

CJEU ruling is victory that resonates for all in favour of greater transparency

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‘CJEU ruling is victory that resonates for all in favour of greater transparency’, HAI

AMSTERDAM— Following today’s much anticipated [ruling](#) from the Court of Justice of the European Union (CJEU) on the transparency of Clinical Study Report (CSR) data submitted by pharmaceutical companies applying for market authorisation, Health Action International (HAI) Senior Policy Advisor, Jaume Vidal, made the following statement:

‘The CJEU ruling is a victory that resonates for all those who favour greater transparency and a powerful endorsement of the EMA’s landmark access to documents policy.

This ruling also has much wider ramifications, with no-less at stake than the transparency of all the EU’s institutions. As much was raised during HAI’s [public discussion](#) on clinical trial transparency last November at the European Parliament.

It should be noted that the CJEU has now clearly stated the limits to commercial confidentiality, has dismissed overarching claims of protection to commercial interests and clarified the extent of data exclusivity in relation to Marketing Authorisations of generic medicinal products.

While commending the ruling of the CJEU, we call on the EMA to ‘hold its course’ in the face of industry pressure and continue to facilitate access to clinical study data essential to the protection and promotion of public health. Finally, the Croatian Presidency of the European Council must decisively push for the full implementation of the European [Clinical Trial Regulation](#).’

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