

PUBLIC REPRIMAND FOR JANSSEN

Janssen has been publicly reprimanded by the Code of Practice Appeal Board for its failure to have oversight or control of a patient-facing service for 28 months and for its delay in making its voluntary admission once the errors had come to the company's attention.

In Case AUTH/3436/12/20 the Code of Practice Panel ruled breaches of the Code including a breach of Clause 2 following a voluntary admission from Janssen for its lack of oversight and management of the Stelara homecare service, including its failures to provide product and pharmacovigilance training to the third party nursing team and to notify them of the summary of product characteristics (SPC) updates for more than two years. Janssen accepted the rulings and provided the requisite undertaking. The Panel considered that some of the matters raised went to the heart of self-regulation and patient safety. The Panel considered that the company's lack of oversight and management of the homecare service at issue had been extremely poor and it decided to report the company to the Appeal Board.

The Appeal Board was deeply concerned about the failings and Janssen's lack of control, checks and oversight. The Appeal Board also considered that the period from discovery to reporting to the PMCPA was inexplicably long at over 7 months and it noted Janssen's acknowledgment in this regard.

In addition to the public reprimand the Appeal Board also decided to require an audit of Janssens's procedures in relation to the Code.