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Life sciences and regulatory newsletter

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 life sciences and regulatory newsletter focuses on important case law developments affecting the life sciences sector.

EU General Court ruling may open the door to far-reaching public access to protected regulatory data

Aarhus Regulation 1367/2006 grants the public right of access to any information held by EU bodies relating to "emissions into the environment". Access can be refused only to protect an ongoing investigation. Thus, unlike other transparency related legislation, the Aarhus Regulation does not allow refusal of access for the purposes of protecting commercial interests. This makes the precise scope of the expression "emissions into the environment" crucial. In its judgment of 8 October 2013, the EU General Court examines that question for the first time (Case T-545/11, *Stichting Greenpeace Nederland and PAN Europe -v- Commission*).

The case was brought before the General Court by environmental NGOs seeking the annulment of the EU Commission's refusal to disclose confidential information submitted to it as part of the approval process for the active substance glyphosate. Such confidential business information (CBI) is submitted in vast quantities to a number of EU bodies as part of a range of regulatory approval processes (for chemicals, plant protection products, etc.). The information is normally protected from disclosure under the relevant sector specific regulation (in this case the plant protection product Regulation 1107/2009), as well as under the general Transparency Regulation 1049/2001.

The EU Commission considered that "emissions" should be interpreted narrowly as releases of substances from technical installations (e.g. factories). This would be in line with the UNECE 2000 Implementation Guide to the Aarhus Convention, as well as the various sector specific EU Regulations protecting CBI. The information requested in this case did not concern releases of substances from technical installations. Instead it related to product composition, the identity and level of impurities, and the notifiers' manufacturing process which competitors – if they were given access – would be able to duplicate without incurring any investment costs. Disclosure would thus leave the notifiers' commercial interests and secret know-how unprotected.

The Court rejected the EU Commission's reading of "emissions". According to the Court, it is enough for the requested information to relate "*in a sufficiently direct manner*" to emissions into the environment. This, in the Court's view, includes release into the air through spraying of the active substance and impurities contained in a plant protection product.

This is potentially an extremely broad reading of the notion of "emissions" and a far-reaching precedent. Is anything sprayed into the air an "emission"? Is anything that ends up in the air, soil or water by a more indirect route an "emission"? How, then, are "emissions" to be distinguished from all other types of "environmental information"? Indeed, the Court's broad reading appears to go far beyond what the Aarhus Convention intended and to conflict with other legislation and international agreements (EU Charter of Fundamental Rights, TRIPS, etc.). If the ruling remains unchallenged it will open up the possibility of unlimited disclosure of large amounts of valuable – and hitherto protected – regulatory data, such as those submitted in authorisation procedures for plant protection products and chemicals.

An appeal against this judgment can be brought before the EU Court of Justice within two months by the Commission, another EU institution, or a Member State. A similar case against the European

Chemicals Agency is pending before the General Court (Case T-245/11, *ClientEarth and International Chemical Secretariat -v- ECHA*). In that case, NGOs also claim that the information requested from ECHA relates to emissions.

No Supplementary Protection certification (SPC) possible for "emergency" plant protection product authorisations, EU Court of Justice says

In a judgment of 17 October 2013, the EU Court of Justice responds to the question put before it by the German Patent and Trade Mark Office on the possible use of emergency marketing authorisation as a basis for the issuance of SPCs for plant protection products (PPPs) under Regulation 1610/96. The Court replied negatively (Case C-210/12, *Sumitomo Chemical Co. Ltd -v- Deutsches Patent- und Markenamt*).

Member States may grant "emergency" authorisations for a maximum period of 120 days allowing the restricted use of PPPs which does not qualify for a normal authorisation, for instance, because they contain an unapproved substance, and provided that no other reasonable means are available to control the danger (see Article 53 of Regulation 1107/2009).

Since emergency authorisations are intended precisely to cover only those PPPs which do not satisfy the safety and efficacy requirements for a normal marketing authorisation and do not require Member States to carry out a prior scientific risk evaluation, the Court considers that emergency authorisations do not fulfil the conditions of Article 3(1)(b) of Regulation 1610/96 for obtaining an SPC.

The Court also clarified in this judgment that an application for an SPC can validly be made only *after* a valid marketing authorisation has been obtained, and not before, since Article 3(1) of Regulation 1610/96 expressly requires each of the conditions to be met on the date at which the application for an SPC is lodged.

The same question has been put before the EU Court of Justice in another pending case C-477/12, *Hogan Lovells International LLP -v- Bayer CropScience K.K.* (see our March 2013 newsletter).

EU Court of Justice blurs the lines: a product can be a medical device and a medicinal product

In response to a preliminary reference case brought by Finland, the EU Court of Justice concludes in a judgment of 3 October 2013 that EU law does not prevent the same product from being classified as a medical device in one Member State and as a medicinal product in another Member State (Case C-109/12, *Laboratoires Lyocentre -v- Lääkealan turvallisuus- ja kehittämiskeskus and Sosiaali- ja terveysalan lupa- ja valvontavirasto*).

At the origin of this case is the 2008 decision of the Finnish Medicines Agency to re-classify the product Gynocaps, a vaginal capsule intended to restore bacterial imbalance, as a medicinal product while it had been placed on the market as a medical device in several Member States, including Finland.

The Agency's decision took account of Gynocaps' pharmacological and metabolic impact mechanism (live lacto bacteria aimed at modifying, correcting or restoring certain physiological functions) and also the fact that another company's similar product – with the

same mode of action and containing the same substance – was already being marketed in Finland as a medicinal product.

The Agency consequently considered that the sale of Gynocaps in Finland required a prior medicines marketing authorisation and that the CE marking had been inappropriately affixed to a product which does not qualify as a medical device. The manufacturer, Laboratoires Lyocentre, brought legal proceedings in Finland against the re-classification decision. The Finnish Supreme Administrative Court decided to stay the proceedings and to ask the EU Court of Justice for its interpretation.

The Court concludes that – until harmonisation of EU law in this area is more complete – it is "difficult to avoid" Member States classifying the same product differently. As it is essentially left up to Member States to authorise the marketing of devices and medicinal products on the basis of the product information available to them (e.g. composition, pharmacological properties, health risk), it should – according to the Court – be accepted that Member States arrive at a different classification where they have to decide on a different set of data or where they assess the information differently.

As the Advocate General rightly points out, differences in product classification across the EU may result in legal uncertainty and frustrate the functioning of the internal market. These are, however, considered by the Advocate General and Court as the unavoidable consequences of the current state of incomplete harmonisation of EU law.

The ruling may therefore serve as a clear signal to EU law makers, especially in the context of the ongoing review of the EU legislative framework governing medicines: a higher degree of harmonisation (e.g. a single product dossier submitted at EU level for a centralised scientific assessment) is the only way to avoid Member State differences and to ensure legal certainty as well as a proper functioning internal market.

The Court also clarifies the consequences of a reclassification decision. In application of Article 18 of the Medical Devices Directive, it is in the first place the manufacturer's responsibility to ensure that the situation of non-compliance is put to an end. The Advocate General explains that Laboratoires Lyocentre should thus have immediately withdrawn the products inappropriately sold as medical devices from the Finnish market following the re-classification decision.

Where the manufacturer fails to take appropriate measures, Member States can take action under Article 18 or Article 8 (the safeguard clause) of the Medical Devices Directive (e.g. product recall). Unlike the Advocate General, the Court does not expressly exclude the possibility of a "grace period" during which the products are allowed to stay on the market until the manufacturer has applied for and obtained the necessary medicines marketing authorisations. The Advocate General however considers that such a grace period would be contrary to the objective of protection of human health.

New actions before the European courts

This section of the newsletter looks at some of the key cases introduced before the European Court of Justice and the European General Court and recently reported in the Official Journal of the European Union[1].

ECHA registration fees – SME status

A new action has been brought against ECHA and the EU Commission, as published in the Official Journal on 5 October 2013 (Case T-392/13, *La Ferla -v- Commission and ECHA*), challenging the legality and the correct application by ECHA of the substantive criteria for the determination of SME status allowing registrants to benefit from lower registration fees. The applicants also challenge the legality of the ECHA Management Board Decisions MB/21/2012/D and MB/D/29/2010 setting the amount of the administrative charges for incorrect classification. A number of similar actions are pending (see our April 2013 newsletter).

Note:

1 Undertakings with an interest in direct actions can request permission to intervene before the court within six weeks of the Official Journal publication. There is no possibility for intervention in the case of requests for preliminary rulings.

Contacts

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