CASE AUTH/3902/5/24 *NO BREACH OF THE CODE*

COMPLAINANT v THERAMEX

Allegations about a representative

CASE SUMMARY

This case was in relation to Theramex's activities at a gynaecological endocrinology congress held in Italy in May 2024 at which it was present with a commercial booth. The complainant's overarching concerns related to an interaction with a Theramex representative who allegedly promoted linzagolix without being clear about its current licence and unavailability in most countries.

The outcome under the 2021 Code was:

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1	**Requirement to maintain high standards at all times**
No Breach of Clause 6.1 (x2)	**Requirement that information, claims and comparisons must not be misleading**
No Breach of Clause 11.1	**Requirement that a medicine must not be promoted prior to the grant of its marketing authorisation**
No Breach of Clause 11.2	**Requirement not to promote a medicine for an unlicensed indication**
No Breach of Clause 17.2	**Requirement that representatives must maintain high standards of ethical conduct in the discharge of their duties and comply with all relevant requirements of the Code**
No Breach of Clause 17.10	**Responsibility of companies for the activities of their representatives if these are within the scope of their employment even if they are acting contrary to the instructions which they have been given**

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

FULL CASE REPORT

A complaint about Theramex HQ UK Ltd was received from a named contactable complainant who described themselves as a doctor based in the UK.

COMPLAINT

The complaint wording is reproduced below:

> "I am writing to express my dissatisfaction and concern regarding an encounter I had with a representative from Theramex during my attendance at the [named gynaecological endocrinology] conference in [Italy] commencing [date].
>
> While visiting the Theramex booth with a colleague (we are doctors based in the UK), we were approached by a representative who courteously offered assistance. Intrigued by the prospect of linzagolix, a product currently licensed for treating uterine fibroids, we conversed with the representative to learn more about its efficacy and potential benefits.
>
> The Theramex representative bombarded us with inquiries regarding our views on the product's effectiveness and comparisons with competitors. We willingly provided feedback. The representative then asked if we had an interest in endometriosis treatment, and proceed to ask more questions. The representative gave us the impression that linzagolix was readily available and was due to have its endometriosis licence very soon.
>
> However, linzagolix was not yet licensed for endometriosis treatment, but rather solely for uterine fibroids.
>
> When we attempted to disengage from the conversation, the representative suggested consulting with one of Theramex's medical professionals regarding the use of linzagolix in endometriosis and referenced ongoing trials supporting this 'new' indication – reminiscent of a used car dealership, when customers are about to walk away.
>
> Subsequent questioning revealed that linzagolix is not available for prescription in the UK and most European countries.
>
> This experience left me feeling misled and inadequately informed about the current licensing status of the product in different disease modalities. It is deeply concerning that a company would promote a product in such a manner without explicitly disclosing its unavailability in most countries, and be clear about the product's current licence.
>
> Patients and healthcare professionals alike deserve transparency and accuracy when it comes to medical products and their licensing status.
>
> Thank you for your attention to this matter."

Following a request from the case preparation manager, the complainant provided further information, reproduced below:

> "With respect to the allegation, the interaction took place on [date] during the lunch break between the congress events. Unfortunately, I did not get the name of the representative, but it was not a UK representative. I have to admit, I am not very good at placing accents.
>
> There was no hardcopy material shared with me or my colleague. When we asked for a flyer/leave piece, we were told that none had been produced. We were drawn to the booth, as we wanted to know more about linzagolix, and from hearing about the medicine from a previous international meeting in [Scotland] last May.
>
> I appreciate that it is hard to prove what happened during a conversation, but I did not feel that what was happening as outlined in my previous email as unethical. If you have any further questions, please do not hesitate to get in touch."

When writing to Theramex, the PMCPA asked it to consider the requirements of Clauses 6.1, 11.1, 11.2, 17.2, 17.10, 5.1 and 2 of the 2021 Code.

THERAMEX'S RESPONSE

The response from Theramex is reproduced below:

> "We write in response to your letter dated 20th May 2024, concerning a complaint by a UK-based doctor who was in attendance at the [named gynaecological endocrinology] congress, which took place in [Italy] between [dates] May 2024. The complainant alleges that he / she, along with their colleague visited the Theramex booth during the lunchtime of [date] to learn more about the efficacy and potential benefits of linzagolix for the treatment of uterine fibroids. During the course of their interaction with a Theramex representative, it is alleged that they were asked about their potential interest in endometriosis treatment by the said individual and that that they were concerned that the company was promoting a product without disclosing its unavailability in most countries.
>
> We would like to express our disappointment on these allegations as we believe that in the absence of evidence, names or written documents, this may be manipulation of facts at the hands of our competitor. Nonetheless, we offer our full co-operation to the PMCPA in the review of this matter.
>
> The complainant's allegation can be broken down as follows:
>
> 1. That the Theramex representative asked if they 'had an interest in endometriosis treatment',
> 2. that the representative gave them the impression that 'linzagolix was readily available and was due to have its endometriosis licence very soon',
> 3. that when they attempted to disengage from the conversation, the representative 'suggested consulting with one of Theramex's medical professionals regarding the use of linzagolix in endometriosis',

4. that the representative referenced ongoing trials supporting this new (endometriosis) indication, reminiscent of a 'used car dealership when customers are about to walk away',
5. that their subsequent questioning revealed that 'linzagolix is not available for prescription in the UK and most European countries',
6. that the experience left them 'feeling misled and inadequately informed about the current licensing status of the product in different disease modalities' and,
7. that the complainant felt it was 'deeply concerning that a company would promote a product in such a manner without explicitly disclosing its unavailability in most countries and be clear about the products current licence'.

Theramex takes its obligation under the ABPI Code of Practice very seriously. All of the activities conducted at the [named gynaecological endocrinology] congress were executed according to Theramex's SOPs and Code of Conduct and were entirely permissible within the UK Code of Practice.

During our response to these allegations, we will establish that:

- Theramex's attendance at the [named gynaecological endocrinology] 2024 congress was carefully planned and executed over months,
- that all Theramex attendees were briefed on the compliance, as well as our internal SOP and policy requirements prior to their attendance at the congress,
- that materials were approved in accordance with the ABPI Code of Practice by a nominated signatory,
- that we have maintained high standards of conduct throughout, and
- that Theramex has robust SOPs and policies in place to ensure that we act with the highest levels of professionalism, integrity and ethical business conduct at all times.

Finally, we will also address each of the complainant's allegations according to the relevant clause(s) of the ABPI code of Practice.

Background to Theramex's presence at the [named gynaecological endocrinology] 2024 Congress in Italy

Yselty (linzagolix) received a license from the European Medicines Agency (EMA) for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age on the 14th June 2022. The UK marketing authorisation was subsequently granted by the Medicines and Healthcare products Regulatory Agency (MHRA) via the European Commission Decision Reliance Procedure on the 27th June 2022.

The [named gynaecological endocrinology] congress, held every two years in [Italy], is widely known as the largest and one of the most significant event on Gynecological Endocrinology worldwide. As such, Theramex's participation at the congress had been carefully planned over many months, including our presence with a commercial booth at the congress. Ahead of the congress, all Theramex internal attendees were

mandated to attend an internal briefing meeting around our key congress activities, including compliance requirements which took place on the 3rd May 2024. During this meeting, attendees were reminded that at the commercial booth, all conversations are to be within the licensed indication of the product in discussion only, and that any unsolicited questions from HCPs relating to unlicensed use of our promoted products must be referred to the medical team via the medical information request form as outlined in the briefing document. Attendees were also reminded to always act with high standards, integrity and professionalism during or outside of the congress, in line with our codes and policies (Congresses and Educational Events SOP and Theramex Code of Conduct policy).

Theramex subsequently attended and had a commercial booth presence at the [named gynaecological endocrinology] congress between [dates] May 2024. Since the congress activity was led by the Global team, headquartered in UK, and the congress took place in Italy, both the ABPI Code and the local Italian Agenzia italiana del farmaco (AIFA) regulations were adhered to.

Response to the alleged breaches of clauses 17.10, 17.2, 11.2, 11.1, 6.1, 5.1 and 2 of the ABPI Code of Practice 2021

Theramex takes its obligations under the ABPI Code of Practice very seriously and immediately launched an internal investigation upon receipt of this complaint. The complaint centres around an interaction that took place between the complainant and a Theramex representative at our commercial booth during the congress lunchtime break on [date]. According to the [named gynaecological endocrinology] scientific programme schedule, the lunchtime break was scheduled around 13:30.

Our investigation revealed that there was very limited personnel and visitor traffic at our booth during this time, with no staff members witnessing or recollecting the complainant's alleged events. Theramex therefore, strongly refutes all of these allegations and any suggestions that Clauses 17.10, 17.2, 11.2, 11.1, 6.1, 5.1 and 2 of the ABPI Code of Practice had been breached.

We will now address these specific code breach allegations in turn.

Clauses 17.2 and 17.10 (Representative activities and the duty to comply with code requirements)

As mentioned above, our internal investigation did not identify the staff member in question. Given the lack of specifics, we are unable to provide any details on the particulars of the complainant's allegations against the said individual.

Please note that the commercial booth was manned by the marketing team and that all Theramex staff attending the [named gynaecological endocrinology] congress were mandated to attend a pre-congress briefing meeting, where key compliance considerations were re-iterated and re-enforced. Attendees were reminded that all conversations at the commercial booth must be within the licensed indication of the product being discussed, and that any unsolicited off-licence questions must be referred to the medical team via the medical information request form as outlined in the briefing document. Attendees were further reminded of their duty to act with high levels

of professionalism, integrity and ethical conduct at all times, in line with our internal code of conduct and SOPs. We believe therefore that we have taken all the necessary steps to minimise any chances of such alleged behaviour to have taken place by one of our staff members, and therefore strongly deny breaches of clauses 17.2 and 17.10.

Clauses 11.1 and 11.2 (Pre-licence promotion and the need to promote in line with the product marketing authorisation)

At our commercial booth, we had a promotional panel on Linzagolix detailing the EMA marketing authorisation for Yselty, namely its indication for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. Although the marketing authorisation for Yselty was granted on the 14th June 2022 by the EMA, the general availability of Yselty is variable due to the ongoing discussions with reimbursement bodies currently taking place, including with the National Institute for Health and Care Excellence (NICE) in the UK. As such, we make no claim with regards to the general availability of Yselty on the promotional panel.

Again, all Theramex congress attendees were mandated to attend an internal briefing meeting pre-congress on the 3rd May 2024, to ensure that any conversations at the commercial booth are in line with the licensed indication of the product, and that any unsolicited unlicensed use enquiries are directed to the medical team via the appropriate channels. Thus, we refute any allegations of having breached clauses 11.1 and 11.2.

Clause 6.1 (Information, claims and comparisons must be accurate, fair, balanced and not misleading)

The promotional panel on Linzagolix at our commercial booth was both simple and factual, detailing only the marketing authorisation for Yselty for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age, and that the medicine is authorised for use in the European Union. This material was approved by our UK-based Global team to ABPI Code standards, before the asset was finalised for use in Italy by our Italian affiliate, in line with their local AIFA regulations.

As mentioned previously, Theramex congress attendees were also reminded of the compliance requirements during a pre-congress briefing meeting, and our internal investigation did not identify any Theramex staff or witnesses who could corroborate the complainant's allegations. We therefore refute breaching clause 6.1.

Clause 5.1 (High standards)

Theramex believes that high standards were maintained at all times and refutes any allegations of breaching this clause. We have provided a detailed outline of the measures we have taken both before and during the congress to ensure that we observe high standards of conduct at all times. We refute any allegations of breaching this clause.

Clause 2 (Discredit to the pharmaceutical industry)

Theramex takes its responsibilities under the Code very seriously. We have robust policies in place to ensure that our employees act with the highest standards of ethical business conduct, professionalism and respect. Our SOP around Congresses and Educational Events clearly stipulates the principles around our interactions at the commercial booth which all employees are expected to adhere to. Additionally, a pre-congress briefing meeting took place for all Theramex congress attendees on the 3rd May, reminding of the importance of compliance requirements as well as the need to adhere with our internal SOP and policies at all times. We are confident therefore, that this matter has not brought discredit to or reduced confidence in the pharmaceutical industry and strongly refute breaching clause 2.

Summary of Theramex's position

Theramex believes it has established that its presence at the [named gynaecological endocrinology] 2024 congress in [Italy] was conducted compliantly and in line with both the ABPI Code of Practice, the local Italian AIFA regulations and Theramex's internal SOPs. Theramex was unable to identify the alleged individual mentioned by the complainant and are therefore, unable to provide any further details to the PMCPA beyond what has been provided to us. We take our obligations under the Code very seriously and have shown that all our staff members in attendance at the congress were briefed of the compliance requirements ahead of the congress, including the requirements to promote only within the marketing authorisation of our products and in an appropriate manner. Furthermore, our SOPs are clear of the professional and ethical standards required by individuals working at Theramex and given the lack of evidence provided by the complainant, we refute all allegations of breaching clauses 17.10, 17.2, 11.2, 11.1, 6.1, 5.1 and 2 of the ABPI Code."

PANEL RULING

This case concerned Theramex's activities at a named gynaecological endocrinology congress held in Italy in May 2024 at which it was present with a commercial booth. The complainant's overarching concerns related to an interaction with a Theramex representative who allegedly promoted linzagolix without being clear about its current licence and unavailability in most countries.

In particular, the complainant alleged that the Theramex representative proactively discussed endometriosis and ongoing clinical trials, and gave the impression that linzagolix would be licensed for this indication shortly. The complainant alleged that the representative gave them the impression that linzagolix was readily available although, at the time, it was not available for prescription in the UK and most European countries.

Yselty (linzagolix) was a gonadotropin-releasing hormone (GnRH) receptor antagonist indicated for the treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age. The Panel noted that, at the time of the [named gynaecological endocrinology] conference in 2024, Yselty was a prescription only medicine but was not licensed for use in endometriosis.

Theramex submitted that company congress attendees were mandated to attend an internal pre-congress briefing which included for all conversations to be in line with the licensed indication and that any unsolicited enquiries about unlicensed use were to be directed to the medical team. Similarly, Theramex's standard operating procedure for 'Sponsorship of Congresses and Educational Events' required any staff involved in sponsorship activities to first complete training on the SOP.

Theramex submitted the booth was staffed by the marketing team and the Panel observed the briefing slides, marked as '"not intended for field-based commercial or sales teams", required that all conversations must be kept within the licensed indication and consistent with the summary of product characteristics. Numerous symposia and oral presentations were listed under a slide summarising Theramex's key activities at the congress, including an oral presentation titled "EDELWEISS-3 trial: Linzagolix effectively reduces endometriosis-associated pain in a placebo-controlled phase III study"; the Panel had no information before it whether or how individuals were directed to the presentation and there was no allegation in this regard.

The Panel noted the complainant did not recall the name of the representative in question and it was unclear whether they were an employee of Theramex UK.

Theramex submitted that there was very limited personnel and visitor traffic at the booth and that no staff members had witnessed or recalled the alleged incident.

The Panel noted that the parties' accounts differed; it was difficult in such cases to know exactly what had transpired. A judgement had to be made on the available evidence, bearing in mind the extreme dissatisfaction usually necessary on the part of an individual before they were moved to actually submit a complaint.

The Panel decided it was not possible to determine what had been said verbally during the alleged interaction and considered it had not been established that a Theramex representative had misled the complainant and promoted Yselty (linzagolix) in a manner that was inconsistent with its summary of product characteristics. The Panel ruled **no breach of Clauses 6.1 and 11.2**. The Panel further considered that it had not been established that a Theramex representative had not maintained a high standard of ethical conduct nor that they had acted contrary to the instructions they had been given. The Panel ruled **no breach of Clause 17.2** and **no breach of Clause 17.10**.

Clause 11.1 prohibited the promotion of a medicine prior to the grant of the marketing authorisation; Yselty was licensed as a prescription only medicine at the time of the congress and the Panel ruled **no breach of Clause 11.1**.

With regard to the alleged misleading impression that linzagolix was readily available, the Panel noted Theramex's submission that the general availability of Yselty was variable due to ongoing discussions with reimbursement bodies, including with NICE; Theramex submitted that, as such, no claim regarding general availability was made on the promotional panel.

The Panel observed the Yselty promotional panel featured prominent Yselty and Theramex logos, included the licensed indication for uterine fibroids and stated the medicine was authorised for use in the European Union. Besides the HQ job code, adverse event reporting statement and reference to prescribing information, the Panel noted the inclusion of "Non commercializzato in Italia - not marketed in Italy".

While the Panel queried the appropriateness of promoting a medicine that was not readily available, it was unclear whether the availability referred to a broader supply issue or was more specifically related to reimbursement and access within public healthcare settings, such as the NHS.

Nonetheless, noting the complaint primarily related to an alleged verbal exchange with a representative, the Panel considered that the complainant had not established that a Theramex representative gave a misleading impression that Yselty was readily available, and therefore ruled **no breach of Clause 6.1**.

The Panel took account of its rulings of no breaches of the Code above, based on the evidence before it, and it followed that it had not been established that Theramex had failed to maintain high standards as alleged. The Panel ruled **no breach of Clause 5.1** and **no breach of Clause 2**.

Complaint received **10 May 2024**

Case completed **30 June 2025**