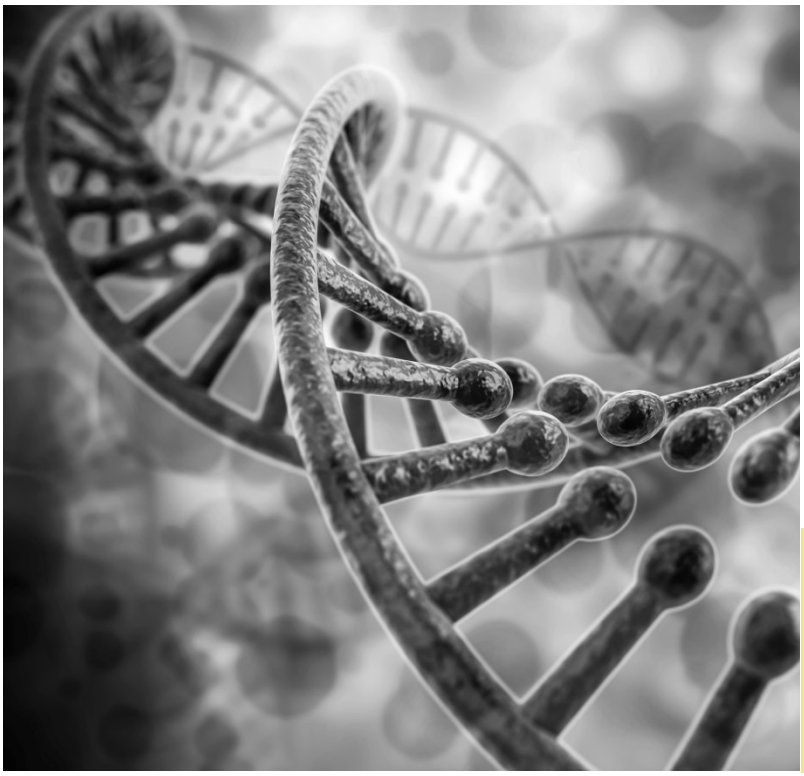

EU life sciences & regulatory newsletter

ASHURST BRUSSELS

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Content

Ashurst has a well-established practice and specialist expertise in life sciences and regulatory, and is regularly listed as one of the leading law firms in the field. Our EU life sciences and regulatory newsletter focuses on important EU case law developments affecting the life sciences sector.

EU substance approval dossier contains no information related to environmental emissions

In its judgment of 21 November 2018, the EU General Court ("GC") rules that an EU substance approval dossier contains no information related to environmental emissions. As a result, the EU Commission was entitled to refuse public disclosure of confidential glyphosate substance data, where this was justified to protect the confidentiality of commercial and industrial information (T-545/11 RENV, Stichting Greenpeace Nederland and PAN Europe -v- Commission).

WHAT YOU NEED TO KNOW – KEY PRACTICAL TAKE-AWAYS

- Citizens are given the widest possible access to documents held by EU regulators. Access may however be refused to protect confidential commercial and industrial information, unless there is an overriding public interest in disclosure.
- The right of access to environmental documents held by EU institutions is governed by the Aarhus Regulation (1367/2006), which implements part of the United Nations Aarhus Convention on access to information, public participation in decision-making and access to justice in environmental matters.
- Article 6(1) of the Aarhus Regulation ("Aarhus Emissions rule") creates an exceptional regime for documents containing "information relating to emissions into the environment". The confidentiality of commercial and industrial information may not be invoked to prevent disclosure of such information. An overriding public interest in disclosure is presumed.
- An EU substance approval dossier contains no information related to environmental emissions. As a result, public disclosure of certain parts of the dossier can be legitimately refused where this is needed to protect the confidentiality of commercial and industrial information.

Background

The judgment marks the end of a five-year legal battle between environmental NGOs and the EU Commission which started when the EU Commission refused to grant the NGOs access to confidential information submitted by glyphosate manufacturers for the initial EU approval of glyphosate. Access had been requested to certain parts of the dossier revealing the detailed chemical composition of the glyphosate substance, its manufacturing process and the impurities and composition of the finished products presented at the time to obtain substance approval at EU level.

The EU Commission explained in its refusal decision that the information requested did not relate to environmental emissions and that, moreover, disclosure should be refused out of a need to protect company knowhow and intellectual property rights of the manufacturers seeking the EU approval of glyphosate (Article 4(2) of the Transparency Regulation (1049/2001)). Disclosure of the information requested would have made it possible to reconstitute the manufacturing process of glyphosate.

The NGOs disagreed arguing that access should be granted since the information in question qualified, in their view, as information relating to

environmental emissions governed by the Aarhus Emissions rule. Accordingly, they argued, disclosure could not have been refused on the grounds that it concerns confidential commercial and industrial information.

The initial judgment of the GC sided with the NGOs (T-545/11, *Stichting Greenpeace Nederland and PAN Europe -v- Commission*) but was successfully appealed by the EU Commission, with the support of Germany and a significant number of European and American industry associations. In 2016, the EU Court of Justice ("*ECJ*") set aside the initial judgment on appeal and referred the case back to the GC for a new assessment (C-673/13 P, *Commission -v- Stichting Greenpeace Nederland and PAN Europe*).

The Court judgment

In its 21 November 2018 judgment, the GC reverses its initial position and upholds the EU Commission's decision to refuse access to the confidential parts of the glyphosate dossier. The GC agrees with the EU Commission that the information requested does not contain information relating to environmental emissions, as defined by the ECJ on appeal.

Given the two-tier nature of the EU regime involving the approval of a substance at EU level and the subsequent authorisation at Member State level of plant protection products containing an approved substance, the GC considers that no information on environmental emissions can be found in the EU substance approval dossier. At EU level, the GC argues, there is no assessment yet of any actual or foreseeable emissions into the environment, since the substance is released only at a later stage "*via a plant protection product subject to the authorisation procedure" and is moreover "not intended to be released into the environment as such, but may be released only once integrated in a plant protection product subject to authorisation*".

The GC's judgment ensures the continued useful application of the sector-specific rules on confidentiality set out in Article 63 of the Plant Protection Products Regulation (1107/2009) which protects specifically listed categories of regulatory information from public disclosure, including information on the method of manufacture and information on the complete product composition. It is in this context particularly helpful to operators that the judgment accepts that the information requested by the NGOs in the present case may reveal sensitive information on the specific substance manufacturing process and that this remains valuable knowhow whose disclosure can harm commercial interests, even where the information has been submitted 15-20 years ago.

This is an important judgment, following on the landmark ruling by the ECJ on appeal, as the GC prescribes for the first time how the Aarhus Emissions rule must be applied concretely to regulatory data submitted by operators in order to obtain the approval or the renewal of a plant protection substance at EU level.

Note: Ashurst LLP acted for the European Crop Protection Association (ECPA) and the European Chemical Industry Council (CEFIC), which intervened in support of the EU Commission before the EU Court of Justice (appeal proceedings) and the EU General Court (referral proceedings).

EU law allows Member States to reimburse off-label use of medicines

In a judgment dated 21 November 2018, the EU Court of Justice ("ECJ") concludes that an EU Member State may reimburse the use of a medicine, such as Avastin, for a treatment not covered by its marketing authorisation ("off-label use"). All necessary authorisations for manufacture and sale of the medicine must however have been obtained in compliance with the Human Medicines Directive ("HMD") (C-29/17, Novartis Farma).

WHAT YOU NEED TO KNOW – KEY PRACTICAL TAKE-AWAYS

- A medicinal product may be used for therapeutic indications not covered by its marketing authorisation (off-label use), and may be repackaged with a view to such use, subject to compliance with EU pharmaceutical rules.
- A Member State may provide for the reimbursement of the off-label use of a medicinal product, provided that this product is manufactured (repackaged) and placed on the market in compliance with the HMD requirements.

Background

Novartis is marketing authorisation holder for Lucentis, a medicine approved in the EU for the treatment of eye diseases. Roche is marketing authorisation holder for Avastin, a medicine approved in the EU for cancer treatment. In practice, Avastin is often used "*off-label*" to treat eye diseases, as it is considerably cheaper than Lucentis. In that case, Avastin must be repackaged from its original vial into ready-to-use syringes suitable for intravitreal injection (i.e. shot of medicine into the eye).

In an attempt to cut healthcare spending, Italy allowed the reimbursement of Avastin's off-label use for eye diseases. Reimbursement was made conditional upon Avastin being repackaged at authorised hospital pharmacies and administered to patients at designated public hospitals, after having obtained the patient's informed consent for the off-label use of the medicine.

Novartis challenged the reimbursement of Avastin before the Italian courts claiming that Italy encouraged the off-label use of Avastin, despite the availability of Lucentis, a medicine specifically authorised to treat eye diseases. Novartis argued that Italy acted in breach of the HMD and in particular the requirement for any medicine to be used in conformity with the terms of its marketing authorisation. The Italian judge referred the matter to the ECJ for a ruling on the compatibility of the Italian decision with the EU legal framework for human medicines.

The Court judgment

In its judgment of 21 November 2018, the ECJ reaffirms that the organisation and management of health services and the allocation of the resources assigned to them are the responsibility of the Member States. This includes the price setting and reimbursement of medicinal products. In exercising that responsibility however Member States must comply with EU law.

The ECJ confirms that the sale and use of Avastin remains governed by the HMD, even after the medicine is repackaged for off-label use. Article 3 of the HMD exempts products prepared in pharmacies, i.e. officinal and magistral preparations, from the scope of the HMD. This exemption does not apply to Avastin, however, as it is produced industrially.

The ECJ then notes that EU pharmaceutical rules prohibit neither the off-label use of a medicine nor its repackaging for such use, but do require those processes to comply with the conditions laid down in those rules, including the requirement of holding the necessary marketing and manufacturing authorisations.

The ECJ concludes however that the process of repackaging of Avastin for off-label use does not require a new marketing authorisation, provided that this process (i) does not alter the composition, form or any other fundamental characteristic of the medicine, and (ii) is performed only by lawfully authorised pharmacies on the basis of an individual prescription.

The ECJ further finds that pharmacies repackaging Avastin do not require a new manufacturing authorisation under Article 40(2) HMD, provided that they are lawfully authorised under national law to repackage medicines on the basis of an individual prescription and the medicine is administered in hospitals.

The conclusion is therefore that Member States, such as Italy in the present case, are allowed under EU law to reimburse the off-label use of medicines, even where another medicine is specifically authorised for such use, provided that the repackaging and off-label use of the repackaged medicine comply with the HMD.

New actions before the EU Courts

Non-compliance with REACH requirements

Germany decided to appeal the EU General Court judgment of 8 May 2018 in T-283/15, *Esso Raffinage -v- European Chemicals Agency (ECHA)*, annulling a 'Statement of Non-Compliance with the REACH Regulation' sent by ECHA to the French authorities in the form of a mere letter. In particular, Germany criticizes the GC's view that ECHA alone is competent (and not Member States) to decide whether registration information complies with the REACH requirements (C-471/18, *Germany -v- Esso Raffinage*, *OJ* of 5 November 2018).

REACH – Classification of siloxanes D4, D5, and D6 as substances of very high concern

A new action has been brought before the EU General Court against the inclusion by the European Chemicals Agency (ECHA) of siloxanes D4, D5, and D6 in the candidate list of substances of very high concern (T-519/18, *Global Silicones Council and Others -v- ECHA*, *OJ* of 5 November 2018).

Plant Protection Products - Non renewal of oxasulfuron

A new action has been brought before the EU General Court against the EU Commission's regulation not to renewal the approval of the active substance oxasulfuron (T-574/18, *Agrochem-Maks -v- Commission*, *OJ* of 26 November 2018). The applicant claims in particular that the EU Commission erroneously applied the precautionary principle.

Non-authorisation of generic medicine

A new action has been brought before the EU General Court against the European Medicines Agency (EMA) for refusing to authorise the generic version of the medicinal product Aubagio®. The applicant incidentally also challenges the EU Commission's 2013 conclusion that Teriflunomide was a new active substance (T-549/18, *Hexal -v- EMA*, *OJ* of 3 December 2018).

Scope of notion of biocidal products

The College van Beroep voor het Bedrijfsleven (Administrative Court of Appeal for Trade and Industry, Netherlands) has asked the EU Court of Justice to clarify whether substances consisting of one or more types of bacteria, enzymes or other constituents should be considered as 'biocidal products' within the meaning of Regulation 528/2012 (C-592/18, *Darie B.V. -v- Staatssecretaris van Infrastructuur en Milieu*, *OJ* of 3 December 2018).

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