German court allows pharma company promotional statements about Rx-drug to counter a "shitstorm" – a trend also for the rest of the EU?

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In the EU, drug companies are not allowed to publicly promote prescription-only medicines. As courts also apply a broad interpretation of the term "promotional", nearly all public statements that mention a prescription drug are likely to be qualified as illegal advertising. In certain circumstances, this may be the case even if no drug is mentioned.

But what should a drug company do if false statements about its product are distributed? What is allowed in case of a so-called shitstorm? What can the company do to counter negative public statements about its drugs by HTA bodies or other institutions of the healthcare system?

In a judgment from 12 January 2018, the Higher Regional Court of Cologne (Oberlandesgericht Köln) has now decided that, when facing a – the following term is a quote from the decision – "shitstorm" in the internet, a pharma company may defend its Rx-drug with public statements even if these statements qualify as promotional. In this case, the manufacturer of a veterinary medicine became victim of defamations in the internet. Several posts with allegations about a flea and tick repellent were published on Facebook. As the allegations lacked a factual basis, the manufacturer reacted with own posts about the product to counter this "shitstorm". Additionally, a webpage was linked where the company responded to the inaccurate allegations and informed consumers and veterinarians.

A competitor of the company applied for a preliminary injunction to prohibit these statements and referred to the legal ban of public advertising for Rx-drugs as set forth in Section 10 (1) of the Act on Advertising for Therapeutic Products (Heilmittelwerbegesetz). In the first instance, a lower court in Cologne in fact prohibited these posts. However, on appeal the Higher Regional Court allowed those statements that aimed at defending against the shitstorm. The higher court considered that in such a situation an overall assessment of the involved rights and interests is necessary. The ban of public advertising for Rx-drugs needs to be weighed against the constitutional rights of the affected manufacturer. Hereby, the court took the view that, as long as the promotional statement can be clearly linked to the shitstorm and responds to the comments made against its product in this campaign, the legal assessment may be in favour of the manufacturer. Then, the manufacturer may exceptionally be allowed to make such statements even if their content could be qualified as promotional.

The decision has a significant practical impact for drug companies: It acknowledges an exception from the ban of public advertising for Rx-drugs and allows companies to defend their products against defamation and false information.

Actually, this new decision of the Higher Regional Court of Cologne is a continuation of the "Sortis"-decision of the German Supreme Court (Bundesgerichtshof) from 2009 (case: I ZR 213/06) in which the court expressed a similar view but for a different scenario. In that case, Pfizer was facing negative public comments on its product Sortis® (Atorvastatin) made by institutions of the German healthcare system. The controversy arose in the context of the drug's evaluation under the German reference pricing and reimbursement rules. Pfizer had reacted by posting own public statements about Sortis® in nationwide newspapers. The new decision of the court in Cologne continues this judicature for the scenario of an internet shitstorm.

Conclusions: in Germany, drug manufacturers are allowed to publicly defend their products against shitstorms. In so doing, they may exceptionally make public statements about Rx-drugs even if these can be qualified as promotional. However, this exception is still subject to quite strict legal requirements with respect to both the type and content of the allegations (shitstorm) against the drug and the scope and limits of the defense statements that the company may publish. Therefore, the individual case scenario and the envisaged defense statements should undergo a very careful legal review.

What does this German judicature mean for the rest of the EU? So far, the Court of Justice of the EU has not issued a decision on this particular issue. As the ban of advertising for Rx-drugs applies in the entire EU and as a shitstorm can hit a company anywhere, a consistent judicature should apply in the EU. There are good arguments in favor of the legal view of the German courts. Hence, sooner or later this German judicature may also be adopted in other EU countries.

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National Law Review, Volume VIII, Number 29

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