CASE AUTH/3267/10/19

EMPLOYEE v LEO PHARMA

Sponsorship of health professionals and staff training

An anonymous, non-contactable individual, who appeared to be a current employee of Leo Pharma, complained about some of the company's promotional practices.

The complainant alleged that one particular manager invited the same few people to congresses year on year and that in some cases this could be construed as a personal incentive to prescribe given the frequency of the all-expenses paid trips abroad. The complainant was further concerned about the level of hospitality provided, including large drinks bills.

The complainant also alleged that Leo sponsored health professionals to attend meetings on request and was concerned that, until recently, payments went into doctors' personal bank accounts. The complainant did not know if delegates ever went to the educational event or went on holiday as their hospitals might not have known they were going abroad since Leo paid them directly. This seemed like bribery and brought the industry into disrepute.

The complainant alleged that sales managers appeared to have limited knowledge of compliance and would not be told how things could be done. The complainant queried whether they had been trained and had passed the ABPI examination.

The detailed response from Leo Pharma is given below.

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted but that, like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant had provided no evidence to support his/her allegations and could not be contacted for more information. The PMCPA was not an investigatory body as such and it was not for the Panel to make out the complaint.

The Panel noted Leo's submission that reactive sponsorship requests from health professionals to attend educational meetings and conferences, local or international, were approved where it was judged that they would benefit patients and/or the NHS and complied with the Code; payment was made to the health professionals only after they submitted valid receipts for expenditure which was related to the dates and location of the events in question.

Although mindful of the impression that it created, the Panel noted that it was not necessarily unacceptable to make such payments directly into a health professional's

personal bank account provided the payments tallied with receipts and otherwise complied with the requirements of the Code.

The Panel did not consider that the complainant had provided evidence that Leo had not maintained high standards; no breach of the Code was ruled. Similarly, there was no evidence provided to support the serious allegation that the direct payment of expenses was such as to bribe health professionals and bring the industry in to disrepute. No breach of the Code was ruled.

With regard to proactive sponsorship, the Panel noted Leo's submission that typically, the health professionals invited to attend international congresses varied from year to year, but a minority might have been invited and attended more than one congress since 2016; the criteria used to select potential delegates to attend one event did not exclude those who had previously received sponsorship to attend another.

The Panel noted Leo's submission that all proposed arrangements, including travel, registration, accommodation and hospitality (restaurant and cost per head of meals) for the group of health professionals to be invited to each congress were certified for compliance with the Code.

The Panel noted Leo's submission that subsistence for a set number of attendees was reserved and guaranteed at international congresses eg a planned dinner for 45 individuals would still result in an invoice relating to 45 individuals even if fewer attended. Leo had submitted that the budgeted cost per head for subsistence meals never exceeded £75 per head and had provided a table summarising costs incurred per meal at international congresses since 2016 which included 3 at more than £75 per head. The Panel noted, however, that the £75 limit did not apply when a meeting was held outside the UK in a European country where the national association was a member of EFPIA and thus covered by EFPIA Codes. In such circumstances, the limit in the host country code would apply and might be less than £75. Leo had not provided details of where the international congresses it referred to had occurred. The Panel noted Leo's submission that the arrangements and payments for the meals were undertaken by a third-party event management agency. The Panel noted the company's submission that these actual costs to Leo per meal included service charges from the vendors, as well as tips/gratuities, charges, exchange rate costs and taxes charged by the restaurant. The Panel was concerned to note that although, according to Leo, the approved planned costs were agreed with the vendor including the specific meal costs incurred at the restaurant, the invoices and documentation related to the meals retained by the vendor did not include an itemised breakdown of costs to include the meal, drinks, service etc.

Although the Panel had some concerns, it noted that the complainant had provided no evidence to show that excessive hospitality had been provided or that any proactive sponsorship could be construed as a personal incentive to prescribe. Given the generality of the allegations, the Panel's view was that the complainant had not satisfied the burden of proof in relation to the relevant clauses of the Code. No breaches of the Code were ruled.

With regard to the very broad and vague allegation that sales managers appeared to have limited knowledge of compliance and whether the sales managers had passed the ABPI examination, the Panel noted that the Code required representatives to take an

appropriate examination within their first year of employment as a representative and must pass it within two years of starting such employment.

The Panel noted Leo's submission that the sales managers in question were regional business managers (RBMs) and that, although field based (in the Republic of Ireland and in the UK), their role was not that of a representative for the purposes of the Code. Whether an employee was a representative for the purposes of the Code depended upon their role, not upon their job title. The Panel noted the job descriptions provided by Leo and considered that the RBMs would call upon health professionals and other relevant decision makers and that such calls would be made for the ultimate purpose of promotion ie to promote the administration, consumption, prescription, purchase, recommendation, sale, supply or use of Leo's medicines. The Panel thus considered that the RBMs were not exempt from the requirement to pass an appropriate examination.

The Panel further noted that it was stated in both the UK and Republic of Ireland job descriptions provided by Leo that the RBMs had to be ABPI qualified.

The Panel noted Leo's submission that its UK RBMs had passed the ABPI examination for representatives and therefore no breach of the Code was ruled in relation to the UK RBMs.

Noting Leo's submission that the RBM's based in the Republic of Ireland covered a large section of the UK, the Panel considered that in so much as both RBMs spent time working in the UK they would, for that portion of their role, be covered by the UK Code and would thus be required to take an appropriate examination.

The Panel noted Leo's submission that whilst the RBMs based in the Republic of Ireland had not passed the ABPI Medical Representatives Examination, they had passed an examination from the educational body for healthcare industry representatives in the Republic of Ireland (MRII). The Panel noted Leo's submission that the MRII qualification required knowledge similar to that required for the ABPI examination. On the limited information before it the Panel noted that whilst the ABPI and MRII examinations were not identical, the subjects studied appeared to be similar; both included components which the other did not. The Panel had no information before it about the standard of the MRII examination.

The Panel noted that this was the first time that a complaint had been submitted regarding the examination status of representatives working cross border between the Republic of Ireland and the UK and in that regard the Panel noted advice on the ABPI Examination website: 'Please note that similar representative exam passes are not recognised by ABPI wherever the exam was passed. There are no mutual recognition arrangements and no exemptions from the requirement to pass the exam if you wish to promote medicines in the UK'.

Taking all of the circumstances into account the Panel thus considered that the RBMs based in the Republic of Ireland and working in the UK needed to take an appropriate examination as required by the Code in relation to that part of their role covered by the UK Code. As no such appropriate, and mutually recognised examination had been taken, a breach of the Code was ruled.

With regard to the overall level of training of the RBMs, the Panel noted that the complainant had provided no evidence to suggest that it might be lacking. The Panel noted Leo's submission that it had a range of detailed procedures and training to ensure compliance with the Code. The Panel considered that the complainant had not shown, on the balance of probabilities, that the RBMs had not been adequately trained. No breach of the Code was ruled.

The Panel did not consider that in the particular circumstances of this case, noting the limited information it had before it about the MRII examination, its ruling of a breach of the Code with regard to the cross border RBMs meant that overall high standards had not been maintained and on balance no breach of the Code was ruled.

The Panel noted that there was no evidence that Leo had brought discredit to, or reduced confidence in, the industry based on the complainant's allegations and no breach of Clause 2 of the Code was ruled.

An anonymous, non-contactable individual, who appeared to be a current employee of Leo Pharma, complained about some of the company's promotional practices.

COMPLAINT

The complainant alleged that one particular manager essentially invited the same few people to congresses year on year and he/she was concerned at the level of hospitality provided to the delegates, including large drinks bills. The complainant alleged that this had been going on for years and in some cases could be construed as a personal incentive to prescribe given the frequency of the all-expenses paid trips abroad. Leo should be asked to provide receipts for these congresses for the past several years, including food and alcohol bills.

The complainant also alleged that Leo sponsored health professionals to attend meetings on request and, until very recently, payments went into doctors' personal bank accounts. The complainant did not think this was right. The complainant did not know if the delegates ever went to the educational event or went on holiday as their hospitals might not have known they were going abroad since Leo paid them directly. This seemed like bribery and brought the industry into disrepute.

The complainant alleged that sales managers appeared to have limited knowledge of compliance and would not be told how things could be done. Some of the knowledge gaps were very large. The complainant queried whether they had been trained and had passed the ABPI examination.

When writing to Leo, the Authority asked it to bear in mind the requirements of Clauses 2, 9.1, 16.1, 16.3, 22.1 and 22.2 of the Code.

RESPONSE

Leo submitted that it took the Code extremely seriously and had detailed procedures and training in place to ensure compliance with it, including for the provision of sponsorships (both reactive and proactive) for a wide range of activities including~~, but not limited to,~~ attendance at international and local congresses.

Leo noted that the complainant had the burden of proving his/her complaint. In this case the complainant had raised general points about activities without reference to any particular or specific instance/activity/material of concern nor any clearly specified time period; no evidence had been provided to support the allegations.

Leo submitted that it had defined the scope of its investigation to Leo-supported attendance at international congresses with proactive sponsorship via the manager referred to by the complainant; reactive sponsorships and their payment; and the role of the 'sales managers' including the ABPI qualification. The investigations into each area included, but was not limited to, interviews with individuals, current standard operating procedures (SOPs), work instructions (WIs), and internal systems (eg Disclosure Database).

1 Sponsorship

Leo referred to its relevant SOP which outlined its procedures with regard to both reactive and proactive sponsorship. Copies were provided.

Reactive sponsorship

Leo submitted that reactive sponsorships were defined as an unsolicited request by an individual received via a sponsorship request letter addressed to Leo Pharma or an employee. These could be for international congresses/symposia or local congresses/symposia but were not limited to such. The process followed was outlined in the above SOP.

Support for reactive sponsorship requests were approved where it was judged that they would benefit patients and/or the NHS and complied with the Code. Any such support was provided as an arm's length arrangement.

On 1 November 2018, a new process was rolled out for the provision of reactive support to health professionals to attend educational meetings and conferences. Prior to this change, the applicable SOP was v2.0. Health professionals had to submit a letter of request for reimbursement of any upfront costs incurred with regard to registration, travel or accommodation. If the request was approved, a letter of agreement setting out the nature and amount of support had to be signed by both parties. Subsequently, payment was made to the health professional only after submission of valid receipts for such incurred expenditure and which related to the dates and location of the congress. These requests would either be for local or international meetings. No payment would be made without submission of valid receipts as described.

If a representative received such a request, and the meeting was local, the representative would set the request up on the internal customer relationship management (CRM) system as a 'Medical Event' and submit it to his/her line manager for approval together with all relevant documentation eg meeting agenda, letter or request, draft sponsorship of attendance agreement and any other relevant documentation such as flight tickets, hotel accommodation and/or registration receipts. These would be reviewed and either approved or rejected based on criteria set out in the Sponsorship SOP.

If the meeting was international, it had to first be submitted to Leo's global on-line approval tool for all cross-border engagements. This then had to be approved locally in the country of the health professional and in the country of the activity, by authorised persons.

Prior to v2.0, the applicable document was v1.0 which was similar to v2.0 but also included the process for grants and donations to healthcare organisations (HCOs).

From 1 November 2018, the practice of paying health professionals directly for proven and valid expenditure stopped and all meeting arrangements for travel, registration and accommodation were made directly by a contracted external vendor on behalf of Leo Pharma UK/IE based on budget availability and compliance with the Code. The SOPupdate reflecting this change was put into effect in July 2019; a planned deviation was in place prior to this.

The process mandated that recipient health professionals had signed letters of agreement which stipulated a number of declarations and commitments incumbent upon them; the relevant text in the agreement was as follows:

- Comply with applicable laws, regulations and rules (including the internal rules and guidelines of the University or Hospital pertinent to your institution) and the receipt of support from third parties such as Leo Pharma.
- Comply with the ethical rules applicable to your organisation.
- Make all required verbal and written disclosures pertaining to the support the RECIPIENT receives from Leo Pharma.
- Obtain all approvals regarding this funding as required by applicable laws, regulations and rules, including required notification to ethics committees, government agencies, your trustees and members, etc.

Furthermore, it was highlighted that; 'For the purposes of clarity, this funding is a stand-alone arrangement. On no account should it be regarded as an incentive or reward to purchase, supply, prescribe, administer or recommend the use of LEO Pharma products'. The agreement further stipulated that the funding was provided on the understanding that it was used in accordance with the statements made in the agreement. The applicant should contact the company immediately if any circumstances changed since the company would reserve the right to withdraw its support should the changes mean the meeting attendance fell outside company policies.

Leo required all employees to undertake training assessment and certification on anti-bribery and anti-corruption. The relevant section of the Leo Code of Conduct stated that business interactions such as providing or receiving hospitality, and sponsorships or other remuneration could be perceived as having an undue influence on business decisions. Employees must never offer, provide or accept any of these in order to win or retain business in exchange for an improper advantage or in a manner or under conditions that might have an improper influence on the recipient.

For sponsorships as described above these should only be provided for the purpose of medical education which would ultimately benefit patients and the NHS.

Leo provided details of the nearly 290 reactive sponsorships approved and supported since January 2016 including how many each year which ranged from 75 in 2016 to less than 60 in 2019. These sponsorships were not limited to meetings but covered a wide range of sponsorship activity. The figures were reflective across the entire UK affiliate including both the thrombosis and dermatology divisions. Just over 170 were in relation to meetings held in the UK. In addition, there were sixteen meetings for which the location was not recorded in the disclosure database.

In summary, reactive sponsorships were approved and provided as an arm's length arrangement for the ultimate benefit for patients and the NHS in accordance with the process described above. Therefore, Leo submitted that there was no breach of the Code.

Proactive sponsorship

Proactive sponsorships were instigated by Leo. Leo listed those in the company who might identify an international event or congress to which it would be appropriate to invite health professionals to attend for the purpose of medical education. Invitations were then sent to health professionals who might benefit from such education and who would share learnings with peers upon their return; principally consultant dermatologists but also other health professionals who might similarly benefit. Health professionals were nominated using internal selection criteria and were considered for attendance at the approved event after approval with the budget holder. Up until July 2019 health professionals were chosen and invited on the basis of their ability to benefit from the medical education at the congress and to disseminate to their peers on their return. After July 2019, criteria for such selection were formalised and documented with a selection criteria proforma sheet made effective in August 2019. Typically, those invited varied from year to year, but a minority might have been invited and attended more than one congress during this time period. The selection criteria did not exclude health professionals who had previously been sponsored to attend. The selection criteria were provided.

The proposed arrangements, including travel, registration, accommodation and hospitality (restaurant and cost per head of meals) for the group of health professionals to be invited to each congress were certified for compliance with the Code. Furthermore, approval for all these arrangements was required to be sought from the Leo person responsible for compliance in the country where the congress etc would take place. This included the budgeted cost per head for subsistence meals which never exceeded £75 per head. Leo submitted that its SOP restricted accommodation to hotels of an acceptable standard with regard to comfort, amenities and safety but must not be regarded as opulent. Five star accommodation was not allowed. These standards also applied to restaurants. The company guidance on hospitality was provided.

During this preparatory process prior to congress, all accepted delegates were required to sign a letter of agreement, which set out the purpose of the sponsorship and their commitments including in relation to the Code.

Leo noted that the complainant had referred to invitations to congresses undertaken by one particular manager. That manager was only involved in proactive sponsorship of individuals within one business unit and so Leo narrowed its area of investigation to that business unit only.

Congresses and subsistence

All proposed arrangements including nature of and per head costs for travel, accommodation, registration and subsistence were certified in accordance with the Code.

Subsistence for a set number of attendees was reserved and guaranteed at international congresses eg a planned dinner for 45 individuals would still result in an invoice relating to 45 individuals regardless of whether fewer attended. These attendees might include delegates who had been proactively sponsored to attend the congress as well as those already at the congress.

Actual costs to Leo

Leo provided a table summarising the number of meals and the cost to Leo per meal at nine international congresses since 2016. The locations of the congresses were not stated. Leo submitted that the arrangements and payments for all of those meals were undertaken by a third party event management agency under contract. This agency further subcontracted elements of its contracted services to other vendors.

The actual costs to Leo per meal included service charges from the vendors, as well as tips/gratuities, charges, exchange rate costs and taxes charged by the restaurant. The invoices and documentation related to the meals retained by the vendor did not include a further itemised breakdown of the meal costs.

The approved planned costs were agreed with the vendor including the specific meal costs incurred at the restaurant.

In summary, a strict budgetary planning and approval process was designed to ensure that the arrangements remained within the requirements of the Code. Therefore, Leo submitted it was not in breach of the Code.

2 Regional business managers

With regard to sales managers as referred to by the complainant, Leo provided details of regional business managers (RBMs) in the UK and in the Republic of Ireland. The RBMs played a fundamental role, line managing their direct reports (account managers). Most of the RBMs reported into the national head of sales, others reported into the business unit directors. The RBM roles were managerial in nature. The job descriptions did not include 1 to 1 calling on health professionals for the purpose of promoting medicines. Furthermore, RBMs were not set any objectives or incentives for 1 to 1 calls or contacts on health professionals. Therefore, the role of an RBM was not that of a representative for the purposes of the Code, and for which Clause 16.3 would require that he/she had passed an appropriate examination. Nevertheless, the UK RBMs had passed the ABPI examination for representatives. The RBMs in the Republic of Ireland covered both the Republic of Ireland and a large section of the UK , details were provided. The job descriptions for these individuals did not mandate a requirement for the ABPI examination. However, the individuals in the roles had passed the MRII examination. This qualification included knowledge of anatomy, physiology, clinical medicine and pharmacology in a manner similar to the ABPI examination. In addition the RBMs based in the Republic of Ireland undertook annual online ABPI Code training, assessment and certification provided by a third party.

In summary, Leo submitted that the RBM role was not that of a representative and so Clause 16.3 was not applicable. Nevertheless, all of the RBMs were suitably trained and knowledgeable including in relation to the Code to a degree required for their role.

Conclusion

Leo submitted that it had a range of detailed procedures and training to ensure compliance with the Code. This included procedures and training for the activities referred to by the complainant. The investigation did not find any activity which was in breach of the Code. On the contrary, Leo had set out the procedures and summary information from the applicable

years on the basis of which it did not believe there had been a breach of Clauses 2, 9.1, 16.1, 16.3, 22.1 and 22.2.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure for the PMCPA stated that anonymous complaints would be accepted but that, like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant had provided no evidence to support his/her allegations and could not be contacted for more information. The PMCPA was not an investigatory body as such and it was not for the Panel to make out the complaint.

The Panel noted the detailed response from Leo. It considered each allegation as follows:

1 Reactive sponsorship

The Panel noted Leo's submission that support for reactive sponsorship requests from health professionals to attend educational meetings and conferences, either local or international, were approved where it was judged that they would benefit patients and/or the NHS and complied with the Code and payment was made to the health professionals only after they submitted valid receipts for such incurred expenditure which was related to the dates and location of the events in question. No payment would be made without submission of valid receipts.

Although mindful of the impression that it created, the Panel noted that it was not necessarily unacceptable to make such payments directly into a health professional's personal bank account provided the payments tallied with receipts and otherwise complied with the requirements of the Code.

The Panel did not consider that the complainant had provided evidence that Leo had not maintained high standards in this regard; no breach of Clause 9.1 was ruled. Similarly, there was no evidence provided to support the serious allegation that the direct payment of expenses was such as to bribe health professionals and bring the industry in to disrepute. No breach of Clause 2 was ruled.

2 Proactive sponsorship

The Panel noted Leo's submission with regards to how health professionals were selected to attend international congresses. The Panel noted Leo's submission that typically, those invited varied from year to year, but a minority might have been invited and attended more than one congress since 2016 as the criteria used to select potential delegates to attend one event did not exclude health professionals who had previously received sponsorship to attend another.

The Panel noted that Clause 22.1 stated that hospitality must be strictly limited to the main purpose of the event and must be secondary to the purpose of the meeting, ie subsistence only. The level of subsistence offered must be appropriate and not out of proportion to the occasion. Clause 22.1 applied to scientific meetings, promotional meetings, scientific congresses and other such meetings and training. The supplementary information to Clause 22.1 also stated that a useful criterion in determining whether the arrangements for any meeting were acceptable was to apply the question 'Would you and your company be willing to have these arrangements

generally known?'. The impression that was created by the arrangements for any meeting must always be kept in mind.

The Panel noted that Clause 22.2 stated that the cost of a meal (including drinks) provided by way of subsistence must not exceed £75 per person excluding VAT and gratuities. The supplementary information included that the maximum of £75 plus VAT and gratuities (or local equivalent) would only be appropriate in very exceptional circumstances such as a dinner at a residential meeting for senior consultants or a learned society conference with substantial educational content. It also made it clear that the limit did not apply when a meeting was held outside the UK in a European country where the national association was a member of EFPIA and thus covered by EFPIA Codes. In such circumstances, the limits in the host country code would apply.

The Panel noted Leo's submission that all proposed arrangements, including travel, registration, accommodation and hospitality (restaurant and cost per head of meals) for the group of health professionals to be invited to each congress were certified for compliance with the Code.

The Panel noted Leo's submission that subsistence for a set number of attendees was reserved and guaranteed at international congresses eg a planned dinner for 45 individuals would still result in an invoice relating to 45 individuals regardless of whether the number that attended was fewer. Leo had submitted that the budgeted cost per head for subsistence meals never exceeded £75 per head and had provided a table summarising costs incurred per meal at international congresses since 2016 which included 3 at more than £75 per head. The Panel noted, however, the supplementary information to Clause 22.2 which stated that the £75 limit did not apply when a meeting was held outside the UK in a European country where the national association was a member of EFPIA and thus covered by EFPIA Codes. In such circumstances, the limit in the host country code would apply and might be less than £75. Leo had not provided details of where the international congresses it referred to had occurred. The Panel noted Leo's submission that the arrangements and payments for all of the meals at these international congresses were undertaken by a third-party event management agency under contract which subcontracted elements of its contracted services to other vendors. The Panel noted the company's submission that these actual costs to Leo per meal included service charges from the vendors, as well as tips/gratuities, charges, exchange rate costs and taxes charged by the restaurant. The Panel was concerned to note that although, according to Leo, the approved planned costs were agreed with the vendor including the specific meal costs incurred at the restaurant, the invoices and documentation related to the meals retained by the vendor did not include an itemised breakdown of costs to include the meal, drinks, service etc.

Although the Panel had some concerns, it noted that the complainant had provided no evidence to show that excessive hospitality had been provided or that any proactive sponsorship could be construed as a personal incentive to prescribe. Given the generality of the allegations, the Panel's view was that the complainant had not satisfied the burden of proof in relation to Clauses 22.1 and 22.2. The Panel therefore ruled no breach of Clauses 22.1 and 22.2.

3 Regional business managers

The Panel noted the very broad and vague allegation that sales managers appeared to have limited knowledge of compliance, would not be told how things could be done and had large gaps in their knowledge. The complainant queried the sales managers' overall level of training and whether they had passed the ABPI examination.

The Panel noted that Clause 16.3 stated that representatives must take an appropriate examination within their first year of employment as a representative and must pass it within two years of starting such employment.

The Panel noted Leo's submission that the sales managers referred to by the complainant were regional business managers (RBMs) and that, although field based, their role was not that of a representative for the purposes of the Code and so they did not need to take the representatives' examination as required by Clause 16.3. Whether an employee was a representative for the purposes of the Code depended upon their role, not upon their job title. In that regard, the Panel noted that the definition of a representative meant a representative calling on members of the health professions and other relevant decision makers in relation to the promotion of medicines. The Panel noted that the job descriptions provided by Leo made it clear that the RBMs had to develop relationships with relevant key external stakeholders and were expected to lead and motivate their teams to deliver against agreed sales targets. In that regard, noting the broad definition of promotion, the Panel considered that the RBMs would call upon health professionals and other relevant decision makers and that such calls would be made for the ultimate purpose of promotion ie to promote the administration, consumption, prescription, purchase, recommendation, sale, supply or use of Leo's medicines. The Panel thus considered that the RBMs were not exempt from the requirement to pass an appropriate examination.

The Panel further noted that it was stated in both the UK and Republic of Ireland job descriptions provided by Leo that the RBMs had to be ABPI qualified.

The Panel noted Leo's submission that its UK RBMs had passed the ABPI examination for representatives and therefore no breach of Clause 16.3 was ruled in relation to the UK RBMs.

The Panel noted Leo's submission that the RBM's based in the Republic of Ireland covered a large section of the UK. The Panel thus considered that in so much as both RBMs spent time working in the UK they would, for that portion of their role, be covered by the UK Code and be required to take an appropriate examination as required by Clause 16.3.

The Panel noted that Clause 16.3 stated that an appropriate examination for medical representatives was one that required a broad understanding of body systems, diseases and treatments, the development of new medicines and the structure and function of the NHS and of the pharmaceutical industry. Such an examination must be a Diploma (at least 37 credits or equivalent learning hours). An appropriate examination could be either the relevant ABPI examination or an examination of at least the same standard as the ABPI examination and covering similar content and learning material as the corresponding ABPI examination. To be acceptable, such an examination must have been accredited to at least Level 3 by an external awarding body recognised by Ofqual. The Panel noted that Ofqual was a body which regulated qualifications, examinations and assessments. The supplementary information to Clause 16.3, Examinations, stated that a company using an examination provider other than the ABPI must be able to demonstrate that its examinations were at least equivalent to those offered by the ABPI.

The Panel noted Leo's submission that whilst the RBMs based in the Republic of Ireland had not passed the ABPI Medical Representatives Examination, they had passed the MRII examination – an examination from the educational body for healthcare industry representatives in Ireland. The Panel noted Leo's submission that the MRII qualification required a knowledge

of anatomy, physiology, clinical medicine and pharmacology in a manner similar to the ABPI examination. From the MRII website it appeared that candidates also had to demonstrate an up-to-date understanding of the industry in which they worked. On the limited information before it the Panel noted that whilst the ABPI Examination and the MRII examination were not identical, the subjects studied appeared to be similar; both included components which the other did not. The Panel had no information before it about the standard of the MRII examination.

The Panel noted that this was the first time that a complaint had been submitted regarding the examination status of representatives working cross border between the Republic of Ireland and Northern Ireland/the whole of Northern UK and in that regard the Panel noted, in addition to the evidence provided by the parties, the following Q&A included on the ABPI Examination website: 'Are medical representative qualifications from other countries recognised in the UK?' the answer was 'Please note that similar representative exam passes are not recognised by ABPI wherever the exam was passed. There are no mutual recognition arrangements and no exemptions from the requirement to pass the exam if you wish to promote medicines in the UK'.

Taking all of the circumstances into account the Panel thus considered that the RBMs based in the Republic of Ireland and working in Northern Ireland/other areas of the UK needed to take an appropriate examination as required by Clause 16.3 in relation to that part of their role covered by the UK Code. As no such appropriate, and mutually recognised examination had been taken, a breach of Clause 16.3 was ruled.

With regard to the overall level of training of the RBMs, the Panel noted that the complainant had provided no evidence to suggest that it might be lacking or that, as alleged, there were large gaps in their knowledge. The Panel noted Leo's submission that it had a range of detailed procedures and training to ensure compliance with the Code. The Panel considered that the complainant had not shown, on the balance of probabilities, that the RBMs had not been adequately trained. No breach of Clause 16.1 was ruled.

The Panel noted whilst the RBMs based in the Republic of Ireland and working in Northern Ireland/other areas of the UK had not passed an appropriate examination as required by Clause 16.3, they had passed the MRII examination which appeared to include similar subjects. The Panel had no information before it about the standard of the MRII examination. The Panel further noted that the job description for one of the RBMs based in the Republic of Ireland stated that essential knowledge included an understanding of the UK healthcare system and Leo submitted that all of the RBMs were suitably trained and knowledgeable including in relation to the Code to a degree required for their role. The Panel noted that the UK RBMs had passed the ABPI Examination. The Panel therefore did not consider that in the particular circumstances of this case, noting the limited information it had before it about the MRII examination, its ruling of a breach of Clause 16.3 with regard to the cross border RBMs meant that overall high standards had not been maintained and on balance no breach of Clause 9.1 was ruled.

The Panel noted that there was no evidence that Leo had brought discredit to, or reduced confidence in, the industry based on the complainant's allegations and no breach of Clause 2 was ruled.

Complaint received 23 October 2019

Case completed **29 January 2021**