

A busy week at the Court of Justice of the European Union

Two significant announcements have hugely contributed to the transparency and access to medicines movement in the EU this week. The announcements came from the Luxembourg-based [Court of Justice of the European Union \(CJEU\)](#), the judicial arm of the [European Union](#). This court comprises two arms: the Court of Justice (colloquially known as the European Court of Justice or ECJ), and the General Court. These announcements have a number of implications for transparency and access to medicines.

Access to documents ruling

HAI and our access to medicines colleagues were delighted to see the anxiously awaited judgement from the CJEU on Wednesday. The decision, which was regarding disclosure of documents submitted in marketing authorisation applications, was contrary to the controversial opinion of the court's Advocate General (AG) Hogan, which had been causing concern since its publication in Autumn 2019.

Hogan's opinion regarding the PTC Therapeutics International V EMA case and an equivalent veterinary medicine case had the potential to undo years of work to achieve greater transparency in clinical trial data. The AG outlined his view that the clinical trial data featured in marketing authorisation applications should be presumed to be commercially sensitive and therefore confidential. This would have resulted in bypassing EU regulations regarding transparency - to the joy of pharmaceutical companies, and the displeasure of access to medicines and transparency advocates.

If the CJEU had adopted this position, it would have undermined the EMA's own access to documents policy (Number 0043) and thereby restricting access to the evidence it needs to critically assess new pharmaceuticals before granting market authorisation. This would pose a challenge to the presumption of public interest that has come to be the norm in the last few years. It also would have had ramifications for the commitment to transparency of EU institutions. In short, it would have been a huge, concerning, step backwards.

Thankfully however, the ruling from the Court rejected the notion that the trial data in question was covered by a general presumption of confidentiality. Whilst this is a great relief, we need to remain vigilant for future challenges to transparency and continue to call on the EU to protect it and other pillars of affordable, accessible and safe medicines. After all, the Court did not completely close the door to hearing new cases on how EMA manages clinical trial data, particularly clinical study reports.



The Court of Justice of the European Union

Kokott opinion

The other positive news for access to medicines advocates this week came in the form of an opinion from Advocate General Juliane Kokott. AG Kokott gave her opinion on a case regarding pharmaceutical giant GlaxoSmithKline's (GSK) actions to postpone the marketing of generic versions of their medicines.

The case began when generic manufacturers disputed the validity of GSK's secondary patents for the active ingredients in anti-depressant medicine paroxetine. To address this, GSK made payments to these companies in exchange for them not entering the market with their own generic versions.

The Competition and Markets Authority (CMA) in the UK believed this constituted anti-competitive behaviour and imposed fines on all involved parties. The European Commission's inquiry into competition enforcement in the pharmaceutical sector hailed the CMA's judgement as a 'landmark decision' against so called 'pay-for-delay' deals. GSK and the other parties involved felt differently however, and went on to appeal the CMA's decision.

The opinion from the Advocate General, published on Wednesday, agreed with the position of the CMA that making payments to generics manufacturers was indeed breaking the prohibition on anti-competitive agreements, and abusing GSK's dominant position in the market. This is positive news because it reinforces bans on activities that prevent

competition and thereby facilitate sky-rocketing prices. Plus, by tackling one of the big names in the pharmaceutical industry, both the CMA and the CJEU are highlighting that no one is exempt from following the rules.

This case is now for the CJEU to hear, but we hope to see the Court rule in line with Kokott's opinion and continue to enforce regulations that protect the public's ability to access medicines.