PUBLIC REPRIMAND FOR GSK

GSK has been publicly reprimanded by the Code of Practice Appeal Board under Paragraph 13.4 of the Constitution and Procedure, for its significant failure to comply with the crucial requirement, expected of all those enjoying the privilege of self-regulation, of complete transparency and openness with the Regulator.

In Case/0874/02/26, the Appeal Board upheld the Panel's findings of a breach of Clause 2 and breaches of Clause 5.1 for GSK's failure to provide a full and frank disclosure in a previous case (Case/0269/08/24). Following that determination, the Appeal Board considered the decision by the Panel to report GSK to the Appeal Board under Paragraph 10.2 of the Constitution and Procedure for consideration of additional sanctions.

The breaches in Case/0874/02/26 related to GSK's failure (in Case/0269/08/24) to provide both the Panel and the Appeal Board with minutes and correspondence between GSK and the UKHSA that was fundamental to the matter at issue.

The Appeal Board did not accept the submissions by those representing GSK at the hearing for Case/0874/02/26 that GSK's conduct in Case/0269/08/24 was simply a poor decision or error of judgment as to relevance of material. There were rather, positive decisions in Case/0269/08/24 by those at GSK who responded to the complaint and then, more egregiously, by those who were involved in the appeal, to withhold material available to them from the UKHSA that was unambiguously contradictory to the company's submissions.

The Appeal Board considered, in particular, two of the points made by the Panel in reporting the case to the Appeal Board:

1. That GSK's conduct and failure of transparency in Case/0269/08/24, which only came to light as a result of the UKHSA contacting the PMCPA, was "totally unacceptable".
2. Further, that the failure to accurately reflect the position of a public body in regulatory proceedings in a therapeutic area where public confidence was paramount, was "unacceptable".

The Appeal Board agreed with the Panel's view. The Appeal Board agreed that the decision by senior UK leaders not to provide crucial material to the Appeal Board in Case/0269/08/24, and not to mention crucial correspondence during questioning by the Appeal Board, was clear evidence that a positive decision had been made not to be transparent in order to avoid undermining the company's submissions on appeal. That behaviour was indeed "totally unacceptable".

The Appeal Board recognised that those who represented GSK at the hearing for Case/0874/02/26 accepted that GSK "should have managed Case/0269/08/24 differently". However, the Appeal Board did not consider that such an acceptance properly recognised the seriousness of GSK's behaviour.

For the public to have trust in the pharmaceutical industry, the public must have trust in the pharmaceutical industry's ability to self-regulate. Self-regulation is administered through the ABPI Code by the PMCPA, and the Appeal Board. Transparency is one of the four key ABPI Principles and is an important means to building and maintaining confidence. GSK's positive decision not to be transparent undermines the premise of the Code, the PMCPA, the Appeal Board and self-regulation.

The Appeal Board considered that GSK's failure to supply full and frank disclosure of relevant material in the company's possession led the Appeal Board to make a finding of no breach in relation to Case/0269/08/24 that it may otherwise not have done. The Appeal Board noted that the PMCPA's Constitution and Procedure does not allow for a setting aside of a decision by the Appeal Board in these circumstances; this may only be done where there has been a "procedural error" (Paragraph 1.12). The ruling made by the Appeal Board in Case/0269/08/24 cannot, therefore, be set aside, even though it was made without crucial information.