ANONYMOUS CONTACTABLE v NOVARTIS

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 Novartis. The complainant stated that the ABPI had, *inter alia*, published news of the collaboration. The complainant had not seen relevant details published on Novartis' 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 Novartis' 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 Novartis 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, according to Novartis, the NHS region had not wanted to contract directly with the pharmaceutical companies and thus the contract was made with the ABPI. The Panel noted the sensitivities. 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, and between the ABPI and each individual company, 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.

In relation to the project at issue, its 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 regional NHS board were relevant to patients and included an audit framework as a basis for improved quality of care for breast cancer patients across a Scottish region and 'Improved capture of patient outcomes'. The four benefits to ABPI/industry included 'Improved reputation by working jointly with NHS to benefit patients' and 'The optimal use of medicines in the appropriate patients which should mean better proactive treatment and management of patients'.

The Panel noted that the four companies had each paid £32,480.50 and that the ABPI SCG had paid £10,000 towards the project giving a total of £139,922. The NHS had contributed £118,309.50. In the Panel's view, the role of the ABPI did not preclude the arrangements being joint working.

The Panel noted Novartis' submission that the project was a joint industry and NHS collaboration. Novartis had certified the protocol as joint working as it considered this was the closet fit to the nature of the project. 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 significant financial contributions 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 accepted the option to appeal.

In addition to the submission from Novartis the Appeal Board noted relevant elements of its rulings in its consideration of the appeals from Pfizer (Case AUTH/3045/6/18) and AstraZeneca (Case AUTH/3046/6/18).

The Appeal Board considered that the documents could have been better worded to more accurately reflect the arrangements and this included the information issued by the ABPI.

The Appeal Board noted Novartis' submission that it had the necessary documents certified using the Novartis joint working Zinc job category as it was the closest fit to the collaborative and non-promotional nature of the project. Novartis did not consider that the project was a joint working project. Novartis considered that the arrangements relating to the project were in line with the requirements of Clause 21 of the Code.

The Appeal Board noted that the whole project included features of joint working, namely, the pooling of industry and NHS resources to implement a project with outcomes listed in the protocol for the benefit of patients and the benefit of the NHS and the four companies involved including Novartis; both the Scottish region health board and the four companies including Novartis had made a significant financial contribution towards the project; and defined project outcomes were to be measured and documented. However, the Appeal Board noted that the protocol of agreement was limited to completing Phase 1. The outcomes of Phase 1 were a data dictionary, a data quality report and example epidemiological, clinical pathway and outcomes reports that would be aggregated and anonymised and only available to the companies when they had been published by the NHS region. Although referred in the protocol, Phases 2 and 3 were not part of the current protocol of agreement and there was no agreement or obligation that the company would be involved in them.

The Appeal Board noted that Novartis in its appeal provided better and further particulars than had been provided to the Panel particularly with regards to the actual outcomes of Phase I. Pfizer (Case AUTH/3045/6/18) and AstraZeneca (Case AUTH/3046/6/18) also commented on the misleading nature of the ABPI press release at their appeals.

The Appeal Board noted that its role was solely to determine whether the activity at issue was joint working thereby triggering the requirement to publish an executive summary.

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 . The appeal on both points was successful.

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 Novartis.

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

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 Novartis' website, noting 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 Novartis' other joint working projects.

The complainant noted that the ABPI news alert stated that funding of the project from the 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 Novartis, the Authority asked it to consider the requirements of Clauses 2, 9.1 and 20.

RESPONSE

Novartis explained that the cancer data project was an ongoing collaboration between a named health board and ABPI that sought to drive adoption of real-world electronic health data relating to current care pathways and patient populations, and to better incorporate such data into health technology assessment (HTA) processes by developing a reproducible, data-driven regional cancer technology evaluation framework. The project aimed to drive improvement in health outcomes, to introduce new models of technology with evidence development and commercial value reimbursement models, and to support the improved use and optimization of medicines. Ultimately, the expectation was that these data-driven improvements would benefit patients in the future by leading to improved patient concordance, adherence and benefit from their therapies, and via the generation of better information as a basis for patient-specific treatment decisions. The project focus was on the breast cancer patient pathway, and the adoption of this pooled real-world data would drive a clearer understanding of the best treatment pathways in breast cancer.

The project started on 20 April 2018 and would last for 18 months. A copy of the project protocol which described the project in detail and set out the benefits of the participating parties was provided.

The project deliverables were:

- To develop a clear understanding of what data existed, and the quality of the data across primary and secondary care within the NHS region, and determine whether these data could be linked to create a data framework;
- To develop a breast cancer data framework;
- To produce publicly available end of milestone reports. The report generated at the end of milestone 3 of the project would seek to demonstrate the robustness of the breast cancer data framework;
- The development of a process within the NHS region for the pharmaceutical industry to engage with and access reports using the new breast cancer data framework; and
- To consider next steps at the conclusion of the project and to consider whether a second project could be explored which would expand the scope of the project regionally and from primary and secondary care to other data sets that looked at societal benefits.

A clinician from the NHS region in question initially contacted the ABPI about the project through Novartis in August 2016. The project was a collaboration between the ABPI and a named health board and was funded by four members of the ABPI Scotland Collaborations Group (SCG), namely Pfizer, AstraZeneca, Roche and Novartis in the sum of £32,480.50 per member, and by the ABPI in the sum of £10,000 (equating to a total industry contribution of £139,922). The total contribution from the NHS towards the project was £118,309.50. A copy of the signed Contribution Agreement and Trade Mark Licence dated 13 March 2018, which set out the contractual terms relating to this project, was provided.

Novartis explained that in return for their funding of the project, an ABPI SCG representative and representatives from the four companies were entitled to attend project steering group meetings in order to monitor implementation of the project and to report back on project progress to the wider ABPI SCG. Additionally, the ABPI SCG could input into the project by advising the NHS region on external communications elements in relation to the project. Further, on completion of the project, the four group members would also be able to pilot the new process of accessing the NHS regional real-world data (an outcome of the project) by asking the data framework questions set out in the project protocol provided. The four group members might use the authors of those questions to support future health technology appraisal (HTA) submissions.

For the avoidance of doubt, the project used existing data within the NHS specific region. The ABPI SCG and the four group members would only see anonymised (ie non-identifiable) and aggregated data.

Classification of the Project

Novartis submitted that the project was a joint industry and NHS collaboration which included some features of joint working, namely:

- The pooling of industry and NHS resources to implement a project for the benefit of patients;
- Outcomes would also benefit the NHS and the ABPI (and the four group members);
- Both the named health board and the ABPI made a significant financial contribution towards the project; and
- Defined project outcomes were to be measured and documented.

However, the project benefits were not explicitly focused on patients, but rather on helping the NHS to use Electronic Health Care Record Data whilst also helping the pharmaceutical industry to explore the potential for a Breast Cancer Data Framework to help HTA research. This took the project outside the scope of joint working arrangements covered by Clause 20. There were several other reasons why this project was not classified as joint working by the ABPI SCG.

Firstly, at the project concept phase, certain stakeholders within the NHS region stated that they would only collaborate and contract with ABPI Scotland in relation to the project; they did not want to contract directly with the four industry members of the ABPI SCG. The proposal went to the ABPI for comment and it was recommended that the project should be overseen by the ABPI SCG. It was decided at an ABPI SCG meeting that the ABPI (which would also make a financial contribution towards the collaboration) would enter into the relevant agreement on behalf of the ABPI SCG.

The four group members saw the benefits in the increased adoption of real-world electronic health data and wanted to contribute financially to the ABPI towards its participation in the project. The ABPI supported this approach. It was hoped that participation in the project would raise the profile and credibility of the industry with healthcare organisations and the Scottish Government and would create future opportunities for collaborative working.

Whilst joint working under Clause 20 might have been a logical fit for this activity, the ABPI advised the four group members that – as an organisation – it could not enter into joint working agreements. The ABPI was satisfied that this was collaborative working between ABPI SCG and its external partners and it drafted a contract for consideration by the four group members.

An agreement drafted by the ABPI reflected the collaborative nature of the project and outlined the benefits received by the ABPI SCG and the four group members in return for their funding. The agreement was signed on behalf of the ABPI.

Before signing, each of the four group member companies sent a confirmation statement to the ABPI in which it confirmed that it was happy for the ABPI to contract on behalf of the ABPI SCG, namely by confirming:

> 'For and on behalf of [company name], I hereby authorise ABPI to enter into this contract on behalf of the ABPI Scotland Collaborations Group, and to pay for the contract using the Group's collected funds.'

The Novartis confirmation was provided.

Classification of activity under the Code

In Novartis' view, the project was not a medical and educational goods and services arrangement falling within the scope of Clause 19 because of the collaborative nature of the project and because the ABPI SCG and the four group members would get certain benefits in return for their funding (as outlined above).

Novartis considered that (for the reasons given above) the project could not be classified as joint working under Clause 20. However, Novartis noted that Clause 21 gave direction on how to manage 'other funding by the company not otherwise covered by the Code'. In line with the requirements of Clause 21, a letter of agreement dated 21 November 2017 had been signed by Novartis and the ABPI (copy provided). This letter of agreement also set out other terms relating to the provision of funding to the ABPI by Novartis, including the basis upon which the ABPI had entered into the agreement with the NHS region. Agreements made it clear that Novartis (and the other three group members) might publicly disclose the funding which they contributed to the total value transferred by the ABPI to the NHS region under the arrangements. Novartis would publish the funding on its website imminently as part of its 2017 funding disclosure exercise.

Internal approval steps

The project was fully reviewed and approved internally by Novartis, including by medical, compliance and legal functions. The project protocol was certified in Zinc (copy approved). Novartis did not have a Zinc job category to cover collaborative projects entered into by the ABPI (towards which it provided funding). It was therefore decided that a 'joint working' Zinc job category should be used for internal approval purposes as this was the closest 'fit' to the collaborative and non-promotional nature of the project. However, it was clearly stated in the job summary within Zinc that this project was an ABPI Collaboration Agreement and not joint working. The job summary was provided. An executive summary was not published on the Novartis website as this was an ABPI-contracted project that had not been classified externally as joint working.

Novartis' response to the complaint

Novartis submitted that whilst including some features of joint working, the project was not structured as joint working, but as a collaboration arrangement under the guidance of the ABPI.

Novartis noted that Clause 21 gave direction on how to manage other funding by the company not otherwise covered by the Code. For the reasons described above, it was purposefully not set up as a joint working arrangement, including because the agreement that was put in place to govern the arrangements was entered into by the ABPI (and not the four individual pharmaceutical companies involved in funding the project) and the ABPI could not itself enter into joint working arrangements. There was no executive summary published because the arrangements were not structured as joint working, and the ABPI (rather than the four group members) was the contracting party to the agreement. Therefore, the provisions of Clause 20 relating to the publication of executive summaries did not apply to the four group members.

The project was fully reviewed and approved internally within Novartis and the necessary documents certified using the Novartis joint working Zinc job category as it was the closest fit to the collaborative and non-promotional nature of the project. Novartis considered that the arrangements relating to the project, including the entering into the Contribution Agreement and Trade Mark Licence by the ABPI on behalf of the ABPI SCG, were appropriate. In line with the requirements of Clause 21, Novartis would publish details of the funding it provided towards the project on its website imminently as part of its 2017 funding disclosure exercise.

Novartis denied a breach of Clause 20.

Novartis' involvement in the project (as a group member of the ABPI SCG) was reviewed and approved internally in accordance with the Code and relevant standard operating procedures (SOPs). Novartis considered that the project was a strong example of non-promotional collaborative working between the pharmaceutical industry and the NHS and that the highest standards were maintained throughout the design, approval and delivery of this innovative oncology-focused project. The ABPI and all four group members of the ABPI SCG agreed on the appropriateness of the classification of the project as a collaboration arrangement which would be entered into by the ABPI on behalf of the ABPI SCG.

Novartis denied a breach of Clause 9.1.

The project had the clear aims of driving improvements in health outcomes, introducing new models of technology with evidence development and commercial value reimbursement models, and supporting the optimisation of treatment options. The data-driven improvements which were the focus of this innovative project had the potential in the future to benefit patients by leading to improved patient concordance, adherence and benefit from their therapies, and by the generation of better information as a basis for patient-specific treatment decisions.

Novartis considered that its management of this project complied with Clause 21. The arrangement was put in place to provide funding for the health board to create the data framework and a model in which both industry and the NHS could use that data. The arrangements were managed via a collaboration coordinated by the ABPI and a contract was put in place with the ABPI. No other clause explicitly defined this type of collaboration.

With this in mind, Novartis considered that rather than bringing the industry into disrepute, the project was an example of collaborative working between the pharmaceutical industry and the NHS with the aim of enabling the NHS to use data more effectively and allowing industry to use the data to bring innovations to the market. Therefore, it served to improve industry reputation rather than to damage it. The generation and use of real-world data would be of significant and of increasing importance both in oncology and more broadly as the healthcare system looked to make more targeted patient-specific treatment decisions in the future, which in turn would drive improved patient outcomes. To this end, Novartis had received positive feedback on the nature of the project from multiple external stakeholders.

Novartis recognized that Clause 2 was a sign of particular censure, and as such was reserved for such circumstances. Novartis denied a breach of Clause 2.

Conclusion and summary of Novartis' position

Novartis denied any breach of Clauses 20, 9.1 or 2. Whilst the project included some features of joint working, it was structured as a collaboration arrangement between industry and the NHS. Whilst not expressly covered by the Code, Novartis treated this as a non-promotional collaboration, and it fully applied the principles of the Code in relation to this activity. In line with the requirements of Clause 21, Novartis would publish details of the funding it provided towards the project on its website imminently as part of its 2017 funding disclosure exercise. The agreement which governed the project arrangements was entered into by the ABPI. An executive summary was not published on the Novartis website as this was an ABPI-contracted project that had not been classified as joint working, and so the provisions of Clause 20 relating to the publication of executive summaries did not apply.

Novartis stated that as a result of this complaint, it would publish on its website executive summaries of all ABPI-led sub-group collaboration arrangements with which it engaged in the future. It would also investigate the addition of a new certification category of collaboration arrangements to its internal Zinc approval system.

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 Novartis. All four companies were members of the ABPI Scotland Collaborations Group (SCG). 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] cancer Network, Version 9, Date of Preparation June 2017, which was appended to the agreement between the ABPI and the Scottish health board dated 13 March 2018. The version certified by Novartis was Version 10 and bore a Date of Preparation of August 2017. 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 regional breast cancer patients 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 the NHS region's contributions as set out in the protocol. The Panel noted the companies' ongoing role on the steering committee. The Panel also noted Novartis' submission that the ABPI SCG could input into the project by advising the NHS region on external communications elements in relation to the project.

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, according to Novartis, the NHS region had not wanted to contract directly with the pharmaceutical companies and thus the contract was made with the ABPI. The Panel noted the sensitivities. The Panel noted 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 contract between the NHS region and the ABPI, and between the ABPI and each individual company, 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 agreement between the ABPI and the NHS region dated 13 March stated at the section headed Compliance in relation to declaration of the companies' involvement in the project that ABPI SCG comprised four named companies including Novartis. The four companies were also listed alongside their financial contributions in an appendix to that agreement. The project protocol appended to the agreement did not name the companies, although the certified version did.

The Panel noted that the four companies had each paid £32,480.50 and that the ABPI SCG had paid £10,000 towards the project giving a total of £139,922. The NHS had contributed £118,309.50. In the Panel's view, the role of the ABPI did not preclude the arrangements being joint working.

The Panel noted Novartis' submission that the project was a joint industry and NHS collaboration. Novartis had certified the protocol as joint working as it considered this to be the closet fit to the nature of the project. 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 the regional health board and the four SCG companies, including Novartis, 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 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 accepted the option to appeal.

APPEAL BY NOVARTIS

Novartis submitted that its primary argument on appeal in relation to the Panel rulings was that, whilst the ultimate expectation of the project was that the outcomes would benefit multiple stakeholders including patients, those elements of the project which Novartis actually supported (as further described below) were not patient-centred in nature, rather they were data-centred. As such, the project was not – and did not need to be - classified as joint working and no executive summary of the written agreement needed to be published.

Novartis submitted that the background to the cancer data project was set out in its response to the complaint. The project was a collaboration between a Scottish region health board and ABPI Scotland (on behalf of the four pharmaceutical companies involved; Novartis, Roche, AstraZeneca and Pfizer) that sought to drive adoption of real-world electronic health data relating to current care pathways and patient populations, and to better incorporate such data into HTA processes by developing a reproducible data-driven Scottish cancer technology evaluation framework. The overall expectation of the project (when all phases had been completed) was that the adoption of pooled real-world data would also drive a clearer understanding of the best treatment pathways in breast cancer.

Novartis submitted that the collaboration between the four companies and the NHS region was limited only to the completion of Phase 1 of a broader project which would involve three phases in total. Phase 1 of the project would be limited to the review of data related to patients' resident, diagnosed or treated within the NHS region. Phase 2 of the project would involve potentially expanding its scope to the other health boards; and Phase 3 would involve potentially expanding its scope across NHS Scotland nationally. There were no plans for the four companies to be involved in Phases 2 and 3 of the project.

Details of the project – data-centred outcomes

Novartis submitted that further details of the three project phases and the detail around Phase 1 of the project were set out in the project protocol. The project protocol was clear that Phase 1 of the project was strictly focused on data-centred rather than patient-centred outcomes. The project involved the development of a breast cancer data framework. The project outcomes as described in the project protocol were as follows:

1 A data dictionary – describing data fields, their origins, historical lifespan, definitions and coding.
2 A data quality report – describing missing data rates, discrepancies between alternative data sources for variables and actions needed for improvement.
3 Example epidemiological, clinical pathway and outcomes reports.

Novartis submitted that the multitude of available datasets upon which the project would be based, both within Edinburgh and nationally within Scotland, were set out in Appendix 1 to the project protocol. The required data fell broadly into four categories: patient characteristics, clinical pathway descriptors, outcome data, and resource use and healthcare burden. Furthermore, the project work plan as set out in the project protocol involved three milestones, namely:

> *Milestone 1 (months 1-12):* Create a technical data dictionary, listing fields contained within each dataset, their definitions, coding, geographical and historical remit. Obtain permissions for milestone 3.
>
> *Milestone 2 (months 1-12):* Create a technical data quality report, including missing data rates, field and coding discrepancies, between-dataset duplication and variation over time and by geographical remit. Limited reporting of population summary statistics. Map data fields to parallel fields reported from other Scottish regional and national datasets.
>
> *Milestone 3 (months 13-18):* Examples for study, reporting on clinical characteristics, patient pathways, outcomes and healthcare resource utilization. The results would be published in an end of milestone report using anonymized and aggregated data and would be used to validate the robustness of the data framework. The report would be made publicly available.

Novartis submitted that the NHS region would use the project and constituent examples to develop and refine a process for analytical specification and information gathering by external parties in order to better inform national regulatory submission. The four companies taking part in the project would then be given the opportunity to pilot this new process.

Novartis submitted that the benefits listed in the project protocol and the milestones in the project work plan were not primarily patient-focused and for the benefit of patients, rather they were data-focused and primarily for the benefit of the NHS and the pharmaceutical industry. The payments per milestone also conveyed the very data focused nature of the work being performed by those involved in the project.

Categorisation of the project

Novartis submitted that the project was a joint industry and NHS collaboration and the whole project included some features of joint working. However, the project outcomes were not focused on patients, but rather on helping the NHS to develop a breast cancer data framework whilst also helping the four pharmaceutical companies to explore the potential for the framework to help HTA research. This data-centred rather than patient-centred approach to the project outcomes took the project outside the scope of joint working arrangements covered by Clause 20 of the Code.

Novartis submitted that in line with the requirements of Clause 21 which gave direction on how to manage 'other funding by the company not otherwise covered by the Code', a letter of agreement dated 21 November 2017 was signed by Novartis and the ABPI. This letter of agreement also set out other terms relating to the provision of funding to ABPI by Novartis, including the basis upon which ABPI was entering into the agreement with the NHS region.

Novartis submitted that for the reasons described above, the project was purposefully not set up as a joint working arrangement. The project was however fully reviewed and approved internally by Novartis, which included involvement from Novartis medical, compliance and legal functions. The project protocol was certified on Novartis' Zinc approval system. Novartis did not have a Zinc job category to cover collaborative projects entered into by ABPI (towards which it provided funding). It was therefore decided that a 'joint working' Zinc job category should be used solely for internal approval purposes as this was the closest 'fit' to the collaborative and non-promotional nature of the project. However, it was clearly stated in the job summary within Zinc that this project was an ABPI Collaboration Agreement and not joint working. An Executive summary was not published on the Novartis website as this was an ABPI-contracted project that had not been classified externally as joint working.

Novartis submitted 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, experiences and/or resources for the joint development and implementation of patient-centred projects and share a commitment to successful delivery. This definition was reproduced in the supplementary information to Clause 20 Joint Working in the Code. 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 was expected that the arrangements would also benefit the NHS

and the pharmaceutical company or companies involved. Clause 20 also 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.

Novartis noted that the Panel stated that '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' and the Panel concluded that it considered that the benefits listed in the protocol in relation to Phase 1 of the project could be predominantly characterized as for the benefit of patients. Novartis respectfully disagreed with this assessment by the Panel.

Novartis submitted that whilst Phases 1 to 3 of the project included some features of joint working as explained above, the outcomes of Phase 1 of the project were focused on data-centred rather than patient-centred outcomes and involved the development of a breast cancer data framework. Joint working projects must have a clear focus on patient benefits. This was not the case in relation to those elements of this project supported by Novartis and the other pharmaceutical companies which were predominantly focused on the benefits to the NHS and industry through the development of the breast cancer data framework.

Novartis submitted that therefore, the project was structured not as joint working, but as a collaboration arrangement. The complainant asked why an executive summary of the project did not appear on the Novartis website. An executive summary was not published on the Novartis website because the arrangements were not joint working. Therefore, the provisions of Clause 20 of the Code relating to the publication of executive summaries of the written agreement between the parties did not apply to the four companies involved in the collaboration.

Novartis submitted that the project was fully reviewed and approved internally within Novartis and the necessary documents certified. The fact that it was not a joint working project was made clear in the Zinc job summary. On this basis, Novartis appealed the Panel ruling of a breach of Clause 20 of the Code.

Novartis submitted that its involvement in this project was reviewed and approved internally in accordance with the Code and its SOPs, maintaining high standards throughout the design, approval and delivery of this innovative and collaborative non-promotional project. On the basis of its argument that this project did not constitute joint working because of its data-centred outcomes, breaches of Clauses 20 and 9.1 were inextricably linked, and if there was no breach of Clause 20 then there could be no argument that high standards were not maintained. Novartis, therefore, also appealed the Panel ruling of a breach of Clause 9.1 of the Code.

COMMENTS FROM THE COMPLAINANT

The complainant provided no comments on the appeal.

APPEAL BOARD RULING

In addition to the submission from Novartis the Appeal Board noted relevant elements of its rulings in its consideration of the appeals from Pfizer (Case AUTH/3045/6/18) and AstraZeneca (Case AUTH/3046/6/18).

The Appeal Board noted that the complaint highlighted the ABPI news publication and tweet about the Scottish collaboration with four of its member companies (including Novartis) in a named Scottish region cancer data project. The Appeal Board noted that the news article stated that 'A ground-breaking collaboration will use real-world data to investigate how well different cancer treatments really work, changing Scotland's approach to breast cancer research like never before.' The Appeal Board noted from the appeals by Pfizer (Case AUTH/3045/6/18) and AstraZeneca (Case AUTH/3046/6/18) that the communications should have been agreed by the companies and this had not been so. The companies had submitted that they would not have approved the ABPI press release as issued.

The Appeal Board 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 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. 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.

The Appeal Board noted the 'ABPI Joint Working A Quick Start Reference Guide for NHS and pharmaceutical industry partners' included a criteria checklist which stated *inter alia* that if the answer was no in response to any one of a list 10 questions then the project would not be a true Joint Working arrangement. The 10 questions included that 'The main benefit of the project is focused on the patient', 'There is a significant contribution of pooled resources (taking into account people, finance, equipment and time) from each of the parties involved', 'There is a shared commitment to joint development, implementation and successful delivery of a patient-centred project by all parties involved' and 'Patient outcomes of the project will be measured and documented'. The Appeal Board

noted that the guidance was not part of the Code or the supplementary information. It nonetheless provided helpful points for the companies to consider when assessing such arrangements. The relevant supplementary information noted that the ABPI Guidance referred to the requirements of the Code but went well beyond them. The 'ABPI Joint Working A Quick Start Reference Guide for NHS and pharmaceutical industry partners' was not referred to by Novartis.

The Appeal Board considered that the documents could have been better worded to more accurately reflect the arrangements and this included the information issued by the ABPI.

The Appeal Board noted that the four companies had each paid £32,480.50 and that the ABPI SCG had paid £10,000 towards the project giving a total of £139,922. The NHS had contributed £118,309.50. In the Appeal Board's view, the role of the ABPI did not preclude the arrangements being joint working. The Appeal Board noted Novartis's involvement in the steering committee was to monitor and report back on its progress.

The Appeal Board noted Novartis submission that it had the necessary documents certified using the Novartis joint working Zinc job category as it was the closest fit to the collaborative and non-promotional nature of the project. Novartis did not consider that the project was a joint working project. Novartis considered that the arrangements relating to the project were in line with the requirements of Clause 21 of the Code.

The Appeal Board noted that the whole project included features of joint working, namely, the pooling of industry and NHS resources to implement a project with outcomes listed in the protocol for the benefit of patients and the benefit of the NHS and the four companies involved including Novartis; both the Scottish region health board and the four companies including Novartis had made a significant financial contribution towards the project; and defined project outcomes were to be measured and documented.

However, the Appeal Board noted that the protocol of agreement was limited to completing Phase 1. The outcomes of Phase 1 were a data dictionary, a data quality report and example epidemiological, clinical pathway and outcomes reports that would be aggregated and anonymised and only available to the companies when they had been published by the NHS region. Although referred in the protocol, Phases 2 and 3 were not part of the current protocol of agreement and there was no agreement or obligation that the company would be involved in them.

The Appeal Board noted that Novartis in its appeal provided better and further particulars than had been provided to the Panel particularly with regards to the actual outcomes of Phase I. Pfizer (Case AUTH/3045/6/18) and AstraZeneca (Case AUTH/3046/6/18) also commented on the misleading nature of the ABPI press release at their appeals.

The Appeal Board noted that its role was solely to determine whether the activity at issue was joint working thereby triggering the requirement to publish an executive summary.

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. The appeal on both points was successful.

Complaint received	**5 June 2018**
Case completed	**22 May 2019**