PHARMACOSMOS A/S V VIFOR PHARMA

Contracts with Health Professionals

Pharmacosmos A/S complained that exclusivity clauses in Vifor Pharma's consultancy contracts with health professionals were in breach of the Code.

Pharmacosmos alleged that several physicians had stated that they were unable to undertake consultancy work on behalf of Pharmacosmos as this would place them in breach of a pre-existing contract with Vifor.

Pharmacosmos was concerned that some of Vifor's consultancy arrangements with NHS service providers (organisations and individuals) were such that they constituted 'retainer' arrangements of the type banned by the Code and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) and European Federation of Pharmaceutical Industries Associations (EFPIA) Codes. Whilst the confidential nature of some consultancy work was recognised there were clearly practical and legal issues that arose from exclusivity clauses including competition law, and barriers to market penetration. There were also patient safety issues and practical considerations for the NHS.

Pharmacosmos was conscious that it had not cited a specific example; however this complaint was based on the wording of the final inter-company response from Vifor:

> **'We cannot comment on whether or not individuals can work on projects for both Vifor and Pharmacosmos at the same time as it will depend on the terms of their particular contracts in question'.**

Pharmacosmos considered this was a clear admission that some contracts contained exclusivity clauses. Pharmacosmos sought confirmation that these were reserved for the most appropriate scenarios and did not, for example routinely prevent health professionals from speaking at meetings or attending advisory boards, etc, organised by other companies.

Pharmacosmos did not wish to interfere with the fair and reasonable contracting arrangements between Vifor and its suppliers and did not seek commercially sensitive information. However it was clear that exclusivity clauses were in use and depending on the wording of such clauses, a breach of the Code was therefore likely.

Pharmacosmos noted the requirements in the Code about the use of consultants and believed that these requirements should limit the use of exclusivity clauses to all but the most important confidential matters and should be used in highly specific and very limited circumstances.

Pharmacosmos submitted that it would be difficult to establish a need for an exclusivity clause as part of a speaker contract, for example, without implying an obligation on the part of the consultant.

Pharmacosmos stated that further considerations then arose as to why certain individuals were selected for the consultancy services – was it because the service was genuinely needed and the individual was the most appropriate, or was it to block that individual's availability to other companies.

Pharmacosmos stated there was recent case precedent whereby a complaint could be raised on the suspicion of inappropriate activity, even though the company complainant could not furnish detailed evidence (Cases AUTH/2479/2/12 and AUTH/2480/2/12). In those cases the complainants suspected inappropriate activity at a symposium but had not seen the slides or been present on the day. The case report indicated that the PMCPA sought copies of the slides and made a judgement based on the material reviewed.

Recognising the delicate nature of this complaint, Pharmacosmos stated that it had no desire to be sent copies of any template or specific contracts used by Vifor. Pharmacosmos hoped that the Authority would consider asking to see a random selection of recent and current contracts used by Vifor in addition to its general templates for routine consultancy arrangements.

The detailed response from Vifor Pharma is given below.

The Panel noted that its role was to consider the case in relation to the requirements of the Code rather than the IFPMA Code of Practice, the EFPIA Code on the Promotion of Prescription-Only Medicines to, and interactions with Healthcare Professionals or UK competition law.

The Panel noted Pharmacosmos' submission that its complaint was based on anecdotal feedback and its reference to Cases AUTH/2479/2/12 and AUTH/2480/2/12. The Panel considered that the nature of the evidence provided in those cases was very different to the present case. Turning to the present case, the Panel noted that the complainant had to establish its complaint on the balance of probabilities. The Panel would consider the evidence provided by both parties.

The Panel noted Pharmacosmos' allegation that some of the consultancy agreements between Vifor and health professionals and Vifor and NHS organisations were such that they constituted 'retainer' arrangements that were banned by, *inter*

***alia*, the Code. However, the Panel noted that the Code did not refer to retainer arrangements or exclusivity clauses and did not, *per se*, prevent such clauses in consultancy contracts. The Panel further noted that Pharmacosmos had submitted that there were some limited situations where exclusivity was appropriate. Vifor acknowledged that a small number of contracts between UK health professionals and its global organisation contained justifiable exclusivity clauses.**

The Panel noted that consultancy agreements would necessarily cover legitimate commercial and business matters beyond the compliance requirements listed in the Code. Matters such as exclusivity terms would not be covered by the Code unless they otherwise rendered an agreement in breach of its requirements.

The Panel noted that Pharmacosmos had implied that some of the contracts between Vifor and health professionals existed to stop that individual working with any other company and that no genuine service to Vifor from the consultant was expected. The Panel noted that Pharmacosmos stated that several physicians were unable to undertake consultancy work for the company as that would place them in breach of a pre-existing contract with Vifor. Pharmacosmos had not identified those physicians or provided any evidence that their contract did not require the physicians to provide a genuine service to Vifor. The Panel noted that it had not seen any of Vifor's current consultancy agreements but noted that Vifors standard operating procedures (SOP), Contracts with Healthcare Professionals, clearly referred to all of the criteria for consultancy listed in the Code and the template contract contained a section headed 'Services' wherein the details of the consulting services could be added. The Panel noted that none of Vifor's standard operating procedure (SOP) template agreements contained exclusivity provisions. The Panel further noted Vifor's submission that no health professional retained by Vifor UK had such clauses in their agreements. A very small number of existing consultancy agreements between UK health professionals and global colleagues contained such provisions. The Panel noted that Pharmacosmos had accepted that exclusivity clauses were not unacceptable *per se*.

The Panel considered that Pharmacosmos had not, on the balance of probabilities, established that Vifor had used exclusivity clauses in the absence of expecting a genuine service for which there was a legitimate need, from the individual concerned. The Panel ruled no breach of the Code.

Pharmacosmos A/S complained that exclusivity clauses in Vifor Pharma Limited's consultancy contracts with health professionals were in breach of the Code.

COMPLAINT

Pharmacosmos alleged that some of Vifor's consultancy arrangements did not or had not met the requirements of Clause 20 of the Code. Specifically, several practising physicians had stated that they were unable to undertake consultancy work on behalf of Pharmacosmos as this would place them in breach of a pre-existing contract with Vifor. This surprised Pharmacosmos and raised some genuine concerns. The company therefore sought clarification that Vifor did not routinely use exclusivity clauses in its consultancy contracts.

Pharmacosmos acknowledged that anything relating to contractual arrangements with third parties was delicate, as recognised in communications to Vifor and previously to the Authority. However Pharmacosmos was concerned that some of Vifor's consultancy arrangements with NHS service providers (organisations and individuals) were such that they constituted 'retainer' arrangements of the type banned by the IFPMA, EFPIA and ABPI Codes. Whilst the confidential nature of some consultancy work was recognised there were clearly practical and legal issues that arose from exclusivity clauses. This included matters of competition law and the barriers to market penetration, but there were also patient safety issues and practical considerations for the NHS.

In submitting this complaint and the accompanying inter-company exchanges, Pharmacosmos was conscious that it had not cited a specific example; this was directly related to those same contracts preventing the individuals (understandably) from sharing the details of the arrangements with Pharmacosmos. The basis for concern arose from feedback from potential health professional consultants to Pharmacosmos who had been approached; however this complaint was based on the wording of the final inter-company response from Vifor:

> 'We cannot comment on whether or not individuals can work on projects for both Vifor and Pharmacosmos at the same time as it will depend on the terms of their particular contracts in question'.

Pharmacosmos considered this was a clear admission that some contracts contained exclusivity clauses. Pharmacosmos sought confirmation that these were reserved for the most appropriate scenarios and did not, for example routinely prevent health professionals from speaking at meetings or attending advisory boards, etc, organised by other companies. Exclusivity in research contracts should also be highly tailored so as not to unnecessarily restrict the progress of medical science.

Pharmacosmos submitted that confidentiality clauses were of course of paramount importance. However exclusivity clauses were often unnecessary if the confidentiality clause was properly constructed. There were some situations where exclusivity was appropriate but Pharmacosmos considered that those situations were few. For example, it was established practice that a research unit and its employees could work on several trials concurrently; indeed, to do otherwise risked delaying important research that might ultimately benefit patient care. However a general exclusivity clause would prevent those individuals and units from working with other companies on a wide range of activities, from

conducting research to speaking at promotional and educational meetings. Exclusivity clauses would also have implications for the customers in terms of their necessary independence. For example it would prevent payors and health professionals from achieving a balanced level of interaction with industry and effectively tie them into one company. Such arrangements also gave rise to external perceptions regarding the appropriateness of such contracts as to the genuine need for the service to exist and the nature of the transparency declaration.

Pharmacosmos noted that the inter-company exchanges referred to competition law and the need for confidentiality in respect of detailed terms and conditions. This made the situation very difficult for Pharmacosmos to explore appropriately. Pharmacosmos did not wish to interfere with the fair and reasonable contracting arrangements between Vifor and its suppliers and did not seek commercially sensitive information regarding the nature of the arrangements and services or the specific contractual details, as made clear in inter-company dialogue. However it was quite clear from the final paragraph in Vifor's letter that exclusivity clauses were in use. Depending on the precise wording of those exclusivity clauses, a breach of Clause 20 of the Code was therefore likely.

Specifically, Clause 20 required that consultancy arrangements were:

- Genuine
- There was a clearly identified, legitimate need for the services
- The criteria for selecting the consultants must be related to the identified need
- The number of consultants must not be greater than the number needed to achieve the identified need
- Token consultancy arrangements must not be used
- The service provider must be required to declare their role as a consultant to the company

Taken together Pharmacosmos believed that these requirements should limit the use of exclusivity clauses to all but the most important confidential matters and should be used in highly specific and very limited circumstances.

Pharmacosmos submitted that it would be difficult to establish a need for an exclusivity clause as part of a speaker contract, for example, without implying an obligation on the part of the consultant. This effectively tied the consultant to that company and placed him/her in the implied position of needing to preserve relationships with that company in order to maintain future business, perhaps by looking more favourably on that company's products or seeing that company's representatives more often. It also called into question the nature of the declaration required from consultants when speaking in public or other occasions when they were required to make declarations concerning company consultancy arrangements; the reaction of the audience was likely to be different according to whether the consultant had accepted a fee for a particular event or whether that individual was exclusively tied to that company; the latter situation would surely require a different declaration even if such an arrangement was ever appropriate.

Pharmacosmos stated that further considerations then arose as to why certain individuals were selected for the consultancy services – was it because the service was genuinely needed and the individual was the most appropriate, or was it to block that individual's availability to other companies with its inevitable impact on the ability of competitor companies to provide educational services?

While Pharmacosmos did not wish to imply that Vifor had deliberately set out to block the availability of consultants to other companies, it was greatly concerned by the anecdotal feedback it had received.

Pharmacosmos stated there was recent case precedent whereby a complaint could be raised on the suspicion of inappropriate activity, even though the company complainant could not furnish detailed evidence (Cases AUTH/2479/2/12 and AUTH/2480/2/12). In those cases the complainants suspected inappropriate activity at a symposium but had not seen the slides or been present on the day. The case report indicated that the PMCPA sought copies of the slides and made a judgement based on the material reviewed.

Recognising the delicate nature of this complaint, Pharmacosmos stated that it had no desire to be sent copies of any template or specific contracts used by Vifor. Pharmacosmos hoped that the Authority would consider asking to see a random selection of recent and current contracts used by Vifor in addition to its general templates for routine consultancy arrangements; this might be for example, to see all contracts in a certain geography in a certain time period for a range of consultancy services.

Pharmacosmos very much hoped that the Authority would be able to explore its concerns in respect of unwarranted exclusivity clauses and could reassure Pharmacosmos that there was nothing to prevent the majority of health professionals from working on projects for both companies (unless, of course, there were particular and specific circumstances that would justify a unique arrangement in that regard). Pharmacosmos recognised the sensitivity in this matter for both companies.

RESPONSE

Vifor stated that Pharmacosmos' complaint was founded solely on it being advised by 'several' practising physicians that they were unable to undertake consultancy work on behalf of Pharmacosmos as this would place them in breach of a pre-existing contract with Vifor. Pharmacosmos had not provided any documentation or proof of its allegations, or even indicated the number of practising physicians, their location or the services under question.

Vifor considered that Pharmacosmos' allegation must also be viewed in light of the fact that, by Pharmacosmos' own admission, 'there were some situations where exclusivity was appropriate…'.

Vifor noted that Clause 20.1 of the Code set out a number of criteria which must be fulfilled when health professionals and appropriate administrative staff were used for genuine consultancy or other services. Clause 20.1 did not prohibit the use of non-compete provisions in consultancy agreements.

The general thrust of Pharmacosmos' complaint was that Vifor's policy was to engage certain health professionals not on the basis of a genuine consultancy requirement, but to block those individuals' availability to other companies. Vifor strongly refuted this allegation. All health professionals' engagements carried out by Vifor were genuine consultancies that complied with Clause 20.1.

- All consultancy work was carried out on the basis of written agreements, agreed in advance and detailing the nature of the services and the basis for payment.
- In each case, there was a clear legitimate need for the services.
- The criteria for selecting consultants were directly related to the identified need for the consultancy.
- The number of consultants retained was not greater than the number reasonably necessary to achieve the identified need.
- Appropriate records were maintained of the services provided.
- The hiring of each consultant was not an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.
- All compensation for services was reasonable and reflected fair market value. Vifor did not enter into token consultancy arrangements.
- Consultancy contracts with health professionals required them to declare their consultancy for Vifor when writing or speaking on a topic related to the company.

Vifor stated that the fact that all health professional consultancies were genuine was further demonstrated by its standard operating procedures (SOPs) which referred to the arrangements for health professionals providing services to the company:

- SOP 007 (Contracts with Healthcare Professionals). Section 5, appendix A, specifically refered to Clause 20.1 and quoted directly from it
- SOP 212 (Approval of Meetings and Hospitality). Section 5.4 included direction on the criteria for use of speakers and section 5.7.1, appendix B, referred to advisory board participants

Both these SOPs covered all arrangements for health professionals providing any service for Vifor and gave clear guidance as to the criteria for engaging the health professionals as well as a clear procedure for the approval of arrangements (in both cases by two managers).

The SOPs also included template agreements (within the appendices) and none of these contained non-compete or exclusivity provisions.

Vifor stated that since the review of these SOPs earlier this year, Vifor also required global colleagues to adhere to the same SOPs. There were a number of existing consultancy agreements raised before this time, a very small number of which contained fully legitimate non-compete provisions. All such provisions were drafted in such as a way as to comply with applicable law and Clause 20.1.

Vifor considered that it was generally accepted in the industry that non-compete provisions represented a legitimate method to protect business interests, and were enforceable provided that they were proportionate and reasonable in their scope. The contracts it had with non-compete clauses numbered in the low single figures and had these clauses to protect the confidentiality and sensitivity of Vifor's legitimate research and/or commercial interests.

Finally, Vifor noted that the sentence in its letter, 'We cannot comment on whether or not particular individuals can work on projects for both Vifor and Pharmacosmos at the same time as this will depend on the terms of their particular contracts in question', was not a clear admission that some contracts contained exclusivity clauses as submitted by Pharmacosmos. It was simply a response to the very general questions posed by Pharmacosmos. As stated clearly above, no health professionals engaged by Vifor Pharma UK had non-compete clauses in their consultancy agreements, and while a very small number of existing consultancy agreements between UK health professionals and global colleagues contained non-compete provisions, they were in compliance with Clause 20.1 and applicable law.

Vifor submitted that it had always reserved the use of non-compete provisions for the most appropriate scenarios and, to answer Pharmacosmos' request for reassurance, it was not aware of anything that would prevent the majority of health professionals from working on projects for both companies. However, Vifor was not in a position to comment on the extent to which non-compete provisions imposed by Pharmacosmos might impact on the ability of a health professional to work for Vifor.

Vifor strongly refuted Pharmacosmos' allegation that some of its consultancy agreements with health professionals did not meet the requirements of the Code. Vifor denied a breach of Clause 20.

PANEL RULING

The Panel noted that its role was to consider the case in relation to the requirements of the Code rather than the IFPMA Code of Practice, the EFPIA Code on the Promotion of Prescription-Only Medicines to, and interactions with Healthcare Professionals or UK competition law.

The Panel noted that Pharmacosmos had alleged a breach of Clause 20 but had not cited the particular sub-clause. The allegations appeared to relate to Clause 20.1. Vifor had responded in relation to Clause 20.1 and thus the Panel considered the complaint in relation to Clause 20.1.

The Panel noted Pharmacosmos' submission that its complaint was based on anecdotal feedback and its reference to Cases AUTH/2479/2/12 and

AUTH/2480/2/12. The Panel considered that the nature of the evidence provided in Cases AUTH/2479/2/12 and AUTH/2480/2/12 was very different to the present case. Pharmacosmos had wrongly submitted that the complainant in Case AUTH/2480/2/12 had not seen the slides or been present at the presentation. A company employee had been at the meeting in question and had seen the material which was the subject of the complaint. Turning to the present case, the Panel noted that the complainant had to establish its complaint on the balance of probabilities. The Panel would consider the evidence provided by both parties.

The Panel noted Pharmacosmos' allegation that some of the consultancy agreements between Vifor and health professionals and Vifor and NHS organisations were such that they constituted 'retainer' arrangements that were banned by, *inter alia*, the Code. However, the Panel noted that Clause 20 did not refer to retainer arrangements or exclusivity clauses and did not, *per se*, prevent such clauses in consultancy contracts. The Panel further noted that Pharmacosmos had submitted that there were some limited situations where exclusivity was appropriate. Vifor acknowledged that a small number of contracts between UK health professionals and its global organisation contained justifiable exclusivity clauses.

The Panel noted that consultancy agreements would necessarily cover legitimate commercial and business matters beyond the compliance requirements listed in Clause 20.1. Matters such as exclusivity terms would not be covered by Clause 20.1 unless they otherwise rendered an agreement in breach of its requirements.

The Panel noted that Pharmacosmos had implied that some of the contracts between Vifor and health professionals existed to stop that individual working with any other company and that no genuine service to Vifor from the consultant was expected. The Panel noted that Pharmacosmos had submitted that several practicing physicians had stated that they were unable to undertake consultancy work for the company as that would place them in breach of a pre-existing contract with Vifor. Pharmacosmos had not identified those physicians or provided any evidence that their contract did not require them to provide a genuine service to Vifor. The Panel noted that it had not seen any of Vifor's current consultancy agreements but noted that SOP 007, Contracts with Healthcare Professionals, clearly referred to all of the criteria for consultancy listed in Clause 20.1 and the template contract contained a section headed 'Services' wherein the details of the consulting services could be added. The Panel noted that none of Vifor's SOP template agreements contained exclusivity provisions. The Panel further noted Vifor's submission that no health professional retained by Vifor UK had such clauses in their agreements. A very small number of existing consultancy agreements between UK health professionals and global colleagues contained such provisions. The Panel noted that Pharmacosmos had accepted that exclusivity clauses were not unacceptable *per se*.

The Panel considered that Pharmacosmos had not, on the balance of probabilities, established that Vifor had used exclusivity clauses in the absence of expecting a genuine service for which there was a legitimate need, from the individual concerned. The Panel ruled no breach of Clause 20.1.

Complaint received **8 November 2012**

Case completed **22 January 2013**