CASE AUTH/3783/6/23

COMPLAINANT v MODERNA

Allegations about a meeting in Madrid for off-label Respiratory Syncytial Virus and COVID-19 vaccines

CASE SUMMARY

This case was in relation to a Moderna global advisory board held in Madrid, Spain which included a total of 56 health professionals from 20 countries. The complainant's allegations were broadly in relation to the overseas meeting not being a genuine advisory board, along with the provision of inappropriate hospitality, referring specifically to the hotel, travel and payments.

The outcome under the 2021 Code was:

Breach of Clause 2	**Bringing discredit upon, and reducing confidence in, the pharmaceutical industry**
Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 11.1	**Promoting a medicine prior to the grant of its marketing authorisation**
Breach of Clause 11.2	**Promoting a medicine in a manner inconsistent with its summary of product characteristics**
Breach of Clause 19.1	**Provision of a pecuniary advantage or benefit to a health professional in connection with the promotion of medicines or as an inducement to prescribe, supply, administer and/or recommend a medicine**

No Breach of Clause 10.1	**Requirement that companies must not provide inappropriate hospitality**

The Appeal Board was concerned about the arrangements for the meeting at issue. The Appeal Board gave consideration to the use of additional sanctions but decided that none were required.

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A complaint was received from an anonymous, non-contactable complainant about Moderna Biotech UK Ltd.

COMPLAINT

The complaint wording is reproduced below:

> "This complaint pertains to a meeting being held by Moderna in Madrid, Spain [date of meeting] which will be attended by at least one UK HCP. This meeting is intended in company circles to be a 'launch meeting' for off-label RSV [respiratory syncytial virus] and COVID vaccines at a high level hotel where Moderna wished for an attendance of 100 but I understand this is around 60 attendees. Given internal discussion this meeting has now been rebadged as an Advisory Board but I believe that given the luxury travel attendance and payments etc this meeting echoes the case we saw Astellas punished for in previous years."

When writing to Moderna, the PMCPA asked it to consider the requirements of Clauses 10.1, 11.1, 11.2, 19.1, 5.1 and 2 of the Code.

MODERNA'S RESPONSE

The response from Moderna is reproduced below:

> "The meeting in question was an international advisory board meeting organized by our US global parent company Moderna Tx, Inc in Spain. The meeting was arranged in line with Spanish requirements. An HCP [healthcare professional] from the UK participated in the advisory board meeting. The UK medical team was responsible for the selection of this HCP. Moderna UK acknowledges that the arrangements for the meeting were therefore subject to the ABPI Code. While the arrangements did meet a number of the requirements of the ABPI Code, in responding to this complaint, Moderna UK accepts and regrets that not all of the ABPI Code requirements were met, as explained below.
>
> As requested, we include a copy of the invitation to the UK HCP to participate in the meeting, the agenda, the pre-read materials shared with the UK HCP, the slides presented during the advisory board meeting, the recorded output of the meeting, the SmPC for Spikevax and any other referenced material.
>
> **Clause 10.1:** The meeting complied with the following requirements set out in Clause 10.1 of the ABPI Code:
>
> - A legitimate need for the advisory board services was identified and documented in advance. The purpose of the advisory board meeting was to gain expert advisor feedback on:
>   1. Prioritization of global populations of interest and those at higher risk for severe disease from respiratory viruses (specifically COVID-19/Respiratory Syncytial Virus (RSV));
>   2. Identification of knowledge gaps for better understanding of scientific/immune characteristics of mRNA respiratory vaccines; and

3. Global scientific messages and data that will inform Moderna's approach to optimize National Immunization Technology Advisory Group and similar bodies' recommendations and prepare for potential future indications of respiratory vaccines.

- The output from the advisory board meeting was recorded by medical writers and will be used by Moderna to inform medical affairs strategies on higher risk groups to better communicate and address mRNA respiratory vaccine concerns, identify research priorities ahead of filing and/or post-licensure for indication expansion, develop resources (i.e., appropriate medical content, publications, etc.) to support filing, scientific engagements, and medical education on respiratory mRNA vaccines.
- Insights from HCPs in multiple different and in different respiratory and infectious disease specialties were required to provide a balanced perspective considering the material differences in vaccination rates, barriers to vaccination, health systems, resources, and patient management practices per country.
- There was a valid reason for holding the meeting outside the UK. In total, 56 HCPs participated from 20 countries - Europe (19 HCPs), Asia (14 HCPs), North America (12 HCPs) and South America (11 HCPs). The location of the meeting was chosen based on the highest number of HCPs being in Europe, with five participants from Spain, together with considerations including travel logistics.
- Moderna engaged one external speaker from Italy and three external panellists from Spain, Singapore, and the US. These HCPs were selected for their respective expertise in Covid vaccines, respiratory viral epidemiology, severely immunocompromised population, and long-term facilities. The speaker and pane[l]lists were paid FMV consultancy fees by Moderna. Additionally, the event featured four internal speakers from Moderna's Medical team.
- The UK medical team identified four HCPs possessing the required expertise to provide the needed advice. These HCPs were subsequently invited by the global team, but only one accepted the invitation. The participating UK HCP was selected based on being an [job role] with expertise in infectious diseases and global health and with a particular interest in respiratory viral infections, including RSV and COVID-19, in accordance with the criteria set out in [the Needs Assessment Form for Consulting Arrangements with Healthcare Professionals], and therefore as having relevant expertise and experience to the advice sought.
- 32 employees from Moderna were present at the event, with several taking on the role of moderators. This group included 1 employee from the UK and 3 employees in global commercial roles. The employees in global commercial roles were there strictly as observers.
- The travel involved was not "luxury" as alleged by the anonymous complainant. The UK HCP travelled by economy class flights landing in Madrid at 7:55pm the night before the meeting and departing at 7:25am the morning after the meeting.
- The meeting was held in a conference room in a 4* business hotel in Madrid, [named hotel], which was appropriate and conducive to the main purpose of the meeting.
- The associated subsistence, accommodation and travel costs for the UK HCP were strictly limited to the main purpose of the meeting for a total of [amount provided] as follows:
  1. economy class flight ticket at a cost of [amount provided];

2. two nights' accommodation at a cost of [amount provided] per night (total [amount provided]), which reflects that the hotel was not a luxury venue and that the UK HCP was unlikely to be attracted to participate by virtue of the venue;
3. transfers from the airport to the hotel and back in Spain at a cost of [amount provided] in total;
4. food and drinks which were limited to the main purpose of the meeting and secondary, appropriate to and in proportion with the occasion, consisting of a breakfast buffet, buffet lunch and snacks during the breaks on the day of the meeting, at a fixed price of [amount provided] per participant;
5. reimbursement of taxi fare from the HCP's home to [city] airport back at a cost of [amount provided] in total;
6. Reimbursement of meals
   - June 23 – lunch at a cost of [amount provided]
   - June 23 – dinner at a cost of [amount provided]
   - June 24 – dinner at a cost of [amount provided]
7. Reimbursements are being processed upon submission of a copy of the relevant receipt.

- Some participants arrived the evening before for a pre-session presentation/discussion of the pre-read materials and were provided with dinner, but the UK HCP did not attend this evening pre-session.
- A fair market value assessment for the individual UK HCP was carried out in advance. A written contract setting out the consultancy services was signed between Moderna Tx, Inc. and the UK HCP in advance of the meeting, which provided for a maximum of up to 11 hours of services relating to preparation and participation in the meeting for a sum not exceeding [amount provided]. We have received the HCP invoice for 9 hours of service for a total of [amount provided – less than the maximum].
- The reportable transfers of value to the UK HCP will be disclosed as part of Moderna's transparency reporting.

Moderna has written instructions on HCP engagements and hospitality and the associated allowable expenditure which clearly state that international travel for UK HCPs must be certified, and meeting materials examined by Moderna's ABPI signatories.

The needs assessment form was reviewed by Moderna Tx, Inc.'s legal team, however, the policy was not followed in relation to this meeting because the travel outside the UK was not certified and the meeting materials were not examined. Moderna UK accepts there was a breach of the ABPI Code and our policy in this respect. After investigating this matter, we are addressing this with the individuals involved, which included a senior member of the UK medical affairs team who also attended the meeting. We are also reviewing our compliance procedures and running additional ABPI training for relevant UK and global personnel on the ABPI Code requirements and Moderna's policy, to ensure that this issue does not occur again.

Clauses 11.1 and 11.2: This information provided at the meeting was non-promotional and was relevant and proportional to the purpose of the advisory board. This information was necessary to ensure that all participants had the same baseline understanding and were fully up to date with the data available for the following discussions which included

identifying and prioritizing knowledge gaps. The meeting was not intended to be a "launch meeting" for off-label RSV and COVID vaccines as alleged by the anonymous complainant. The slides included a statement that some information related to products still in development and that were therefore not licensed – it was necessary to provide this information in order to gain the pre-identified insights including on how recommending bodies will likely evaluate these products. The slides presented during the meeting and the discussion guides were reviewed and approved by Moderna Tx, Inc.'s legal team.

The purpose of the meeting was not to promote unlicensed product but rather to provide appropriate information to produce well-informed insights from the participating HCPs. As can be seen from the agenda the majority of working time was spent gathering insights. The meeting ran from 9am to 5pm with:

- two 15-minute breaks and 1 hour for lunch, totalling 1 hours 30 minutes;
- welcome/objectives, presentations/Q&A and conclusions totalling 2 hours 20 minutes;
- three breakout insight gathering sessions of 1 hour 20 minutes each, totalling 4 hours.

In the breakout sessions the participants were split randomly into small tables with a medical writer assigned to each table to ensure that output from each was captured and recorded. We attach the output prepared by the scientific writer at the table at which the UK HCP sat. Please note each table did not address every question.

Clause 19.1: The remuneration and expenses payments made to the UK HCP were fair market value and reasonable in return for legitimate consultancy services provided in relation to an advisory board meeting. These payments were not, and were not intended to be, an inducement to the UK HCP to prescribe, supply, administer or recommend Moderna's products, as stated expressly in the consultancy agreement between Moderna and the UK HCP.

Clause 5.1: The overseas travel for the UK HCP should have been certified and the related event materials should have been examined by Moderna UK, and because that did not occur in this specific situation, high standards as outlined in the ABPI, were not maintained.

Moderna UK has in place policies that reflect these requirements, and the requirements of the ABPI Code more broadly. As mentioned above, we have addressed the expectation and importance that these policies be followed at all times with the individuals involved and are providing further training for all UK personnel and global employees interacting with UK HCPs on compliance with the ABPI Code requirements, to ensure that Moderna UK's policies and the ABPI Code are followed at all times in future.

Clause 2: Again, we accept that the overseas travel for the UK HCP should have been certified and the related event materials should have been examined by Moderna UK's ABPI signatories. If the Panel considers that the advisory board meeting and related arrangements did not comply with the ABPI Code with respect to the UK HCP, Moderna UK accepts that in light of the payment to a UK HCP involved, this would likely constitute a breach of Clause 2.

As the PMCPA is aware, Moderna UK recently joined the ABPI. We would like to reassure the PMCPA that Moderna UK has put in place policies and procedures that reflect the requirements of the ABPI Code and is taking immediate steps to ensure that all personnel are aware of those requirements going forward. Moderna UK takes adherence to the ABPI Code seriously."

PANEL RULING

The complaint related to a Moderna global advisory board that was held in Spain in June 2023. Moderna submitted that the meeting at issue, organised by its US parent company, included a total of 56 health professionals from 20 countries and the location was chosen based on the highest number of health professionals being in Europe, with five participants from Spain. Moderna UK accepted the meeting was subject to the Code as one UK health professional that had been selected by Moderna UK attended.

The complainant's allegations were broadly in relation to the overseas meeting not being a genuine advisory board, along with the provision of inappropriate hospitality, referring specifically to the hotel, travel and payments.

The Panel noted that the supplementary information to Clause 10.1, Events/Meetings held Outside the UK, stated that meetings organised by pharmaceutical companies which involved UK health professionals at venues outside the UK were not necessarily unacceptable. There had, however, to be valid and cogent reasons for holding meetings at such venues. These were that most of the invitees were from outside the UK and, given their countries of origin, it made greater logistical sense to hold the meeting outside the UK or, given the location of the relevant resource or expertise that was the object or subject matter of the meeting, it made greater logistical sense to hold the meeting outside the UK. Consideration should be given to the use of technology to avoid travel outside the UK, e.g. webinars, virtual meetings.

The Panel noted that it was acceptable for companies to pay health professionals and others for relevant advice. Nonetheless, the arrangements for such had to comply with the Code, particularly Clause 24. To be considered a legitimate advisory board, the choice and number of participants should stand up to independent scrutiny; each should be chosen according to their expertise such that they would be able to contribute meaningfully to the purpose and expected outcomes of the advisory board. The number of participants should be limited so as to allow active participation by all. The agenda should allow adequate time for discussion. The number of meetings and the number of participants should be driven by need and not the invitees' willingness to attend. The nature of the meeting should be made clear to invitees: invitations to participate should state the purpose of the advisory board meeting, the expected advisory role and the amount of work to be undertaken. A written contract or agreement must be agreed in advance of such services and if an honorarium was offered, it should be made clear that it was a payment for such work and advice. Honoraria must be reasonable and reflect the fair market value of the time and effort involved.

The Panel noted the invitation sent to the UK participant described the purpose of the advisory board as to "seek advice from key experts such as yourself to gain insights into populations at higher risk for severe disease from SARS-CoV-2 and RSV respiratory viruses, identify knowledge gaps for better understanding of scientific and immune characteristics of mRNA respiratory vaccines, and provide feedback on global scientific messages and data". The invitation went on

to describe the programme to “consist of plenary and focused breakout insight gathering sessions for each topic that will then be summarized, presented to, and discussed among the entire group” and that “Moderna would be offering travel and accommodations, as well as renumeration for the time spent reviewing pre-meeting materials and participating in the meeting”.

The Panel noted participants had been provided with documents for pre-reading and that some attended a “pre-session presentation/discussion of the pre-read materials” the evening before the advisory board; the UK participant did not attend. The presentation on the day of the advisory board appeared to be composed of a total of 149 slides based on the slide numbers, although Moderna had only provided 121 slides, and consisted mostly of data.

The Panel noted Moderna submitted that the information provided at the meeting was non-promotional, relevant and proportional to the purpose of the advisory board, and that the information was necessary to ensure that participants were fully up to date with the data available for the following discussions, which included identifying and prioritising knowledge gaps. In this regard, the Panel noted Moderna submitted that the slides included a statement that some information related to products still in development and that were therefore not licensed and that it was necessary to provide this information in order to gain the pre-identified insights, including on how recommending bodies will likely evaluate these products.

The Panel examined the agenda. The agenda consisted of three distinct sections across a full day, between 9.00 am and 5.00 pm, with 90 minutes of breaks. Each section consisted of a presentation, followed by an associated Q&A and a breakout group. The Panel noted, in total, the agenda included approximately two hours of presentation, 45 minutes of which was associated Q&A time; the Panel considered that the Q&A sessions were for the attendees to ask questions such that they were equipped to participate in the subsequent breakout sessions, rather than a means of providing advice to the company. Advice was sought in the form of the three breakout sessions of 80 minutes each, which included feedback time and amounted to four hours on the agenda, one hour of which was allocated for each breakout table to share back to the group, 20 minutes per breakout session.

To be considered a legitimate advisory board, amongst other things, the agenda and arrangements should allow sufficient time for discussion and feedback from the participants which was the primary purpose of the meeting. In this regard, the Panel considered only a relatively small proportion of the time should be spent on company presentations to provide a foundation for subsequent discussion and the number of advisors should be limited to allow active participation by all.

The Panel noted that a total of three hours of discussion time was planned and queried whether this was sufficient time for discussion in the context of an eight-hour agenda. In this regard, the Panel noted with concern that, according to the Outcome Notes from the UK participant’s table, a number of questions had not been answered by the participants and considered that it was particularly important in the context of an advisory board that all of the company’s questions were addressed.

The Panel further had concerns about the large number of attendees. The advisory board consisted of 56 health professionals and 32 company employees along with a third-party agency from whom there were numerous medical writers. The Panel did not know how many third-party employees were present but noted there appeared to be at least one per table and the Panel was

aware of a minimum of 8 tables. The Panel estimated the number of individuals representing Moderna, inclusive of agency staff, to be above 40. The Panel noted that the Needs Assessment Form listed 18 Moderna attendee individuals/categories of attendee and therefore noted that the arrangements had been internally approved without accurate information about the final number of staff attendees. The Panel noted that it was an established principle that the number of company attendees (including agency staff) should normally be well below the number of advisors and in this regard considered the ratio of company attendees to advisors unacceptable.

The Panel considered it was not unacceptable to hold a global advisory board but that it might be difficult to receive meaningful advice, particularly on national differences, without a relatively large number of participants; in this regard, the Panel considered this might be inconsistent with the established principle that the number of participants at a genuine advisory board should be limited. The Panel noted Moderna's justification for the number of attendees from numerous countries, on its needs assessment form, was "based on differences in health systems and resources and patient management practices; and geographical considerations for Moderna's respiratory vaccine portfolio and collecting data to support upcoming regulatory submissions. One global event would also streamline the collection of advisor feedback using medical resources and speakers' attendance as well as gain expert advice on Moderna's mRNA platform". Reference was also made to differences in vaccination rates which would allow sharing of best practices and to cultural and 'national programmatic differences' in vaccine confidence.

In the Panel's view, a global advisory board held, in part, on the premise of collecting insights from different geographical locations, would report relevant outcomes by country or region and place emphasis on geographical differences. However, this was not so. The Panel reviewed the contents of the executive summary along with the notes from the UK advisor's table; there were only two points that made a differentiation for non-specified Latin American countries and one mention of South Korea in the executive summary but these appeared in the summary of discussion points rather than the linked "Implications and Possible Action Points" section. The latter section which summarised action points based on the expert advice made two references to national differences: "Utilize different communication strategies for different populations/countries" and "Localise vaccine implementation strategies according to geographic region and factors such as culture". The Panel queried the need for expert advice to determine these action points. The Panel further noted a general comment within the notes from the UK advisor's table ("there are different recommendations from different countries") with no further detail.

Taking all factors into account, including the outputs of the meeting which lacked national differences, along with the number of staff and participants, the Panel did not consider that the arrangements were such that the UK health professional had attended a genuine advisory board meeting.

The Panel noted it was not entirely clear whether the complainant was concerned about the principle of payment or the level of payment but considered that appropriate payments were only acceptable in relation to genuine advisory boards and thus any payment would be excessive in the circumstances of this case. The Panel, noting its views above, considered health professionals had, in effect, received the payment of a fee to attend a promotional event, which was unacceptable, and an inducement to prescribe, administer or recommend Moderna's medicines. The Panel therefore ruled a **breach of Clause 19.1**.

The Panel noted Moderna's acknowledgement that, in order to provide appropriate information to produce insights from participants, some information in the presentation related to products still in development and not licensed. The Panel considered that, as it had ruled the arrangements did not meet the criteria for genuine advisory boards, UK health professionals had been paid to attend a meeting where an investigational product (mRNA-1345) had been promoted prior to its marketing authorisation. The Panel ruled a **breach of Clause 11.1**.

The Panel further considered that the inclusion of clinical data in which the booster dose used for Spikevax (mRNA-1273) was 100 mcg, when the Great Britain Spikevax SPC referred to a booster dose of 50 mcg, meant that Spikevax had been promoted in a manner that was inconsistent with its SPC. A **breach of Clause 11.2** was ruled.

In relation to the arrangements for the meeting, Clause 10.1 included that the venue must be appropriate and conducive to the main purpose of the event/meeting and that hospitality must be strictly limited to the main purpose of the event and must be secondary to the purpose of the meeting. The level of subsistence offered must be appropriate and not out of proportion to the occasion. The Panel noted that the complainant's concerns were limited to the standard of hotel and travel.

The Panel noted the meeting was held in a conference room in a four-star business hotel in Madrid, and that the participants' accommodation was at the same hotel. Moderna submitted that the associated subsistence, accommodation and travel costs for the UK health professional were strictly limited to the main purpose of the meeting. The Panel reviewed the impression and cost of the subsistence, economy class flight, four-star accommodation and venue; the Panel further noted the UK health professional's economy class flight arrived the night before the advisory board and departed the morning after. The UK health professional was also provided with a return taxi to the airport. In the Panel's view, the complainant had not established that the meeting took place at a "high level hotel" nor that "luxury travel attendance" had been provided as alleged. The Panel considered there was no evidence that the hospitality provided to the UK health professional in relation to travel and accommodation was disproportionate or excessive. The Panel therefore ruled **no breach of Clause 10.1**.

While the Panel noted its no breach ruling in relation to the arrangements for the UK health professional, the supplementary information to Clause 10.1 also included that events/meetings which involve travel outside the UK must be certified as set out in Clause 8.2. In this regard, the Panel noted Moderna's submission that it had contravened the Code and its policy which required international travel for UK health professionals to be certified and meeting materials to be examined by Moderna's signatories. The Panel was concerned about Moderna's governance.

Taking into account its findings above, the Panel considered that Moderna had, in effect, made a payment to a UK health professional to attend a promotional meeting which detailed an investigational product which at the time did not have marketing authorisation and an indication for a medicine that was inconsistent with its SPC. Moderna had failed to maintain high standards and a **breach of Clause 5.1** was ruled.

The Panel noted that unacceptable payments was listed in the supplementary information to Clause 2 as an example of an activity likely to be in breach of that Clause. The Panel, additionally noting its concerns around Moderna UK's governance, considered that the overseas advisory board was such that it brought discredit upon and reduced confidence in the pharmaceutical industry. A **breach of Clause 2** was ruled.

APPEAL BOARD CONSIDERATION OF THE CASE REPORT

Moderna provided the requisite undertaking and assurance and, as the case completed at Panel level, the Appeal Board received the case report as set out in Paragraph 13.4 of the 2021 Constitution and Procedure.

On reviewing the Panel decision, the Appeal Board was very concerned about the arrangements for the meeting at issue. It was apparent that the meeting did not fulfil the requirements of an advisory board. In particular, the Appeal Board had concerns with the number of attendees and drew parallels with the Astellas case.

The Appeal Board was of the view that consideration should be given to the imposition of additional sanctions under Paragraph 11.1 of the 2021 Constitution and Procedure. The Appeal Board decided that Moderna should be asked to respond to these concerns in writing, and be invited to attend a meeting of the Appeal Board when this matter would be considered. Moderna was provided with a copy of the papers for the report.

COMMENTS FROM MODERNA

Moderna's written response is reproduced below.

> "We acknowledge receipt of your letter dated 10 October 2024 and wish to confirm that Moderna Biotech UK Ltd takes these matters extremely seriously. We remain committed to full compliance with the ABPI Code of Practice and have taken meaningful steps in response to both the initial complaint raised and the Panel's ruling issued on 22 August 2024, in addition to the steps already taken.
>
> In our previous response dated 21 July 2023, we explained our intended purpose of the global advisory board in Madrid. While the meeting sought to gather expert insights on mRNA respiratory vaccines, we fully accept the Panel's ruling of breaches to Clauses 2, 5.1, 11.1, 11.2, and 19.1 of the Code. Our decision not to appeal reflects the above and our determination to address the issues identified and use these learnings as an opportunity to strengthen our compliance framework.
>
> We have taken steps to address the Panel's concerns, including initiating a review of our governance and event protocols. Additionally, we have established a working group intended to monitor compliance and support continuous improvement and are implementing further targeted training for our teams.
>
> We acknowledge the Appeal Board's concerns, referenced in your letter, in relation to the overall number of attendees at the global advisory board, which is now reflected in our event protocols. We also acknowledge the Appeal Board's reference to the Astellas case but would note there are differences both in relation to the facts and our response.
>
> We hope that our full acceptance of the ruling and the steps we have taken and are taking to strengthen our compliance will be considered in the context of the possible imposition of additional sanctions."

At the consideration of this matter Moderna's representatives presented that:

> "Moderna takes compliance with the ABPI Code very seriously and fully accepted the Panel's ruling, including of a Clause 2 breach.
>
> As noted in our response, Moderna has used the learnings from this case as an opportunity to strengthen our compliance framework.
>
> The steps we have taken to address the points notes in the Panel's ruling include:
> - initiating a review of our governance and event protocols;
> - established a working group intended to monitor compliance and support continuous improvement;
> - implementing further targeted training on advisory boards for our teams.
>
> We hope that our full acceptance of the ruling and the active steps we have taken and are taking to strengthen our compliance will be considered in the context of the possible imposition of additional sanctions."

APPEAL BOARD CONSIDERATION

The Appeal Board remained concerned about the case which had been ruled in breach of the Code.

The Appeal Board took account of the submissions from the representatives from Moderna at the Appeal Board meeting that the company had fully accepted the Panel's breaches of the Code and had taken appropriate steps to strengthen its compliance programme. In particular, there were now new processes in place for internal approval for all events globally involving UK health professionals.

The Appeal Board recognised that Moderna was a new and rapidly growing organisation which had recently joined the ABPI and accepted the jurisdiction of the PMCPA in December 2022. The Appeal Board encouraged Moderna to maintain its focus on the fundamentals of a compliance programme and its continuous improvement programme including monitoring to ensure ongoing compliance with the Code. Moderna said that it considered it important for the Global teams as well as the UK team to understand the requirements of the ABPI Code, and the Appeal Board welcomed that approach. The Appeal Board gave consideration to the use of additional sanctions but decided that none were required.

Complaint received	**23 June 2023**
Case completed	**2 September 2024**
Appeal Board consideration	**19 September 2024 and 28 November 2024**