

NEWS

MSD Italy is criticised for threatening legal action over prescription advice to GPs

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The Italian branch of the drug company Merck Sharp and Dohme (MSD) has stopped a leading public health doctor and administrator from circulating texts to GPs advising them about the use of one of the company's drugs.

In the texts, Alberto Donzelli—the head of education, appropriateness, and evidence based medicine at the public health authority of Milan (Milan Healthcare)—had analysed the published evidence on the cholesterol lowering drug ezetimibe and discouraged its prescription in addition to statins. A letter telling Donzelli to “cease and desist” was sent in February by MSD's medical director, Patrizia Nardini, and was cosigned by the company's director of legal affairs. They accused Donzelli of serious misconduct and a breach of medical ethics and threatened to sue him and Milan Healthcare for as much as €1.3m (£1m; \$1.78m). The letter was addressed to Donzelli, with a copy sent to Milan Healthcare's director general and to the president of the Order of Physicians of Milan (the doctors' regulatory body), Roberto Carlo Rossi.

Rossi replied in April, declaring that the medical commission had analysed and discussed the issue in depth and concluding that there was no reason to object on ethical grounds to Donzelli's behaviour. Donzelli also replied to each point raised in the letter. “I exercised my right to tell the general practitioners what emerged from our in-depth analyses of the published literature, on a peer to peer basis,” he told *The BMJ*.

Nevertheless, in late May the company sent a second “cease and desist” letter to Donzelli, listing several decisions by international and Italian regulatory authorities and international guidelines that favoured ezetimibe. The letter also lamented the impossibility of establishing “a fruitful scientific dialogue” with Donzelli.

MSD Italy reaffirmed its intention to go to court unless Donzelli stopped his “seriously damaging activity, [that was] tarnishing the company's and the drug's image and reputation.” Donzelli

said that the prescriptions of ezetimibe in Milan had remained stable in recent years and that the company's figure of €1.3m was extrapolated from an increase in prescriptions seen in areas around Lombardy. MSD neither confirmed nor denied the extrapolation.

In mid-June, Donzelli bowed to the request and removed the relevant material from his website “until the issue is further clarified within the scientific community.”

Justifying MSD Italy's actions, Nardini said, “We are in favour of balanced information, and we decided to write those letters because we didn't see a willingness to evaluate all the information in a balanced way.” She added that, since those materials had been removed from the website, the company was not planning to sue.

In light of the controversy, however, the editors of the five Italian publications belonging to the International Society of Drug Bulletins sided with Donzelli. They published a statement at the end of June, saying, “In the educational and informational process, the disagreement should be expressed on the pages of scientific journals as a debate among peers, including the readers who will be able to decide freely what is the most appropriate choice for patients.”

The editors noted that this was not the first time that the company had used such tactics. They cited a previous case in which MSD had sued the editor of a Catalan independent bulletin and was defeated in court.¹ They added, “We deem it important for Milan Healthcare to continue with its laudable activities of [providing] information independent of commercial interests, to balance pharmaceutical marketing.”

¹ Meek C. Spanish journal wins lawsuit over COX-2 drug editorial. *CMAJ* 2004;170:940.

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