PUBLIC REPRIMAND FOR THERAMEX HQ UK LTD

Theramex HQ UK Ltd has been publicly reprimanded by the Code of Practice Appeal Board for the fundamental compliance errors highlighted by this case, including failing to provide up-to-date prescribing information leading to breaches of the ABPI Code. Further, the Appeal Board considered Theramex's decision to leave self-regulation while sanctions were ongoing and the case was not yet complete, evidenced a failure to take responsibility for addressing its failings within the self-regulatory framework.

In Case/0303/09/24, the Code of Practice Panel ruled 13 breaches, including that Theramex had brought discredit upon, and reduced confidence in, the pharmaceutical industry. The Panel was particularly concerned about Theramex's failures to promptly update prescribing information following changes to the summary of product characteristics and thereby failing to provide up-to-date prescribing information for the Evorel (estradiol) range and Intrarosa (prasterone) for several years. The Panel, concerned that the breaches indicated a systemic failure in compliance oversight, reported the company to the Appeal Board, in accordance with Paragraph 10.2 of the Constitution and Procedure.

At the May 2025 Appeal Board meeting, representatives of Theramex fully acknowledged that the failures "reflected deeper deficiencies in internal processes and governance structures specifically around the timely updating of information and ensuring appropriate transparency" but assured the Appeal Board that Theramex had taken steps to address these specific issues and the company was improving both process and training and Theramex had commissioned a third-party external compliance audit. The Appeal Board was very concerned about the "fundamental compliance errors… particularly those relating to safety and regulatory issues that were fundamental to protecting patients" and required that a senior representative of Theramex be invited to attend the December 2025 meeting to report on the outputs from the external compliance audit and any staff survey results, and present a detailed compliance action plan to address any issues identified. The Appeal Board reserved the decision regarding the application of additional sanctions until consideration of this information. This meeting was subsequently postponed, by agreement, until February 2026.

On 28 January 2026, ahead of the February 2026 Appeal Board meeting, Theramex informed the PMCPA that it would no longer accept the jurisdiction of the PMCPA or be part of the self-regulatory framework for the pharmaceutical industry in the UK. Theramex declined to attend the February 2026 Appeal Board meeting or provide a written submission in relation to the Appeal Board's request outlined above.

The Appeal Board is extremely disappointed that Theramex has decided to leave self-regulation having been found in breach of the Code, but while sanctions were

ongoing and the case was not yet complete. It is the Appeal Board's view that this shows a derogation of responsibility under self-regulation as a pharmaceutical company to its employees and, most importantly, to public safety. By the company's failure to provide the Appeal Board with evidence of the actions taken since May 2025 to address the significant issues identified and requiring the MHRA to assume full responsibility for regulating the company, Theramex has inevitably delayed any regulatory action and oversight.

In addition to the public reprimand, the Appeal Board also decided to require an audit of Theramex's procedures in relation to the Code to be carried out by the PMCPA. Theramex must comply with the requirement for a PMCPA audit should it request to rejoin self-regulation in the future.

The PMCPA is no longer responsible for Theramex under the self-regulatory framework and the company is now fully under the responsibility of the Medicines and Healthcare products Regulatory Agency.