ANONYMOUS CONTACTABLE v PFIZER

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 Pfizer. The complainant stated that the ABPI had, *inter alia*, published news of the collaboration. The complainant had not seen relevant details published on Pfizer'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 Pfizer' 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 Pfizer 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 Pfizer the NHS region had requested that the contract and funding for the project were managed by the ABPI on behalf of the four funding companies. Relevant email correspondence was provided. 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 Pfizer's submission that the project was a financial grant which was classified as a MEGS. It appeared to have been certified as such. The Panel further noted Pfizer's submission that its internal policy prevented it from being able to take any form of direct benefit in return for the provision of a grant. Pfizer would, therefore, not be participating in any piloting of the HTA process. Only very brief details appeared in the protocol. This did not appear to be part of Phase 1 of the project with NHS region. 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. This ruling was not appealed.

Upon appeal by Pfizer 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 Pfizer's submission that the project was a financial grant which was classified as a MEGS. At the appeal Pfizer submitted that its position on the steering committee was good financial auditing practice to ensure that the grant was spent as agreed.

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 Pfizer; both the Scottish region health board and the four companies including Pfizer 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 to 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 Pfizer 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 and what Pfizer considered to be the misleading nature of the ABPI press release.

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 its comments above and considered that the benefits listed in the protocol in relation to patients would only come about if Phases 2 and 3 were undertaken and completed; there was no patient centred benefit at the end of Phase 1. The purpose of Phase 1 and its outputs were data centred rather than patient centred. The Appeal Board considered that the arrangements at Phase 1 of the project in relation to 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 in this regard. The appeal on both points was successful.

Following its completion of the consideration of the appeals in Case AUTH/3045/6/18 and Case AUTH/3046/6/18 (AstraZeneca), the Appeal Board noted that the respondent companies in Case AUTH/3043/6/18 (Novartis) and Case AUTH/3044/6/18 (Roche), had accepted the Panel's rulings of breaches of the Code and had not appealed. AstraZeneca had appealed Case AUTH/3046/6/18.

The Appeal Board agreed that Novartis and Roche should be contacted and informed of the outcome of the appeals in Case AUTH/3045/6/18 and Case AUTH/3046/6/18. 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 should each be offered the opportunity to appeal out of time and the appeal process would operate in the usual way. The complainant should also be informed. The reports for Case AUTH/3043/6/18 and Case AUTH/3044/6/18 should be updated to reflect the situation and to cross refer to the cases which were successfully appealed. 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 Pfizer.

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

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 Pfizer's' 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 Pfizer's 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 Pfizer, the Authority asked it to consider the requirements of Clauses 2, 9.1 and 20.

RESPONSE

Pfizer stated that the project had not been set up as a joint working project and was therefore not subject to the requirements of Clause 20. The collaborative project had been designed to explore how comprehensive linked local, regional and national cancer datasets could be used to facilitate treatment decisions and deliver better outcomes and experiences for patients in Scotland. Pfizer did not consider that the project proposal met the criteria for a joint working initiative:

- The support requested from Pfizer was funding rather than pooling of skills and resources to enable delivery of the project and
- Whilst the overarching aim of the project was to better use Scottish cancer patient data to optimise patient care, a direct measurable benefit for patients would not be delivered during the execution of the project.

For these reasons Pfizer elected to support the project by provision of a financial grant towards the costs of the project in line with the requirements of Clause 19.2.

The arrangements for the Medical and Educational Goods and Services (MEGS) Grant were:

- The ABPI coordinated funding for the project on behalf of four member companies of the ABPI Scotland Collaborations Group (SCG). The total amount of funding to be provided to the NHS region was made up of contributions of £32,480.50 from each of the four companies, plus a payment of £10,000 from member company subscriptions to the ABPI SCG, held by the ABPI. The ABPI made an upfront payment of £123,681.75 on 20 April 2018, the project initiation date, and a second payment of £16,240.25 was due to be made 12 months later (documents concerning the arrangements were provided).

- At the NHS region's request the contract and funding for the project was managed by the ABPI on behalf of the four funding member companies.

- A letter of agreement between Pfizer and the ABPI set out the arrangements with respect to funding of the project. This agreement included the following provisions:
  - The ABPI must enter into a contract with the NHS region with respect to the arrangements for the project and associated funding declarations.
  - It was acknowledged that the funding was not provided to the ABPI or the NHS region to induce, influence or reward any actions.
  - The ABPI consented to relevant disclosures being made against the ABPI if applicable.
  - The ABPI and Pfizer should comply with applicable laws, regulations and industry Codes in relation to the funding.

- The ABPI then put an agreement in place with the NHS region with respect to the project activities and declarations and disclosures of funding. This agreement contained the following provisions:
  - As required by Clause 19.2, the parties acknowledged that funding was not provided to influence prescribing or purchasing decisions for any medicines.
  - As set out in the supplementary information to Clause 19.2, the contracting parties acknowledged the disclosure requirements for the funding companies. The NHS region had agreed to provide any information which might be needed to calculate the percentage of support from the companies.
  - In line with the supplementary information to Clause 19.1, the NHS region was required to prominently display the ABPI logo and funding companies' names on all materials related to the project to make the industry's involvement in the project clear from the outset.
  - Member companies must review draft materials produced in connection with the project to ensure that funding companies' names were suitably prominent. The agreement did not give funding companies the right to review the content of materials and the agreement explicitly stated that NHS region retained full control and liability concerning the activity and all promotional and marketing activities in connection with it. The project protocol also stated that no data and analyses related to clinical outcomes would be shared with the steering committee until it had been published and made publicly accessible.
  - Each member company would have the right to nominate an employee to represent it on the project steering committee which would monitor implementation of milestones, approve release of the milestone payment and potentially support the development of sub-study work packages

- These agreements had been non-promotionally certified by Pfizer in line with paragraph 8 of the supplementary information of Clause 19.1 and Clause 14.3.

- Pfizer was currently processing a payment of £32,480.50 to the ABPI, which was the company's contribution to the costs of the project. In line with the supplementary information Clause 19.2, Pfizer intended to disclose this transfer of value to the NHS region in its 2018 disclosure data.

Pfizer stated that as described above and in the enclosures, the arrangements for it to support the cancer data project complied with Clause 19. The arrangements were therefore not within scope of Clause 20 and Pfizer did not believe that any aspect of the arrangements represented a breach of that clause. The grant had been appropriately documented and kept on record by Pfizer; Pfizer submitted that it had maintained high standards in all aspects of its support for the project and had not brought discredit upon or reduced confidence in the industry. Pfizer thus strongly refuted any allegation of breaches of Clause 9.1 or Clause 2.

In response to a request for further information Pfizer submitted that it understood the meeting held on 31 January 2017 to be an exploratory meeting designed to enable the NHS region colleagues to present their project to key stakeholders and potential supporters and enable members of the ABPI SCG to determine their interest in supporting the project. The meeting invitation clearly stated that attendance at the meeting did not represent commitment to support the project. Therefore whilst the meeting minutes recorded agreement of the proposed aims and objectives of the project, this was in the context of early preliminary discussions not limited to the eventual funding companies.

At the meeting a consultant physician presented an overview of the project identifying three key aims to be addressed by linking cancer datasets. Could comprehensive linked local, regional and national cancer datasets be used to:

- understand the epidemiology of a tumour specific group to support health technology assessment (HTA)?
- facilitate the assessment of outcomes including effectiveness, tolerability and value of recently adopted new technologies for cancer?
- support improvement in patients' experience through medicines optimisation?

Two objectives were also identified for the project that would support the aims described above:

- to describe the data completeness, data quality and scope of a comprehensive linked regional cancer dataset.
- to build an analytics 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 minutes of the meeting reflected that the attendees agreed that the scope of the project was of general interest and suggestions for refinement of the project protocol were also minuted.

Companies took an action from the meeting to confirm their interest in supporting the project. Pfizer assessed the project as having clear patient and NHS benefit through the potential for the NHS to better assess the outcomes associated with the introduction of new technologies for cancer as well as improved patient experience through medicines optimisation.

The potential for companies to access the linked datasets to support HTA was also of interest to Pfizer; however, it understood this potential benefit not to be limited just to the funding companies but that, if the project was successful, any company would be able to commission analyses of the linked cancer datasets. Given these aims and objectives along with the NHS region's request for financial support, rather than colleague resource, Pfizer determined that the project should be supported following the framework set out in Clause 19.

Pfizer submitted that as a funder of the project it had a very limited role on the project steering committee. Under the terms of the agreement put in place between the ABPI and the NHS region, each member company had the right to nominate an employee to represent them on the project steering committee which would monitor implementation of milestones, approve release of the milestone payment and potentially support the development of sub-study work packages. Pfizer noted that it would consider any potential sub-study work package developing from the project as a separate activity and would assess whether and/or how to support, based on the details of the work package and any associated request from the NHS region.

Pfizer's nominated representative on the project steering committee was invited to a project kick off meeting on 20 March 2018 but he/she was unable to attend. A second Pfizer representative did attend in place of the first representative. The meeting minutes summarised the topics discussed at the meeting and included the following sessions:

- Presentation of the overarching aims, objectives and deliverables of the project-consultant physician the NHS region.

- NHS region presentation of a summary of the Information Governance workstream. This presentation included a request for the four ABPI member companies supporting the project to provide advice on the potential data requirements that pharmaceutical companies would have of the comprehensive linked regional cancer dataset to support HTA applications in the future. Any advice provided by the four ABPI member companies would be used by the project governance workstream to develop a robust and appropriate information governance framework for the project. Pfizer's understanding of this request is that the information to be provided by the companies would be representative of the pharmaceutical industry's requirements as a whole and not specific to any individual companies' medicines or requirements. Although an action to provide this feedback was minuted at the kick off meeting on 20 March 2018, to date Pfizer had not provided any feedback of this nature to the project group.

- Agreement that the steering committee would meet face-to-face at months 12 and 18 of the project. This was designed to align with the project reporting milestones and in particular would enable review of the project's progress at

the 12 month point in order for the ABPI member companies to authorise release of the second tranche of funding (£16,240.25), if appropriate. Interim tele/video-conferencing steering group meetings had been agreed in order to continue to monitor progress against the project timeline.

- A communications framework for the project was discussed and the need for any proposed publications or outputs from the project to be reviewed by the ABPI member companies was reiterated. This was consistent with the Contribution Agreement and Trade Mark Licence which stated that member companies must review draft materials were produced in connection with the project to ensure that funding companies' names were suitably prominent.

An interim steering committee teleconference was held on the 2 July 2018. Pfizer's steering committee member was unavailable to attend and his/her nominated delegate failed to join the meeting due to connectivity problems. The minutes of the meeting indicated that a general progress update was provided to the group.

Pfizer submitted that this was the total extent of its ongoing involvement with the project.

Pfizer submitted that although the contract set out that the ABPI member companies supporting the project would have an opportunity to pilot the new process, Pfizer would not take up this opportunity. Pfizer's internal policy on provision of Medical and Educational Goods and Services (MEGS) prevented Pfizer being able to take any form of direct benefit in return for the provision of a grant. Pfizer suggested that each of the four member companies individually contract directly with the NHS region so that each company could address its own policy requirements within its contract, however, the NHS region requested that the contract and funding for this project be managed by the ABPI on behalf of the four funding member companies. As the member companies supporting the project had differing polices governing whether they were able to participate in piloting the process, the provision remained in the agreement but was not an opportunity that Pfizer would be able to progress.

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 Pfizer. 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 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.

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 Pfizer the NHS region had requested that the contract and funding for the project were managed by the ABPI on behalf of the four funding companies. Relevant email correspondence was provided. 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 Pfizer. 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.

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 Pfizer's submission that the project was a financial grant which was classified as a MEGS. It appeared to have been certified as such. The Panel further noted Pfizer's submission that its internal policy prevented it from being able to take any form of direct benefit in return for the provision of a grant. Pfizer would, therefore, not be participating in any piloting of the HTA process. Only very brief details appeared in the protocol. This did not appear to be part of Phase 1 of the project with NHS region. 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 the regional health board and the four SCG companies, including Pfizer, 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.

APPEAL BY PFIZER

Pfizer submitted that the project arrangements failed to meet the requirements of a Joint Working initiative and were therefore not in breach of Clauses 20 and

9.1 of the Code for the following reasons:

1 The project did not deliver a direct, tangible and measurable benefit to patients.
2 The project protocol was not jointly developed by the NHS region/named university and the ABPI SCG member companies.
3 The support provided for the project by the ABPI SCG was simply funding and did not involve significant pooling of resources for the joint implementation of the project protocol.

The details of Pfizer's assessment of the project against these criteria were set out below.

Reasons for Appeal Point 1 Objectives and Benefits of Joint Working Projects

Pfizer submitted the following relevant Code and ABPI Guidance on the Benefits and Objectives of Joint Working:

- Clause 20 of the Code and the ABPI Guidance Notes on Joint Working defined Joint Working as situations where, **for the benefit of patients**, the NHS and pharmaceutical industry pooled skills, experience and/or resources for the joint development and implementation of **patient centred projects** and shared a commitment to successful delivery.
- The joint working checklist published in the ABPI Quick Start Reference Guide required that **patient outcomes of the project would be measured and documented**.
- The ABPI Joint Working with the Pharmaceutical Industry, Guide and Case Studies defined joint working as having the shared aim of **achieving pre-determined improvements for patients**.
- The ABPI Guidance Notes on Joint Working also recommended that **a set of baseline measurements should be established at the outset of the project to measure the success of the project aims, particularly patient outcomes**. The guidance notes also recommended that for longer projects (>1 year) patient outcomes should be analysed at least every six months as a minimum to ensure anticipated patient benefits were being delivered. Examples of how patient outcomes of a Joint Working project might be measured were provided in the ABPI Guidance Notes and included examples such as an increase in the number of appropriately diagnosed/ treated patients or a decrease in the number of inappropriately diagnosed/treated patients as well as changes in parameters such as patient satisfaction, understanding, concordance and adherence to therapy.
- Clause 20 of the Code and the ABPI Guidance Notes both recognised that whilst a Joint Working project must be for the benefit of patients, it was expected that the arrangements would also benefit the NHS and the pharmaceutical companies involved.

Pfizer's Interpretation of the Code and ABPI Guidance:

Pfizer understood these definitions and guidance notes to mean that an essential and primary requirement of a Joint Working project was a direct, tangible and measurable impact on patients during the actual implementation period of the project, such that a change in a patient focused parameter could be evaluated between the beginning and end of the project. The examples provided in the ABPI Guidance Notes of how the patient outcomes of a Joint Working project might be measured underpinned this understanding. Whilst Pfizer recognised that a Joint Working project might also benefit the NHS and pharmaceutical companies it understood that there must be a primary direct benefit to patients.

Objectives and Benefits of the cancer data project:

Pfizer submitted that the cancer data project was a data intelligence initiative with a high level objective of harnessing the unique data opportunities in Scotland for the primary purpose of improved health technology appraisal (HTA). Patient benefits were described as subsequent to the objective of improved HTA.

Pfizer submitted that the first step in being able to use Scottish data to improve HTA was described in the project protocol as an urgent requirement to understand the detail of what was currently possible and what further developments must be undertaken to deliver on the objective. To this end the first phase of the project, supported by the ABPI SCG, was focused on the Breast Cancer Patient Pathway in a named region of Scotland. Phase 1 of the project and the subject of this complaint had the objective of:

1 Describing the data completeness, data quality and scope of a comprehensive linked regional cancer dataset.

2 Building an analytics 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 protocol went on to describe the project outcomes as:

1 A data dictionary – describing data fields, their origins, historical life span, definitions and coding.

2 A data source 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.

The protocol later listed the benefits for patients as being:

- improved patient concordance, adherence and benefit from therapy through additional support of data to ensure optimal use of their medicines
- better information as a basis for specific treatment decisions.

Pfizer submitted that however these benefits would only be delivered for patients if all 3 phases of the protocol were delivered and then fully implemented at a later date. The stated objectives or outcomes for Phase 1 of the protocol were not able to deliver the patient benefits described above over the 18 month timeframe of the project. The planned outcomes or deliverables for Phase 1 of the protocol were data and data-infrastructure focused with no impact on patients during this phase of the project. Whilst milestone 3 would deliver example epidemiological, clinical pathway and outcomes reports there was no plan to implement and evaluate any changes to patient care based on these reports. For these reasons Pfizer did not believe that the project met the patient benefit requirements for Joint Working as set out in Clause 20 of the Code and ABPI Guidance Notes on Joint Working. The project objectives and outcomes of Phase 1 of the protocol primarily benefited the NHS. Whilst benefits to the NHS and Industry partners were acceptable within a Joint Working arrangement the primary objective for a Joint Working arrangement must always be a direct, tangible and measurable benefit for patients.

Reasons for Appeal Point 2 Development of Joint Working Projects

Pfizer submitted the following relevant Code and ABPI Guidance on the Development of Joint Working:

- Clause 20 of the Code and the ABPI Guidance Notes on Joint Working defined Joint Working as situations where, for the benefit of patients, the NHS and pharmaceutical industry pooled skills, experience and/or resources **for the joint development** and implementation of patient centred projects and shared a commitment to successful delivery.

- The Joint Working checklist published in the ABPI Quick Start Reference Guide required that there was a shared commitment to **joint development**, implementation and successful delivery of a patient- centred project by all parties involved.

Pfizer's Interpretation of the Code and ABPI Guidance:

Pfizer understood these definitions and guidance notes to mean that a key requirement of a Joint Working project was that the NHS and industry organisations worked together to develop the project plan or protocol. This joint responsibility for the development of the project was a key differentiator between Joint Working projects and those supported by Medical and Educational Goods and Services (MEGS) grants under Clause 19 of the Code.

Development of the cancer data project:

Pfizer submitted that the cancer data project aims, objectives and protocol were presented by a consultant physician from a named university to interested industry parties at a meeting held on 31 January 2017. Whilst companies attending the meeting were able to make suggestions on developments to the protocol; the aims, objectives and protocol were developed by the NHS region and the named university and did not involve any input from Pfizer. This did not represent joint development of a Joint Working initiative.

Reasons for Appeal Point 3 Pooling of Skills, Experience and/or Resources in Joint Working Projects

Pfizer submitted the following relevant Code and ABPI Guidance on Pooling of Skills, Experience and/or Resources:

- Clause 20 of the Code and the ABPI Guidance Notes on Joint Working defined Joint working as situations where, for the benefit of patients, **the NHS and pharmaceutical industry pool skills, experience and/or resources for the joint development and implementation** of patient centred projects and share a commitment to successful delivery.

- The ABPI Guidance Notes on Joint Working stated that **there must be a 'pooling' of resources** between the pharmaceutical company or companies and the NHS organisation(s) involved. **Each party must therefore make a significant contribution to the Joint Working Project to avoid the arrangement being considered as merely a gift, benefit in kind, donation** or some other non-promotional/commercial practice. Resources might come in various forms, including people, expertise, equipment, communication channels, information technology and finance.

- The Joint Working Toolkit described Joint Working projects as being distinctly different from sponsorship. **In sponsorship arrangements pharmaceutical companies simply provided funds for a specific event or work programme.**

Pfizer Interpretation of the Code and ABPI Guidance:

Pfizer understood these definitions and guidance notes to mean that it was important for pharmaceutical industry involvement in Joint Working projects to be clearly differentiated from the funding and services arrangements provided to Healthcare Organisations as MEGS grants under Clause 19 of the Code. This differentiation was often achieved through the pooling of resources over and above funding. Pfizer usually expected to see Pfizer colleague resource and expertise involved in the joint development and delivery of a project, in addition to any financial support provided. On occasions where Pfizer colleague resource was not required or appropriate for the delivery of a project, Pfizer would expect to see significant Pfizer colleague involvement in the development of a project plan, in addition to provision of funding, for the project to be considered to meet the requirements for Joint Working.

Pooling of Skills, Experience and/or Resources in the cancer data project:

Pfizer submitted that schedule three of the project plan set out the contributions to the project from each party. This section clearly showed that the only support being provided for the project by the ABPI SCG was direct funding and that there

was no 'in-kind' ABPI SCG member resource or expertise involved in the implementation of the project. This was further evidenced by the roles and responsibilities described in the project protocol. The NHS region and the ABPI SCG were identified as the funders of the project whereas the NHS region and the named university were identified as the sponsors of the project and therefore the parties responsible for implementation of the protocol.

Pfizer submitted that although each of the ABPI SCG funding companies had a seat on the project steering committee, the responsibilities of the steering committee, in relation to Phase 1 of the project, were limited to monitoring implementation of the project milestones and authorising the milestone funding payment as appropriate. The steering committee had no role in the joint delivery of the project milestones.

Pfizer submitted that in addition to the lack of joint implementation of the protocol, it did not believe there was a balanced contribution of direct or 'in kind' resources from both parties. The breakdown of costings set out in schedule 3 indicated the total industry direct funding of £139,922 to be approximately matched by £118,309.50 of 'in kind' and direct funding from the NHS. This however included £17,082 of NHS direct funding and £48,178 of 'in kind' NHS resource for the Cross-cutting Information Governance (IG) work package. This work package was not identified as an outcome of Phase 1 of the project but was instead described as a requirement for analytical specification and information gathering by external parties to better inform national regulatory submission and therefore related to Phase 3 of the project which had a national scope and not Phase 1. If the costs of the Cross-cutting IG work package were removed from the calculations, the NHS region's actual contribution to Phase 1 of the project was £53,049.50 and did not represent true pooling of resources as was required for a Joint Working arrangement.

Pfizer submitted that it did not contribute to the development of the project protocol, that there was no ABPI SCG colleague resource involved in the delivery/implementation of the project and that there was not a balanced contribution of resources, Pfizer did not believe that the ABPI SCG input into the project met the Joint Working requirements of significant pooling of resources for joint implementation of a project. This was a situation where funding was simply being provided for the delivery of the protocol developed by the NHS region and the named university.

Reasons for Appeal Point 4 Joint Working Checklist

Pfizer submitted that the 'ABPI Joint Working Quick Start Reference Guide for NHS and Pharmaceutical Partners' required that potential Joint Working projects were reviewed against the Joint Working criteria checklist to ensure that the criteria for Joint Working were met. The guidance stated that if the answer to any of the red questions was no, then the project was not a true Joint Working arrangement and should not be viewed as such.
Pfizer submitted that based on the explanations provided in points 1 to 3 above, when it assessed the NHS region cancer data intelligence project against the questions on the Joint Working criteria checklist, the project failed to meet several of the criteria set out on the checklist and was therefore not considered to constitute a Joint Working arrangement.

	NHS region cancer data intelligence project Red Questions	Yes	No
1	The main benefit of the project is focused on the patient		✔
2	All parties acknowledge the arrangements may also benefit the NHS and pharmaceutical partners involved	✔	
3	Any subsequent benefits are at an organisational level and not specific to any individual	✔	
4	There is a significant contribution of pooled resources (taking into account people, finance, equipment and time) from each of the parties involved		✔
5	There is a shared commitment to joint development, implementation and successful delivery of a patient-centred project by all parties involved		✔
6	Patient outcomes of the project will be measured and documented		✔
7	All partners are committed to publishing an executive summary of the Joint Working agreement		*
8	All proposed treatments involved are in line with national guidance where such exists		✔**
9	All activities are to be conducted in an open and transparent manner	✔	
10	Exit strategy and any contingency arrangements have been agreed		✔

* Not considered or discussed
**Project designed to inform future development of national guidance rather than to implement existing national guidance

COMMENTS FROM THE COMPLAINANT

The complainant apologised if he/she misinterpreted or concluded anything. Deciphering the details and complexities of this project was difficult for an individual not connected with the project and with a layman scientific understanding. It was disappointing to see that Pfizer had chosen to appeal the Panel's ruling of breaches of the Code. The complainant alleged that his/her response addressed 3 key aspects of this project that set it apart from the requirements of the definition of joint working.

1 The project did not deliver a direct, tangible and measurable benefit to patients:

The complainant stated that he/she was unclear why Pfizer submitted that a project must have direct, tangible and measurable benefits to patients

as this statement did not exist in the Guidance document. Section 2 (Background to Joint Working) of the ABPI Guidance to Joint Working quoting from the Department of Health (DH) published its Joint Working Guidance in February 2008 stated that the NHS perspective was 'We will involve the industry systematically to support better forward planning and to develop ways of measuring the uptake of clinically and cost effective medicines once introduced'. It also stated later in this section 'However, for Joint Working to be sustainable in the longer term, it should also bring benefits to both the NHS organisation and the pharmaceutical industry partner, such as cost effective use of NHS resources and increase in shareholder value respectively'. Therefore, it made clear that projects could be those which look to better support planning activities and ones that were looking at measurements ie be long-term in their aims.

The complainant alleged that whilst industry and the NHS could enter into business to business arrangements which should have a protocol attached to the contract quite clearly laying out the schedule of the activity and also what was being supported by the money.

The complainant alleged that a Joint Working project must be focused on benefits to patients however he/she did not accept that there was a need for this exclusively be projects which had direct, tangible and measurable benefits to patients. Furthermore, Pfizer was currently involved in such a joint working project documented on its website. For this project Pfizer cited patient benefits as below which the complainant did not see as being 'direct, tangible and measurable'.

Benefits for Patients:

- Improved early stage education and risk awareness of disease
- Improved activation, screening and detection of underlying conditions
- Improved patient engagement, empowerment and control over their personal care journey (overall patient experience)
- Access to preventative services including health, wellness, social and mental health interventions
- Improved access to health, wellbeing and social care services, leading to increased speed of service attainment and easier navigation of a 'one-stop shop environment', that might improve attendance and convenience for patients, their care givers and their families
- Participation in a culture of clinical research via an ethos that all patients were candidates for clinical studies
- Improved active monitoring of condition progression, management and routine check-ups to optimise clinical and or health system response
- Continual adaptation of pathways and patient interventions to balance outcome improvement with patient control over living a full and positive life with their condition.

Therefore, the complainant did not accept that this was a valid reason why Pfizer did not see this activity as a Joint Working project.

2 The project protocol was not jointly developed by the NHS region/named university and the ABPI Scotland Collaborations Group (SCG) member companies:

The complainant noted that Novartis in its response (Case AUTH/3043/6/18) stated that its representative on the ABPI SCG was in talks with representatives from the NHS region board during 2016. This representative brought the project to the ABPI SCG meeting. Furthermore, this person was specifically named on the protocol alongside the authors. In addition, there were further meetings where the NHS region board participants presented to and discussed the project with the ABPI SCG as documented in the enclosures from Pfizer.

The complainant stated that all it required was to meet the second key principle of joint working – that ii) there must be a 'pooling' of resources between the pharmaceutical company or companies and the NHS organisation(s) involved. Each party must, therefore, make a significant contribution to the Joint Working project to avoid the arrangement being construed as merely a gift, benefit in kind, donation or some other nonpromotional/commercial practice. Resources might come in various forms, including people, expertise, equipment, communication channels, information technology, and finance.

The complainant stated that in this case the NHS region board contribution was the data and the expertise and the pharmaceutical companies' contribution was mainly financial. The complainant therefore did not accept Pfizer's statement and refuted that there was anything in the ABPI Guidance Notes on Joint Working which required that a joint working project must be jointly developed.

3 The support provided for the project by the ABPI SCG was simply funding and did not involve significant pooling of resources for the joint implementation of the project protocol.

The complainant noted no statements which precluded consideration of an activity as a Joint Working project if the pharmaceutical company provided funding alone. Nevertheless, the complainant noted that:

i) Novartis' representative had been in discussion with the NHS region board since 2016 and was named on the protocol. The ABPI SCG entering into a project was jointly responsible or accountable for the activities of any of the other partnering companies.
ii) At the meeting on 31 Jan 2017 one of the objectives of this meeting was stated as 'Group Discussion to agree protocol and outcome measures with timelines – All'.
iii) In the more detailed elements of the detailed minutes and actions from meeting 31 January 2017 it was outlined that amendments to

the project initiation document (PID) was undertaken by three individuals including a Novartis representative. There were additional statements building additional activity into the proposal 'to inform a process of engagement of the NHS region with the pharma industry to access the results of analyses of healthcare data to better inform NHS regulatory submissions in the future. To support the development of these recommendations the project participating pharmaceutical companies could pilot an engagement process as part of the project and use the subsequent experience to inform the recommendations'. Additionally, the project partners were asked to submit real-world data questions that they might want answered – to be sent to the Novartis representative who would include them in the protocol.

These actions highlighted the joint development of the final protocol by the NHS and industry and also possibly for ongoing steering such that funding alone was not the sole contribution as claimed by Pfizer.

iv) The protocol had been set out covering elements of joint working – pooling of resources by the parties with funding from the companies and data and expertise from the NHS, benefits outlined for patients, industry and NHS – therefore it appeared that the NHS and the Novartis representative set out their proposal as per Joint Working.

v) The Joint Working governance (section 6 of the ABPI Guidance notes to Joint Working) advised that governance included 'entering into appropriate Joint Working agreements, establishing steering groups and consulting with relevant stakeholders about each particular Joint Working project'. In this case there was a steering group and industry and NHS representatives on the steering committee. At the meeting on 31 January 2017 one of the statements was 'Next Steps -NHS/ABPI approval process and timelines, project governance, proposed membership of the steering committee with one representative from industry, the NHS [region], NHS GGC [and others]'.

The complainant alleged that these were just a small number of reasons why he/she refuted Pfizer's claim that its contribution was solely financial in nature or that this was a basis for why this could not be considered Joint Working. The complainant therefore concluded that the three reasons given by Pfizer as the basis for its appeal were not warranted and should be rejected.

The complainant was unclear why the Scottish region health board sought to provide equity in the collaboration with the four companies by choosing the ABPI to act as a representative body for the companies. The complainant understood the advice given by the ABPI was that they could not enter into a Joint Working agreement. From the details gathered from the four separate company's responses it was possible to make the following observations: It was unclear why the NHS group wished to partner with ABPI Scotland (as stated in Novartis response letter - no evidence was given to support ABPI SCG meeting (9 May 2017) minutes). **It might simply have been that they anticipated complexities in trying to manage creating and signing separate contracts with each of the four companies.** However, the complainant alleged that it was up to the industry partners to explain the valid and compliant ways in which the project could be supported rather than concede and rush to support through funding through some collaborative arrangement which had no place in the Code. It might be that the four companies could have sought for the ABPI to draft a single contract for them to use or that lawyers from each company could have come together to draw up a single contract before providing this to the NHS and similarly had letters of intent (as they had with the ABPI) signing up to the single contract with the NHS.

The complainant alleged that the ABPI did not appear to be a 'supporter'; and state in the contract that it was acting on behalf of the ABPI SCG which it stated was also known as 'the Group' – it later defined this group as being made up of the 4 named company supporters each paying a fee of £32,480.50 each. However, going back to the meeting minutes highlighted earlier the ABPI SCG appeared to be many more companies (based on the company attendees and those who sent their apologies) and in addition in the Supporter Terms and Conditions Section 5 Fees – the wider ABPI SCG (around 23 pharma companies) appeared to have provided an additional separate funding of £10,000. The meeting minutes recorded: 'Suggested that SCG use some of its residual funds to plug any funding gaps, if it meant project could proceed where otherwise it might not'. Based on the terminology used in the minutes the complainant made an assumption that the companies who were members of this working group pool funding into a central pot rather than this money coming from the ABPI itself. The use of the ABPI Scotland Collaborations Group to define two separate and distinct groups within the contract was confusing.

The complainant alleged that it did not read that the complexity of the provision of £10,000 from the ABPI SCG had been considered – how would transparency of this funding be made apparent and disclosed as required under Clause 24. If, as suspected, this came from funds which had been contributed by the wider ABPI SCG group were these companies (an additional 19 other companies to the 4 participating companies of Roche, Novartis, AstraZeneca and Pfizer) also subject to a responsibility to disclose their indirect contribution to this activity? If it was ABPI funds – were these disclosed by the ABPI under Clause 24?

Finally, the complainant alleged that looking at Section 1 of the ABPI Guidance notes which stated 'The ABPI Code was sometimes interpreted differently by companies, in line with their own understanding of the Code and legal requirements and taking into account their individual company policies and procedures'. This could cause confusion, both between and within companies, and also externally when companies responded differently

to similar customer or NHS requests. Individual company governance arrangements were also likely to differ as ultimately, each company was responsible for managing its own activities' and that was certainly what appeared to have happened here – two companies having placed it under Clause 21, Pfizer under Clause 19 as a MEGS, another certifying it as Joint Working but documenting in certificate noted that it was not Joint Working but not considering any clause under which it could legitimately be placed.

The complainant alleged that as in his/her original complaint he/she did not deny that it might be a worthwhile project but it was the responsibility of the companies to comply with the ABPI Code and to ensure the correct and compliant procedures were followed and where necessary to advise NHS partners as to how something could be done compliantly.

APPEAL BOARD RULING

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 Pfizer) 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 Pfizer's representatives at the appeal that the communications should have been agreed by Pfizer and this had not been so. Pfizer submitted that it 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 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 that Pfizer's involvement in the steering committee was to monitor progress and authorised the milestone funding payment.

The Appeal Board noted Pfizer's submission that the project was a financial grant which was classified as a MEGS. Pfizer's representatives at the appeal submitted that its position on the steering committee was good financial auditing practice to ensure that the grant was spent as agreed.

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 Pfizer; both the Scottish region health board and the four companies including Pfizer 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 to 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 Pfizer 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 and what Pfizer considered to be the misleading nature of the ABPI press release.

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 its comments above and considered that the benefits listed in the protocol in relation to patients and would only come about if Phases 2 and 3 were undertaken and completed; there was no patient centred benefit at the end of Phase 1. The purpose of Phase 1 and its outputs 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 breach of Clause 20 in this regard and consequently no breach of Clause 9.1 was ruled. The appeal on both points was successful.

During its consideration of this case the Appeal Board noted that the ABPI advice on joint working was last revised in 2008. In the Appeal Board's view, it would be helpful if such advice was revised. The type of project in the above case concerning data was increasing.

Following its completion of the consideration of the appeals in Case AUTH/3045/6/18 and Case noted that AUTH/3046/6/18 (AstraZeneca), the Appeal Board the respondent companies in Case AUTH/3043/6/18 (Novartis) and Case AUTH/3044/6/18 (Roche), had accepted the Panel's rulings of breaches of the Code and had not appealed. AstraZeneca had appealed Case AUTH/3046/6/18.

The Appeal Board agreed that Novartis and Roche should be contacted and informed of the outcome of the appeals in Case AUTH/3045/6/18 and Case AUTH/3046/6/18. 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 should each be offered the opportunity to appeal out of time and the appeal process would operate in the usual way. The complainant should also be informed. The reports for Case AUTH/3043/6/18 and Case AUTH/3044/6/18 should be updated to reflect the situation and to cross refer to the cases which were successfully appealed. 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	**17 January 2019**