protocol was set out in a document titled Data Intelligence for the Value Appraisal of Personalised Healthcare Technologies for Cancer within the [named] Scotland Cancer Network, Version 9, Date of Preparation June 2017 which was appended to the agreement between the ABPI and the Scottish health board, which was neither signed nor dated. The background section of the project protocol explained that the parties had identified a need to provide a robust and prospectively designed technology adoption and evaluation framework

to exploit rich routinely collected datasets for value assessment and evidence development in real world settings. The protocol explained that such data was needed by NHS decision makers and, *inter alia*, local service managers. It was noted that existing patient access schemes were inefficient and such data would also make possible more preferable population level schemes. It was also noted that there was potential for such data to be exploited by others including academic communities which relied on routine capture of electronic health data. The protocol explained that there was an urgent need to understand the detail of what was currently possible and what further developments needed to be undertaken. There were three geographical phases to the overall project: Phase 1 in relation to breast cancer patients and the NHS region; Phase 2 in relation to four health boards comprising the named cancer network; and Phase 3 was national in scope and broader than breast cancer and would be in collaboration with another organisation.

The project work plan including costings set out in the protocol was in relation to Phase 1 of the project only and had 3 milestones. Breast cancer data had been identified for Phase 1 of the project and hence the proposed collaboration with the NHS region health board which had a pre-existing data set. In the Panel's view the complaint was about this regional Phase 1 collaboration rather than subsequent phases of the project which were referred to but not detailed in the protocol. The funding provided was in relation to Phase 1 of the project.

In relation to the project at issue, the protocol set out benefits for stakeholders. Benefits for patients were listed first and described as 'Improved patient concordance, adherence and benefit from therapy through additional support of data to ensure optimal use of their medicines'; and 'Better information as a basis for patient specific treatment decisions'. The first two of three benefits for the NHS named health board were relevant to patients and included an audit framework as a basis for improved quality of care for breast cancer patients across south east Scotland and 'Improved capture of patient outcomes'. The four benefits to ABPI/industry were listed as 'Improved reputation by working jointly with NHS to benefit patients', 'Improved professional and transparent relationship and trust between ABPI, Industry and NHS Health Boards', 'Access to anonymized aggregated data through public domain reporting to highlight the outcomes of the project to allow greater disease understanding' and 'The optimal use of medicines in the appropriate patients which should mean better proactive treatment and management of patients'.

Four sub-project work packages were listed and included direct-from-data clinical pathway modelling for outcomes estimation in support of, *inter alia*, cost-effectiveness modelling for Scottish Medicines Consortium Submissions and local business cases and expanding beyond NHS activity into social care. It appeared, although it was not entirely clear, that the sub work packages related to Phases (work packages) 2 and 3 rather than the phase in question.

In relation to Phase 1 of the project, the Panel noted the companies' and NHS region's contribution as set out in the unexecuted contract between the NHS and the ABPI. The Panel noted the companies' ongoing role on the steering committee.

To determine whether an arrangement was joint working one had to consider whether the project was for the benefit of patients. The Panel noted the benefits for all stakeholders listed in the protocol and considered that these were primarily although not exclusively for the benefit of patients. In the Panel's view, that there were ancillary benefits to pharmaceutical companies did not preclude the overall arrangements being considered a joint working project even if such benefits primarily influenced a company's decision to participate.

The Panel noted that Roche had not explained why the contract was between the ABPI and NHS region rather than directly with the companies in question. The Panel acknowledged that there had been discussion between the ABPI and the companies about the classification of the project. Ultimately and irrespective of such discussions companies had to take responsibility for the project classification under the Code. In the Panel's view it was clear from an overall evaluation of the unexecuted contract between NHS region and the ABPI that the ABPI was contracting on behalf of the four companies and the use of a third party did not, in the Panel's view, mean that the companies could circumvent the requirements of the Code. The unexecuted contracted between the NHS and the ABPI stated at the section headed Compliance, in relation to declarations of the companies' involvement that the ABPI Scotland Collaborations Group comprised four named companies including Roche. A footnote stated that this statement would not be included in the wet copy contract signed by the ABPI and NHS region. The four companies were, however, listed alongside their financial contributions in Section 5 of an Appendix, Supporter Terms and Conditions, to that Agreement. The certified project protocol annexed to the certified Contribution Agreement and Trade Mark Licence did not name the companies in question.

The Panel noted that the four companies had each paid £32,480.50 and that the ABPI Scottish Collaborations Group had paid £10,000 towards the project giving a total of £139,922. The NHS had contributed £118,309.50. The Contribution Agreement and Trade Mark Licence referred to the four companies. In the Panel's view, the role of the ABPI did not preclude the arrangements being joint working.

The Panel noted Roche's submission that the NHS was acting as a service provider and the arrangements for the project fell under Clause 21. The Panel noted that the project included features of joint working, namely, the pooling of industry and NHS resources to implement a project for the benefit of patients; outcomes that would also benefit the NHS and the four SCG group members; both region health board and the four companies including Roche had made a significant financial contribution towards the project; and defined project

outcomes were to be measured and documented. However, not all of the benefits for stakeholders as set out in the protocol were for the benefit of patients. The Panel noted its comments above in this regard and considered that the benefits as listed in the protocol in relation to Phase 1 of the project could be predominantly characterized as for the benefit of patients. The Panel considered that the arrangements at Phase 1 of the project in relation to NHS region were a joint working project and thus an executive summary of the written agreement ought to have been published before the arrangements were implemented. The Panel ruled a breach of Clause 20 in this regard. High standards had not been maintained, a breach of Clause 9.1 was ruled. In the Panel's view the circumstances did not warrant a ruling of a breach of Clause 2 which was reserved to indicate particular disapproval of a company's activities and reserved for such use. No breach of Clause 2 was ruled.

The four pharmaceutical companies involved in the above project were each subject to a complaint. Novartis (Case AUTH/3043/6/18) and Roche (Case AUTH/3044/6/18) accepted the Panel's rulings of breaches of Clauses 20 and 9.1. AstraZeneca (Case AUTH/3046/6/18) and Pfizer (Case AUTH/3045/6/18) appealed those rulings.

At the appeals of Case AUTH/3045/6/18 and Case AUTH/3046/6/18 on 17 January the Appeal Board noted that although the whole project (Phases 1-3) included features of joint working the protocol of agreement between the four companies and the NHS region was limited to completing Phase 1. The outcomes of Phase 1 were data centred rather than patient centred. The Appeal Board considered that the arrangements at Phase 1 of the project in relation to the NHS region were not a joint working project and thus no executive summary of the written agreement needed to have been published before the arrangements were implemented. The Appeal Board ruled no breaches of Clauses 20 and 9.1.

After the consideration of the appeals by AstraZeneca and Pfizer the Appeal Board agreed that Novartis and Roche should be contacted and informed of the outcome. The PMCPA Constitution and Procedure did not cover this unusual situation where more than one company was involved in the same set of circumstances and the Appeal Board had taken a different view to the Panel. Novartis and Roche were each offered the opportunity to appeal out of time. The complainant was also informed. Roche declined the opportunity to appeal. Novartis appealed and the Appeal Board subsequently ruled no breach of Clauses 9.1 and 20.

Complaint received **5 June 2018**

Case completed **12 November 2018**