HEALTH PROFESSIONAL v MERCK SHARP & DOHME

Alleged promotion of unlicensed medicines

An anonymous, non-contactable health professional alleged that Merck Sharp & Dohme had promoted unlicensed medicines at a meeting of the European Society of Gynaecological Oncology (ESGO) in Liverpool 2013.

The complainant stated that he/she understood that a medicine could not be promoted before the grant of a marketing authorization but that certain limited activities could take place eg legitimate scientific exchange or responding to an unsolicited request for information. At the Merck Sharp & Dohme stand at ESGO there were large exhibition panels which advertised the company's pipeline products eg Programmed Death–1 (PD-1) Inhibitor, Cyclin Dependent Kinase (CDK) Inhibitor and Extracellular Signal – Regulated Kinase (ERK) Inhibitor and their mode of actions and on-going trials. The complainant queried how this was legitimate exchange as it was on an exhibition panel. The complainant considered that this was the company getting delegates to ask about the products - in his/her view this was not unsolicited.

The complainant was not aware that any of these products were licensed anywhere and whilst it was important that health professionals were kept up-to-date on developments and trial options for patients, he/she considered that the health professionals should review the data themselves and discuss with clinical research and medical at the companies; they should not be faced with what looked like promotional panels for medicines which had not had their efficacy and safety evaluated. There were patient groups and potentially carers present at such conferences these days and they would inevitably ask for these new compounds. The complainant alleged that such activity was misleading and promoting before the grant of a licence.

The detailed response from Merck Sharp & Dohme is given below.

The Panel noted that the complainant was anonymous and non-contactable. As stated in the introduction to the Constitution and Procedure, anonymous complainants were accepted and like all complaints, judged on the evidence provided by the parties. Complainants had the burden of proving their complaints on the balance of probabilities.

The Panel noted that the Code prohibited the promotion of a medicine prior to the grant of its marketing authorization. It also required that promotion must be in accordance with the marketing authorization and not be inconsistent with the summary of product characteristics (SPC). The supplementary information provided additional details, including that the legitimate exchange of medical and scientific information during the development of a medicine was not prohibited provided that this did not constitute promotion which was prohibited.

The Code defined 'promotion' as 'any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines'.

The Panel noted that the PMCPA Guidance about Clause 3 included advice about the legitimate exchange of medical and scientific information during the development of a medicine. Companies must ensure that such activities constituted a genuine exchange of information and were not promotional. Documents must not have the appearance of promotional material. It should be borne in mind that it would be a breach of the Code if non-promotional information on products or indications that were not licensed was used for a promotional purpose.

The Panel did not consider that the arrangements for the exhibition stand at issue could take the benefit of the exemption to the definition of promotion for unsolicited enquiries. It noted that Merck Sharp & Dohme held a company sponsored satellite symposium. There was no complaint about the satellite symposium and the Panel had no information about it. The Panel was only considering the exhibition stand.

The Panel examined the information on the 6 exhibition stand posters. Three of them referred to particular inhibitors ERK, PD-1 and CDK. Each was illustrated with a diagram of cell activity. This was followed by a description of the pathway or molecule. The final part of each of these three posters referred to the Merck Sharp & Dohme product under development and the final statement 'The agent or uses depicted are investigational'. The PD-1 poster referred to in vivo and *in vitro* data which showed the effect of blockade. The fourth poster (exhibition stand panel 6) gave details about the PROCEED trial which was a phase 3 trial of vintafolide in platinum-resistant ovarian cancer. At the bottom of the poster was an invitation 'to learn more'. This mentioned the availability of additional information as well as how to find out how to participate in the trial by speaking to the representative on the booth or calling a US/international number or visiting clinicaltrials.gov. The fifth poster depicted the Merck Sharp & Dohme oncology research pipeline giving details of the investigational compound and description of the target. Again, the phrase 'The agents or

uses depicted here have not been approved by any regulatory agency' appeared. The final poster was a Merck Sharp & Dohme oncology corporate poster. It had no reference to products.

The Panel noted the research phase of each product and its licensing status. Only one of the molecules referred to on the exhibition stand had been submitted to any regulatory agency around the world. When the ESGO meeting was held, any regulatory approval, if granted, was estimated to be some time away, and was still speculative.

The Panel considered that relevant factors for consideration in such circumstances included the nature of the meeting, the status of attendees, the location of the Merck Sharp & Dohme stand and whether it constituted the legitimate exchange of medical and scientific information during the development of a medicine.

The Panel noted Merck Sharp & Dohme's submission that the ESGO meeting was a meeting of high scientific standing and attendees would include researchers etc.

The Panel noted that the posters primarily detailed the effect of the target for the investigational compounds, the PD1 poster, however, was slightly different as was the poster describing the PROCEED trial. The Panel noted Merck Sharp & Dohme's submission that it had not promoted any of its licensed products on the exhibition stand. Merck Sharp & Dohme referred to the products as investigational molecules/agents. Whilst this term was not defined, the Panel queried whether products subject to Phase III trials (vintafolide and MK3475) and for which a licence was anticipated within a year would be considered investigational molecules.

The Panel considered that delegates were likely to view the exhibition space as a whole as promotional and might not necessarily appreciate the differences between promoting products and promoting research. The Panel noted Merck Sharp & Dohme's submission that the exhibition hall was used as part of the scientific programme as it hosted the ESGO poster display area.

The Panel considered that it was difficult to decide whether the materials were in line with the requirements of the supplementary information to the Code. It noted that one of Merck Sharp & Dohme's aims was to raise awareness of the company's commitment to oncology and to talk with basic and clinical scientists. The company also wanted to make clinicians aware of the ongoing Phase III clinical trial. The Panel noted that the style of the posters was low key and scientific. The stand was manned by scientific and medical staff. Only one of the products had been submitted for approval but this was not expected for some time.

The Panel did not know whether the meeting agenda included any content that could be considered the legitimate exchange of medical and scientific information during the development of the Merck Sharp & Dohme products. Merck Sharp & Dohme had sponsored a satellite symposium but there was no complaint about that and the Panel had no information about it.

The Panel was only concerned about the PD-1 poster and the PROCEED trial poster. The PROCEED trial poster in particular was materially different to the other posters both in content and the licensing status of the product. The poster advised delegates that the trial was currently recruiting and was thus an invitation to participate. In the Panel's view the invitation would necessarily solicit enquiries. The Panel queried whether any associated discussion about the logistics of trial participation and the provision of information about the medicine in relation to the trial could fairly be described as the legitimate exchange of medical and scientific information. The Panel however had no evidence before it about such discussions. Given the discrete nature of such discussions the Panel queried whether it was appropriate to display the PROCEED trial poster alongside the others.

The Panel considered that the other four posters did not constitute advertising a product prior to the grant of the marketing authorization. There was very limited information about the efficacy of any potential product on these four posters and the products were a long way from receiving any licence. Similarly, whilst the Panel was concerned about the in vivo and *in vitro* data in the PD1 poster it was, nonetheless, limited and on balance the Panel did not consider that it was advertising a product prior to the grant of its marketing authorisation. No breach was ruled in relation to the five posters.

The Panel noted its concerns about the PROCEED trial poster set out above. The Panel considered that within the context of the exhibition stand it did not satisfy the requirements for the legitimate exchange of medical and scientific information during the development of a medicine. Nevertheless, given the narrow grounds of the complaint and on balance, the Panel did not consider that the poster amounted to the promotion of an unlicensed medicine and no breach was ruled.

The Panel noted the allegation that the Merck Sharp & Dohme stand would encourage requests for the new products as patient groups and carers might be present at the meeting. It did not appear that the meeting was aimed at such an audience and the data provided by Merck Sharp & Dohme in relation to the attendees at the 2011 meeting did not mention patient groups or carers. The Panel considered that the complainant had not discharged his/her burden of proof and thus ruled no breach including Clause 2.

An anonymous, non-contactable health professional alleged that Merck Sharp & Dohme Limited had promoted unlicensed medicines at a meeting of the European Society of Gynaecological Oncology (ESGO) in Liverpool, 19-22 October, 2013.

COMPLAINT

The complainant stated that he/she understood from the Code that a medicine could not be promoted before the grant of a marketing authorization but that certain limited activities could take place eg legitimate scientific exchange or responding to an unsolicited request for information. At the Merck Sharp & Dohme stand at ESGO there were large exhibition panels which advertised the company's pipeline products eg Programmed Death–1 (PD-1) Inhibitor, Cyclin Dependent Kinase (CDK) Inhibitor and Extracellular Signal – Regulated Kinase (ERK) Inhibitor and their mode of actions and on-going trials. The complainant queried how this was legitimate exchange as it was on an exhibition panel. The complainant considered that this was the company getting delegates to ask about the products - in his/her view this was not unsolicited.

The complainant was not aware that any of these products were licensed anywhere else in the world outside of the UK and whilst it was important that health professionals were kept up-to-date on developments and trial options for patients, he/she considered that the health professionals should review the data themselves and discuss with clinical research and medical at the companies; they should not be faced with what looked like promotional panels for medicines which had not had their efficacy and safety evaluated. There were patient groups and potentially carers present at such conferences these days and they would inevitably ask for these new compounds when they saw such materials as these. The complainant alleged that such activity was misleading and promoted before the grant of a licence.

When writing to Merck Sharp & Dohme the Authority asked it to bear in mind Clauses 2, 3.1, 9.1, 22.1 and 22.2 of the Code.

RESPONSE

Merck Sharp & Dohme explained that oncology was a highly specialized therapeutic area. The science was fast moving and constantly changed as new data emerged. The design of studies was complex and interpretation of the data was challenging. The data were often preliminary and incomplete. There was a constant focus by the clinical community on minimizing the number of patients exposed to potential harm and maximizing the therapeutic opportunity. The time window for clinical intervention was often limited by disease progression. The clinical community challenged researchers to share data at the earliest appropriate time.

The meeting in question was the 18th International Meeting of ESGO, a biennial meeting of high scientific standing. The ESGO website stated that:

> 'Each ESGO meeting offers attendees many opportunities for the dissemination, discussion and debate of the updated medical and scientific information for gynaecological cancer treatment and care.'
>
> 'More than 2500 gynaecological oncologists, researchers, residents and students will be gathering for the 18th International Meeting of the European Society of Gynaecological Oncology. Join your colleagues and take part in an extraordinary educational forum, where you will learn about the latest development, techniques and practices from world renowned speakers on all the latest topics.'

Merck Sharp & Dohme submitted that its global oncology team decided to support the meeting based on the highly specialist and research oriented nature of the gynaecological oncologists who would attend. The company's objectives in participating in this meeting were:

- To raise awareness of Merck Sharp & Dohme's commitment to oncology – the company made a significant investment in basic and clinical research into novel oncology targets but was not currently known as a major oncology company. The purpose of this awareness raising included things such as generating collaborative research opportunities, licensing opportunities and bidirectional scientific dialogue. Only by talking with basic and clinical scientists could the company and scientists make progress together.
- To share with the clinical community the novel biological pathways that Merck Sharp & Dohme targeted with its research. Some of these targets were currently thought to be relevant to the gynae-oncology community, others less so. As was common in oncology, many of these would not result in effective medicines but through this research the company's understanding of cancer biology would advance incrementally.
- To make clinicians aware of a clinical trial in platinum-resistant ovarian cancer which was currently recruiting patients in Europe. This was an area of unmet need with limited options available for patients, where clinicians wanted to know what trials were available for their patients. In the UK, it was a stated goal of the NHS that more patients were recruited into research.

Merck Sharp & Dohme had a presence in the exhibition hall and sponsored a satellite symposium entitled 'Recurrent Ovarian Cancer: Is Personalized Medicine a Reality for Patients?'. The meeting attracted around 2,500 delegates who specialized in medical oncology (who generally acted as investigators in clinical trials), clinical oncology, gynaecological surgery, and researchers in the field of gynaecological oncology. Merck Sharp & Dohme submitted that the meeting was highly scientific and was therefore an appropriate setting for genuine scientific exchange between the pharmaceutical industry, academic researchers and health professionals to occur. Pharmaceutical companies, medical device companies, diagnostic companies, the medical press and professional societies such as ESGO and the International Gynaecologic Cancer Society (IGCS) exhibited at the meeting.

The exhibition hall was used as part of the scientific programme as it hosted the poster display area. A diagram showing the hall layout was provided.

Merck Sharp & Dohme stated that its exhibition space was not used to promote any products. It comprised an unbranded medical and scientific affairs stand, and was intended to demonstrate the company's commitment to the development of new oncology therapies. Conscious of the challenges posed in combining scientific discussions with promotional activities at the same venue, Merck Sharp & Dohme decided not to have any material or promotion related to its licensed oncology and women's health products which could have been promoted, but which were not. Likewise, the company decided to focus on the science - mechanisms and biological pathways, biomarkers etc. - rather than present clinical efficacy or safety data, where it existed, and to staff the stand with appropriately trained scientific and medical staff. The stand was staffed exclusively by members of the medical affairs team during the meeting; it was never manned by members of sales or marketing and no sales people attended at the congress.

The stand was manned fulltime by a pharmacist employed as a medical information and product specialist who had extensive experience in handling scientific enquiries from health professionals. She was supported during breaks by an oncology medical science liaison (MSL). The MSL role was a non promotional, field-based medical affairs employee responsible for a therapeutic area such as oncology. Also present at times, and as delegates at the meeting, were two Merck Sharp & Dohme oncology physicians, one from oncology medical affairs, Germany and the other responsible for oncology medical affairs in Europe. As experienced medical affairs employees, no written briefing was given specific to this congress. A verbal briefing was given by the UK oncology medical adviser and UK medical information product specialist to the international Merck Sharp & Dohme medical affairs attendees. The key points of the briefing were:

- the requirements under the Code, as the meeting was an international congress which took place in the UK
- that promotion of unlicensed medicines was not allowed
- that staff were to respond to enquiries reactively, not to initiate discussion
- that there should be no proactive discussion of licensing status or possible timelines of regulatory milestones
- that staff should ensure all enquiries were logged, and subsequently passed to the scientific service for the Merck Sharp & Dohme affiliate in the country of the enquirer.

Merck Sharp & Dohme summarized the contents of the exhibition panels:

- panel 1: 'Merck Sharp & Dohme Oncology' panel highlighted the company's commitment to patients – image and slogan
- panels 2- 5: The panels highlighted the novel mechanisms and biological targets in development in the company's oncology pipeline. There was no detail of the tumour types studied. There were no statements on the panels about efficacy or adverse event profiles, nor was there any comparisons with any other oncology treatments. The panel made clear that the molecules were investigational
- panel 6: This panel summarized the design of a phase III study currently recruiting in Europe, including the UK, for patients with platinum-resistant ovarian cancer.

No materials were available on the stand for attendees and there was no invitation that 'more information is available on request'.

Merck Sharp & Dohme submitted that the exhibition panels were examined before the meeting by the oncology medical adviser and director of medical affairs as this exhibition was regarded as a non-promotional activity. The UK medical adviser had been trained extensively on the Code, including an exit assessment. Merck Sharp & Dohme provided details of its training programme. The UK MSLs and medical advisers received additional training on the guidance on Clause 3 of the Code in quarter 2 2013.

The UK medical affairs department working practice document articulated the company's guiding principles. The process for management of medical information stands at global congresses was described in a global SOP.

Merck Sharp & Dohme stated that the molecules mentioned on the panels were all in early phase research. The ERK inhibitor and HDM2 inhibitor were both in Phase I. MK3475 was being studied across various tumour types in Phase I to III. Phase III studies in melanoma and non-small cell (NSC) lung cancer started shortly after this congress took place. Vintafolide was in Phase II for non-small cell lung cancer and Phase III for ovarian cancer.

None of the molecules displayed on the stand panels had been submitted to any regulatory agency around the world, with the exception of vintafolide. Vintafolide had been submitted to the European Medicines Agency (EMA). When the ESGO meeting was held, regulatory approval, if granted, was estimated to be at least six to nine months away, and was still speculative.

The next molecule likely to become available was MK3475, assuming the studies confirmed the preliminary data. The other molecules were further from regulatory review.

None of these investigational agents were available for clinical use outside clinical trials – no compassionate use, expanded access or named patient programmes.

Merck Sharp & Dohme submitted that its activities at ESGO represented the legitimate exchange of medical and scientific information during the

development of a medicine, as permitted by the Code. The company did not consider that its activities could be interpreted as promotion of a medicine prior to the grant of a marketing authorization.

- none of the products were available to prescribe, outside the clinical trial setting
- the ESGO congress was an international congress of high scientific standing appropriate to the legitimate exchange of medical and scientific information
- there was no mention on the exhibition panels of any potential indication or specific tumour type, except when describing a clinical trial for which patients may be referred
- it was clearly stated that all agents were investigational
- no data were presented or claims made regarding efficacy or safety
- there were no details provided of regulatory timelines
- the activity was staffed solely and reactively by appropriately trained and experienced scientific staff, based within the company's medical function.

For these reasons, Merck Sharp & Dohme submitted that these activities did not amount to a breach of Clause 3.1.

Merck Sharp & Dohme submitted that, as described above, the primary purpose of the ESGO meeting was scientific, directed at a highly specialised group of clinical and research professionals. There was no evidence that members of the public attended the scientific meeting itself nor was there provision for patients to register as delegates. The ESGO Sponsorship and Exhibition Prospectus provided a detailed breakdown of delegates who attended the 2011 ESGO in Milan and there was no mention of patient groups or members of the public registering as delegates. The professional expertise listed were obstetrics & gynaecology (56%), oncology (34%), radiation oncology (4%), molecular cell biology (2%), pathology (2%), internal medicine (1%) and radiology/imaging (1%) which accounted for 100% of the delegates.

Merck Sharp & Dohme submitted therefore that the exhibition and poster area were primarily intended for clinicians, scientists and researchers and not for members of the public or patients. In any event, the activity on Merck Sharp & Dohme's stand was not promotional, and could not constitute promotion to the public.

Merck Sharp & Dohme submitted that Clauses 22.1 or 22.2 had not been breached.

Merck Sharp & Dohme denied breaches of Clauses 3.1, 22.1 and 22.2. Indeed, the company submitted that it had been particularly careful to maintain high standards of scientific exchange and that, far from bringing discredit upon the industry, this type of activity, carefully planned and executed, was an essential part of academic engagement that enhanced collaboration during the development of medicines, for the ultimate benefit of cancer patients.

Merck Sharp & Dohme thus denied breaches of Clauses 9.1 and 2.

In summary, Merck Sharp & Dohme stated that its stand at the ESGO meeting was scientific in nature and demonstrated to the healthcare community that the company was committed to develop new oncology therapies. The stand was manned at all times by experienced medical affairs staff, not by promotional staff members, and was intended for the legitimate scientific exchange at a meeting which was scientific by its very nature. There were no claims on the exhibition panels about efficacy or safety of any of the molecules. No materials were provided on the stand. Merck Sharp & Dohme strongly rejected the claims that it had promoted a medicine prior to a marketing authorization or that it advertised a prescription medicine to members of the public.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. As stated in the introduction to the Constitution and Procedure, anonymous complainants were accepted and like all complaints, judged on the evidence provided by the parties. Complainants had the burden of proving their complaints on the balance of probabilities. The Panel noted that as the complainant was non-contactable it was not possible to ask him/her for further information.

The Panel noted that Clause 3 prohibited the promotion of a medicine prior to the grant of its marketing authorization. It also required that promotion must be in accordance with the marketing authorization and not be inconsistent with the summary of product characteristics (SPC). The supplementary information to Clause 3 provided additional details, including a clear statement that the legitimate exchange of medical and scientific information during the development of a medicine was not prohibited provided that this did not constitute promotion which was prohibited by Clause 3 or any other clause in the Code.

Clause 1.2 defined 'promotion' as 'any activity undertaken by a pharmaceutical company or with its authority which promotes the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines'.

The Panel noted that the PMCPA Guidance about Clause 3 included advice about the legitimate exchange of medical and scientific information during the development of a medicine. This was not prohibited provided that any such information or activity did not constitute promotion which was prohibited under this or any other clause. Companies must ensure that such activities constituted a genuine exchange of information and were not promotional. Documents must not have

the appearance of promotional material. It should be borne in mind that it would be a breach of the Code if non-promotional information on products or indications that were not licensed was used for a promotional purpose.

The Panel did not consider that the arrangements could take the benefit of the exemption to the definition of promotion for unsolicited enquiries. It noted that Merck Sharp & Dohme held a company sponsored satellite symposium in addition to the exhibition stand at issue. There was no complaint about the satellite symposium and the Panel had no information about it. The Panel was only considering the exhibition stand.

The Panel examined the information on the 6 exhibition stand posters. Three of them referred to particular inhibitors ERK, PD-1 and CDK. Each was illustrated with a diagram of cell activity. This was followed by a description of the pathway or molecule. The final part of each of these three posters referred to the Merck Sharp & Dohme product under development and the final statement 'The agent or uses depicted are investigational'. The PD-1 poster referred to *in vivo* and *in vitro* data which showed that PD1 and/or PD-L1 blockade using monoclonal antibodies enhanced tumour cell-specific T-cell activation, cytokcine production, anti-tumour effector mechanisms, and clearance of tumour cells by the immune system. The fourth poster (exhibition stand panel 6) gave details about the PROCEED trial which was a phase 3 trial of vintafolide in platinum-resistant ovarian cancer. It was headed 'Now enrolling patients with platinum-resistant ovarian cancer'. It stated that vintafolide was a conjugate of folate linked to a named chemotherapy agent which was being used in conjunction with etarfolatide to identify patients with tumors that expressed folate receptors. The poster gave details about the study design, outcome measurements as well as the inclusion and exclusion criteria. At the bottom of the poster was an invitation 'to learn more'. This mentioned the availability of additional information as well as how to find out how to participate in the trial by speaking to the representative on the booth or calling a US/international number or visiting clinicaltrials.gov. The fifth poster depicted the Merck Sharp & Dohme oncology research pipeline giving details of the investigational compound and description of the target. Again, the phrase 'The agents or uses depicted here have not been approved by any regulatory agency' appeared. The final poster was a Merck Sharp & Dohme oncology corporate poster. It had no reference to products.

The Panel noted the research phase of each product. The ERK inhibitor and HDM2 inhibitor were both in Phase I. MK3475 was being studied across various tumour types in Phase I to III. Phase III studies in melanoma and non-small cell (NSC) lung cancer started shortly after this congress took place. Vintafolide was in Phase II for non-small cell lung cancer and Phase III for ovarian cancer.

The Panel also noted each product's licensing status. Only one of the molecules referred to on the exhibition stand had been submitted to any regulatory agency around the world. Vintafolide had been submitted to the European Medicines Agency (EMA) for conditional approval for the treatment of platinum-resistant ovarian cancer based on preliminary phase II data. When the ESGO meeting was held, regulatory approval, if granted, was estimated to be at least six to nine months away, and was still speculative.

The Panel considered that relevant factors for consideration in such circumstances included the nature of the meeting, the status of attendees, the location of the Merck Sharp & Dohme stand and whether it constituted the legitimate exchange of medical and scientific information during the development of a medicine.

The Panel noted Merck Sharp & Dohme's submission that the ESGO meeting was a meeting of high scientific standing and attendees would include researchers etc.

The Panel noted that the posters primarily detailed the effect of the target for the investigational compounds, the PD1 poster, however, was slightly different as was the poster describing the PROCEED trial. The Panel noted Merck Sharp & Dohme's submission that it had not promoted any of its licensed products on the exhibition stand. Merck Sharp & Dohme referred to the products as investigational molecules/agents. Whilst this term was not defined, the Panel queried whether products subject to Phase III trials (vintafolide and MK3475) and for which a conditional licence was anticipated within 12 months (vintafolide) would be considered investigational molecules.

The Panel considered that delegates were likely to view the exhibition space as a whole as promotional and might not necessarily appreciate the differences between promoting products and promoting research. The Panel noted Merck Sharp & Dohme's submission that the exhibition hall was used as part of the scientific programme as it hosted the ESGO poster display area.

The Panel considered that it was difficult to decide whether the materials were in line with the requirements of the supplementary information to Clause 3. It noted that one of Merck Sharp & Dohme's aims was to raise awareness of the company's commitment to oncology and to talk with basic and clinical scientists. The company also wanted to make clinicians aware of the ongoing Phase III clinical trial. The Panel noted that the style of the posters was low key and scientific. The stand was manned by scientific and medical staff. Only one of the products had been submitted for approval but this was not expected for at least six to nine months.

The Panel did not know whether the meeting agenda included any content that could be considered the legitimate exchange of medical and scientific information during the development of the Merck Sharp & Dohme products. Merck Sharp & Dohme had sponsored a satellite symposium but there

was no complaint about that and the Panel had no information about it.

The Panel was only concerned about the PD-1 poster and the PROCEED trial poster. The PROCEED trial poster in particular was materially different to the other posters both in content and the licensing status of the product. The poster advised delegates that the trial was currently recruiting and was thus an invitation to participate. In the Panel's view the invitation would necessarily solicit enquiries. The Panel queried whether any associated discussion about the logistics of trial participation and the provision of information about the medicine in relation to the trial could fairly be described as the legitimate exchange of medical and scientific information. The Panel however had no evidence before it about such discussions. Given the discrete nature of such discussions the Panel queried whether it was appropriate to display the PROCEED trial poster alongside the others.

The Panel considered that the other four posters did not constitute advertising a product prior to the grant of the marketing authorization. There was very limited information about the efficacy of any potential product on these four posters and the products were a long way from receiving any licence. Similarly, whilst the Panel was concerned about the *in vivo* and *in vitro* data in the PD1 poster it was, nonetheless, limited and on balance the Panel did not consider that it was advertising a product prior to the grant of its marketing authorisation. No breach of Clause 3.1 was ruled in relation to the five posters.

The Panel noted its concerns about the PROCEED trial poster set out above. The Panel considered that within the context of the exhibition stand it did not satisfy the requirements for the legitimate exchange of medical and scientific information during the development of a medicine. Nevertheless, given the narrow grounds of the complaint and on balance, the Panel did not consider the poster amounted to the promotion of an unlicensed medicine and no breach of Clause 3.1 was ruled.

The Panel noted the allegation that the Merck Sharp & Dohme stand would encourage requests for the new products as patient groups and carers might be present at the meeting. It did not appear that the meeting was aimed at such an audience and the data provided by Merck Sharp & Dohme in relation to the attendees at the 2011 meeting did not mention patient groups or carers. The Panel considered that the complainant had not discharged his/her burden of proof and thus ruled no breach of Clause 22.1 and 22.2. Noting its rulings above the Panel ruled no breach of Clauses 2 and 9.1.

Complaint received **8 November 2013**

Case completed **11 December 2013**