AbbVie to face potentially groundbreaking case over Humira

Litigants allege that the Dutch health system was overcharged €1·2 billion for the drug, used to treat conditions such as arthritis. Ferry Biedermann reports from Amsterdam.

A Dutch court has cleared the way for a potentially groundbreaking case to proceed against pharmaceutical company AbbVie over the alleged excessive pricing of its patented blockbuster drug Humira. The procedural ruling means that the organisation bringing the case, the Pharmaceutical Accountability Foundation (FTV, by its Dutch initials) has been given sufficient standing and the claim will now be examined on its substance.

AbbVie said it was disappointed with the ruling but emphasised in a statement that "the decision says nothing about the merits of the case". The company said it strongly rejects FTV's allegations and warned that these "could contribute to stifling future innovation" in health care in the Netherlands. FTV, however, welcomed the ruling and the court's decision to go directly to the substance of the case, rather than insist on further procedural stages. FTV's Chairman, Wilbert Bannenberg, told *The Lancet* that the foundation had not expected the court to skip these steps but that it was "good news that we can proceed faster to the substantive discussion".

The case is brought under new collective action legislation in the Netherlands, in force since 2020, known as WAMCA. It regulates collective action lawsuits, among others, allowing claims for monetary damages, while also tightening the eligibility criteria for bringing such cases. Business groups at the time warned that it could give rise to a US claims culture. But several studies, albeit using limited data, appear to show that the number of such cases has not increased.

FTV is not claiming compensation or damages from AbbVie. Instead, it is seeking a declaratory judgement from the court in Amsterdam that the company acted unlawfully. It claims that from 2004 to 2018, while Humira enjoyed market dominance and no biosimilars were available, AbbVie overcharged the Dutch health-care system €1·2 billion, on total sales in the Netherlands of €2·3 billion. Humira is the brand name for adalimumab, a tumour necrosis factor blocker used to treat rheumatic arthritis and other inflammatory conditions, such as certain forms of psoriasis, ulcerative colitis, and Crohn's disease. FTV states that it was the world's largest-selling drug from 2012 to 2020.

FTV further claims that because of the finite resources in the health-care system, this led to a displacement of care; the excess money for Humira could not be spent for other purposes. Using the quality-adjusted life-year figure of US$80 000 per life-year gained, it then calculates that as a result, "16 300 people died 1 year too early in the Netherlands".

It frames the case as a human rights issue—namely, the right to health, including access to medicines. In a reaction to the court ruling on July 17, Bannenberg stated: "Pharmaceutical companies don't sell luxury products but lifesaving medicines. By charging excessive prices, AbbVie violates human rights and neglects its duty of social accountability". The company said that "AbbVie's focus remains on furthering access to medicines for patients and collaborating to improve Dutch healthcare."

Dutch courts have, in recent years, been receptive to the human rights argument, albeit in radically different environmental cases. Marcel Canoy, endowed Professor in Health Economics at the Amsterdam's Vrije Universiteit, told *The Lancet* that FTV's human rights argument is an interesting one, "that's not inherently doomed to fail". AbbVie in its initial response to FTV's subpoena pointed out that even a declaratory judgement could have consequences for the company. It also said the company should not just be subpoenaed to serve as an example.

The new ruling accepts, however, that FTV can bring the case in the public interest. Although the final ruling could have repercussions on business practices and especially the pharmaceutical industry, the July 17 procedural vote also has significance in itself. Ianika Tzankova, a lawyer and the first European Chair in the field of Class Actions and Mass Claim Dispute Resolution at Tilburg University Law School in the Netherlands, said that "interest groups should be very pleased with this outcome". The skipping of several procedural stages meant that such cases could proceed faster, more simply, and cheaper. However, should FTV eventually win the case, it is still unclear how this will affect subsequent individual or collective actions for damages, she said.

FTV had earlier been successful in an appeal to the Dutch competition and markets authority, ACM, over excessive pricing of the drug chenodeoxycholic acid made by Leadiant. But Canoy said that such actions only touched the "tip of the iceberg" and were slow, cumbersome, and rare. "They're not the way to discipline an entire sector." Hence FTV's court action, he said.

The parties have up to 12 weeks to present substantive arguments, with both sides expected to be in court again in early 2025.

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