CASE AUTH/3567/10/21 ***NO BREACH OF THE CODE***

EMPLOYEE v ZOGENIX

Concerns about arrangements for advisory boards

An anonymous, non-contactable employee alleged that a senior medical employee in Zogenix undertook some activities which were not in the best interest of patients or doctors and created expectations for them by running advisory boards in Eastern European countries (namely Croatia, Poland and Hungary), when there was no presence. The senior medical employee utilised consultants and contractors to undertake this work and also certified these, when he/she had a team, with signatories who were not involved. The Zogenix consultants and contractors did not have a full overview of the business and rules and regulations in each of these countries and worked independently. The complainant stated that the senior medical employee had been advised not to go ahead since there were sensitivities within these countries and there was no sound reason to conduct advisory boards in these countries as Zogenix had considerable knowledge from a safety and regulatory perspective. The senior medical employee was also trying to influence the hourly rates for doctors and academics since he/she utilised his/her partner to participate in a number of activities which was a direct conflict of interest.

The complainant stated that the consultants used were sourced by the medical affairs employee, but one did not have a contract of services in place to conduct medical activities and was advising sponsorship of meetings and payments which were not compliant. The complainant was concerned this would affect everything Zogenix was trying to do ethically and his/her behaviour was affecting so many good people within Zogenix, who were trying to do the right thing and it was a reflection of the conduct and ethical behaviour within the pharmaceutical industry. The complainant further alleged that prior consultants had been discharged of their services if the senior medical employee was challenged and that the senior medical employee manipulated his/her experience and knowledge to suit his/her needs when working with the Zogenix commercial team.

The detailed response from Zogenix is given below.

The Panel noted Zogenix's submission that, upon receipt of this complaint, it postponed the Croatian advisory board until it could complete a full internal investigation. The advisory boards for Hungary and Poland were in early planning stages for the end of November 2021 but plans had not been finalised. The Panel noted Zogenix's conclusion that the proposed advisory boards to be held in Croatia, Hungary and Poland were for a legitimate purpose and were planned in compliance with the Code.

Zogenix provided materials in relation to the Croatian advisory board including the invitation, agenda, advisor selection and honorarium information and the arrangements including the certificates, all of which had been signed off by a final medical signatory.

Other meeting materials were still in development and had not yet been presented for review.

The Panel noted Zogenix's submission that within the concept approval form, the medical affairs team addressed the need to gather information about the diagnosis and treatment of patients in Croatia to better understand how to assist patients and healthcare providers; this need was discussed with designated reviewers, including staff from other departments.

The Panel noted Zogenix's submission that the number of advisors in Croatia was limited to four thought leaders and that fair market rates were used as well as industry guidance to consider the advisors' scientific and/or clinical expertise in the areas to be addressed. The Panel further noted Zogenix's submission that the advisors' contracts were drafted and approved by the legal team, three of which were fully executed and one only partially due to the postponement of the Croatian advisory board.

At the time of the complaint, none of the three advisory boards in question had taken place and no payments had been made.

The complainant bore the burden of proof and the Panel did not consider that the complainant had proved, on the balance of probabilities, that the planned advisory boards would fail to meet the requirements of the Code as alleged, nor that any of the proposed payments would be inappropriate. On this narrow ground, the Panel ruled no breaches of the Code.

The documentation and arrangements provided in relation to the Croatian advisory board, whether required or not, appeared to have been certified; there was no evidence that the person certifying those materials was the person responsible for developing or drawing up the material as alleged. The Panel therefore ruled no breaches of the Code.

The Panel noted Zogenix's submission that there was no involvement by the senior medical employee's partner in the process of developing the advisory boards at issue as alleged. The Panel did not consider that the complainant had established that high standards had not been maintained in this regard and no breach of the Code was ruled.

Nor did the Panel consider that the complainant had established that any sponsorships of meetings and payments were not compliant or that previous consultants to Zogenix had been discharged if the senior medical employee was challenged or that the senior medical employee manipulated his/her experience and knowledge to suit his/her needs when working with the Zogenix commercial team as alleged. The Panel did not consider that the complainant had established that high standards had not been maintained in this regard and no breach of the Code was ruled.

Overall, the Panel did not consider that there was evidence to show that high standards had not been maintained as alleged and no breaches of the Code were ruled including no breach of Clause 2.

An anonymous non-contactable employee complained about some of the actions within medical affairs within Zogenix.

COMPLAINT

The complainant stated that from a promotional perspective, Zogenix had done everything appropriately with pre-vetting of materials post-licensing with the Medicines and Healthcare products Regulatory Agency (MHRA) and approved prescribing information and everything was documented.

The complainant alleged that a named senior medical employee, however, was utilising his/her position to undertake some activities, which were not in the best interest of patients or doctors and creating expectations for them by running advisory boards in Eastern European countries (namely Croatia, Poland and Hungary), when there was no presence there currently. The senior medical employee utilised consultants and contractors to undertake this work and also certified these in the Veeva approval system, when he/she had a team, with signatories who were not involved. The consultants and contractors did not have a full overview of the business and rules and regulations in each of these countries and worked independently. The senior medical employee should have overall accountability and overview of the business and had been advised not to go ahead since there were sensitivities within these countries. There was no sound reason to conduct advisory boards in these countries as Zogenix had considerable knowledge from a safety and regulatory perspective. The complainant alleged that the senior medical employee was also trying to influence the hourly rates for the doctors as well as academics (who did not see patients) since he/she utilised his/her partner to participate in a number of activities, paid for by Zogenix, which was a direct conflict of interest.

The complainant stated that the consultants used were sourced by the medical employee, but one did not have a contract of services in place to conduct medical activities and was advising sponsorship of meetings and payments, which were not in line from a compliance perspective. The consultants did not necessarily abide by Zogenix's internal codes of conduct and compliance and legal were not necessarily fully conversant with the Code and the complainant was concerned this would affect everything Zogenix was trying to do ethically, because of this one individual who was in a senior position. Prior consultants had been discharged of their services if he/she was challenged and the commercial team deferred to his/her experience and knowledge, which he/she manipulated to suit his/her needs. His/her behaviour was affecting so many good people within Zogenix, who were trying to do the right thing and it was a reflection of the conduct and ethical behaviour within the pharmaceutical industry. Zogenix had always been patient-focused and there was a risk of this credibility being affected.

When writing to Zogenix, the Authority asked it to consider the requirements of Clauses 2, 5.1, 8.1, 8.2, 19.1 and 24.2 of the 2021 Code.

RESPONSE

Upon receipt of this complaint, Zogenix decided to postpone the Croatia advisory board set for 8 October 2021 until it could complete a full internal investigation and address the questions raised. This step had been taken as a precautionary measure since the company considered business ethics and compliance a key element of its culture and of how the company first and foremost addressed its patients' needs. The advisory boards for Hungary and Poland were in early planning stages potentially for the end of November 2021 but plans had not been finalised.

Zogenix submitted that after having reviewed the documentation related to those planned advisory boards in Eastern Europe and having spoken to the employees and consultants

involved in this process, Zogenix had reached the conclusion that the proposed advisory boards to be held in Croatia, Hungary and Poland were for a legitimate purpose and planned in compliance with the requirements of Clauses 24.2, 19.1, 8.1, 8.2, 5.1 and 2 of the 2021 Code. Zogenix, of course, appreciated the Panel had a duty to run an independent assessment of the complaint and offered its full co-operation in this matter.

Zogenix provided a copy of its concept approval form in relation to the Croatian Advisory Board which it submitted was completed pursuant to its written standard operating procedures (SOP) on review and approval of promotional and non-promotional materials and signed off. The signed concept approval form was uploaded in Veeva system within the review and approval steps for the advisory board materials. In particular, a copy of those materials included:

- the approved invitation email and certificate;
- the approved agenda and certificate;
- the approved selection/honorarium rates for advisors and certificate and
- the approved meeting arrangement and certificate.

Zogenix submitted that all of the above materials, where the review process was fully completed, were signed by a registered medical practitioner which met the requirements of Clause 8.1. The final medical signatory was a UK GMC-registered physician with substantial experience as final signatory. There were other meeting materials still in development but these had not yet been presented for review.

In the concept approval, the medical affairs team addressed the need to gather information about the diagnosis and treatment of patients in Croatia so that Zogenix could better understand how it could assist those patients and healthcare providers. This need was discussed with designated Zogenix reviewers, which included staff from other Zogenix departments like commercial and legal affairs. This aspect of the process was also aimed at managing potential conflicts of interest and made sure that independent views were gathered before a project started. Zogenix addressed potential conflicts of interests in its Code of Business Conduct and Ethics which all employees were regularly trained on and agreed to comply.

Zogenix stated that the number of advisors in Croatia was limited to four important thought leaders in order to gain their experience and receive their advice as to the diagnosis and treatment paradigm in this country. The plan was to have only four Zogenix medical affairs personnel also present to gather feedback for the meeting. To define the compensation, 2021 Fair Market rates were used as well as industry guidance to consider the advisors' scientific and/or clinical expertise in the areas to be addressed.

Zogenix stated that it also developed written contracts with the selected advisors, which were drafted and approved by the legal team. Three of those agreements were fully executed and one only partially executed due to the decision to postpone the advisory board in Croatia.

Finally, Zogenix stated that there was no involvement by the senior medical employee's partner in this process to develop these advisory boards. If any such potential conflict of interest was to arise the matter would be raised with Zogenix's compliance department for a complete assessment. In any situation, creating such potential conflict Zogenix requested the employee recuse himself/herself from involvement in any final decision making regarding the project.

PANEL RULING

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 further information.

The Panel noted that it appeared that the advisory boards at issue were being organised by Zogenix International Limited which was headquartered in the UK and therefore were required to comply with the UK Code as well as the national code of the country in which the advisory boards took place, as set out in the supplementary information to Clause 3.4.

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

The Panel noted Zogenix's submission that, upon receipt of this complaint, it postponed the Croatian advisory board until it could complete a full internal investigation. The advisory boards for Hungary and Poland were in early planning stages for the end of November 2021 but plans had not been finalised. The Panel noted Zogenix's submission that after having reviewed the documentation and spoken to the employees and consultants involved in the process, it had reached the conclusion that the proposed advisory boards to be held in Croatia, Hungary and Poland were for a legitimate purpose and were planned in compliance with the requirements of the Code.

The Panel noted that Zogenix provided materials in relation to the Croatian advisory board including the invitation, agenda, advisor selection and honorarium information and the arrangements including the certificates, all of which had been signed off by a final medical signatory. Other meeting materials were still in development, but these had not yet been presented for review.

The Panel further noted Zogenix's submission that within the concept approval form, the medical affairs team addressed the need to gather information about the diagnosis and treatment of patients in Croatia to better understand how it could assist those patients and healthcare providers. This need was discussed with designated reviewers, including staff from other departments like commercial and legal affairs.

The Panel noted Zogenix's submission that the number of advisors in Croatia was limited to four thought leaders in order to gain their experience and receive their advice as to the diagnosis

and treatment paradigm. The 2021 fair market rates were used as well as industry guidance to consider their scientific and/or clinical expertise in the areas to be addressed. The Panel further noted Zogenix's submission that the advisors' written contracts were drafted and approved by the legal team. Three of those agreements were fully executed and one only partially executed due to the decision to postpone the advisory board in Croatia.

The Panel noted that at the time the complaint was submitted, none of the three advisory boards referred to by the complainant had taken place and no payments had been made.

The Panel noted that the complainant bore the burden of proof and did not consider that the complainant had proved, on the balance of probabilities, that the planned advisory boards would fail to meet the requirements of the Code as alleged, nor that any of the proposed payments would be inappropriate. On this narrow ground, the Panel ruled no breach of Clauses 24.2 and 19.1.

All of the documentation provided in relation to the advisory board to be held in Croatia, whether required to be or not, and the arrangements appeared to have been certified. The Panel further noted that there was no evidence that the person certifying those materials on behalf of the company was the person responsible for developing or drawing up the material as alleged. The Panel therefore ruled no breach of Clauses 8.1 and 8.2.

With regard to the allegation that the medical employee utilised his/her partner to participate in a number of activities which was a conflict of interest, the Panel noted Zogenix's submission that there was no involvement by the medical employee's partner in the process of developing the advisory boards at issue. The Panel did not consider that the complainant had established that high standards had not been maintained in this regard and no breach of Clause 5.1 was ruled.

Nor did the Panel consider that the complainant had established that any sponsorships of meetings and payments were not compliant or that previous consultants to Zogenix had been discharged if the senior medical employee was challenged or that the senior medical employee manipulated his/her experience and knowledge to suit his/her needs when working with the Zogenix commercial team as alleged. The Panel did not consider that the complainant had established that high standards had not been maintained in this regard and no breach of Clause 5.1 was ruled.

Overall, the Panel did not consider that there was evidence to show that high standards had not been maintained as alleged and no breach of Clause 5.1 was ruled.

Noting its rulings of no breaches above, the Panel consequently ruled no breach of Clause 2.

Complaint received **4 October 2021**

Case completed **11 August 2022**