September 2014

Principles for Balanced Transparency of Regulatory Data in the European Union

Recent reviews of access to documents policies by EU regulatory agencies have confirmed a trend to greater openness to access requests, coupled with more extensive proactive data dissemination. This trend is based on considerations that enhanced transparency increases public confidence in the institutions.

The initiatives were prompted by requests from interested parties to gain access to detailed data on medicines, GMOs, chemicals and plant protection products and pressure to broaden public access rights to the data underpinning regulatory submissions or decision-making.

Innovative companies are required to submit very detailed data packages to EU authorities under various regulatory procedures. These packages routinely contain commercially confidential information (CCI)[1], which is an important intangible component of a company's valuable business assets. The possibility that CCI submitted to regulatory agencies may be disclosed to the public and thus available to unfair use can be a disincentive for innovation and investment in research and development - and can also detract from a more structured sharing of data between interested parties. This may result in lower competitiveness of the industry and can even jeopardize the survival of companies by providing competitors with an unfair competitive advantage.

An adequate level of protection of CCI requires a fair balance between competing interests. However, recent developments have shown that this balance is not sufficiently implemented in EU law and that protection of CCI is increasingly conceded in face of increasing demands for "total transparency", at the expense of the competitiveness of EU companies and without proper evaluation of the merits of each case.

Industry actively supports balanced transparency and calls for a fair and predictable approach towards access to regulatory data, implementing the Access to Documents Regulation (1049/2001) and the Aarhus Regulation (1367/2006) in a manner that stimulates innovation and industry's competitiveness.

[1] Sometimes also referred to as confidential business information (CBI).

Any initiative or practice to increase transparency of regulatory data held by EU institutions, agencies and bodies should observe the following principles:

1. **Predictability.** Industry needs to know in advance whether, how and when the data it submits to EU authorities will be disclosed to third parties. In practice, this means that:

   - Before submitting the data to EU authorities, the company should know whether the data will be treated as confidential or not, and under which conditions (e.g. if a confidentiality request must be submitted).

   - If the authority intends to deny confidential treatment, the company must be given the opportunity to make its point of view known (right to be heard). The supplier of the data needs to be consulted and have a reasonable timeframe to reply. The company must also be granted the right to request that a decision to disclose be reviewed by an independent administrative authority (right to administrative review). Finally, the company should have sufficient time to seek judicial suspension and annulment of the final administrative decision before disclosure (right to judicial review).

   - Because companies know the economic and competitive conditions in which they operate, where a request for access is submitted with regard to data provided by a company, appropriate consideration should be given to that company's assessment of whether disclosure would undermine the protection of commercial interests.

2. **Fairness.** A fair balance must be achieved between the right of the public to access documents of EU institutions and bodies (Art. 15 TFEU, Art. 42 Charter of Fundamental Rights of the EU) and the right to confidentiality and protection of professional and business secrecy and of property rights (Art. 339 TFEU, Art. 7, 15, 16, 17 and 41(2)(b) Charter of Fundamental Rights of the EU). The protection of confidentiality is particularly important for data submitted by companies in the context of regulatory procedures.

   - Proactive disclosure of data originating from companies should be possible only where EU authorities and bodies have an explicit and unequivocal mandate in the legislation to do so.

   - Increasing dissemination of such data cannot be justified by a need to reduce the administrative burden of EU authorities linked to the handling of access to document requests.

   - Where access to CCI is requested by a third party, EU authorities and bodies should always carry out a careful weighing up of interests to determine whether there is an overriding public interest justifying disclosure. A mechanical approach of complete disclosure on the basis of an alleged automatic priority in favour of the general public interest in transparency does as a rule not allow for the optimal balancing of interests which will ultimately be in the public interest; nor is it consistent with the law[2].

[2] The overriding public interest – as referred to in Art. 4(2) of the Access to Documents Regulation (1049/2001) is distinct from the principle of transparency. See Joined cases C-514/07P, C-528/07P, C-532/07P *Sweden v API.*

3. **Proportionality.** The scope and manner in which data is disclosed to the public or to a third party should be proportional to the interests at stake[3].

   - In general it may be possible to distinguish information that is not CCI and can be proactively published with no controls; information that is of a highly valuable nature that should not be disclosed at all; and a middle ground of information that can be disclosed but subject to controls on how it is used and further disseminated. This should be assessed in conjunction with the sectors concerned.

   - The risk of commercial harm is more immediate where the data is proactively disseminated to the public (typically on a website) than where it is made available to individual persons upon their request, even though the latter are in principle free to further disseminate the information[4]. Hence, the proactive dissemination route should be used only for data of general public interest that is not commercially sensitive, unless other adequate safeguards can be provided.

   - As soon as disclosure risks undermining the commercial interests of the data supplier, the information should -- subject to an overriding public interest that is established after consultation with the entity that submitted the data -- remain available upon request only. This allows the EU authority to balance the interests at stake, taking into consideration all the circumstances of the case, including the identity of the requestor and persons obtaining access (e.g. if disclosure leads to data becoming available to a competing company). In addition, the authority should take account of the potential uses and understanding of the information by the person obtaining access (e.g. the impact of detailed information related to medicines on patients who may not be able to interpret the data correctly).

   - Parameters for controlled access to highly sensitive data (*e.g.* use of reading rooms) should be explored on a case-by-case basis. This would allow access to detailed data for, for instance, interested experts, with adequate guarantees that the same data would not be used for competitive purposes by other companies. Such controlled access schemes can most efficiently be established by industry.[5]

   - Finally, where data held by EU authorities contains personal data, the privacy rights of the data subjects must be respected.

---

[3] See, for instance, the decision by the Court of Justice in Case C-453/03, *ABNA v Secretary of State for Health and others*, where the Court ruled that the obligation for manufacturers to indicate the exact composition of a feedingstuff at a customer's demand was infringing the proportionality principle, as this could not be justified by the objective of protecting public health.

[4] Dissemination of data through the Internet increases the risk of unfair commercial use by competitors, as it will be extremely difficult for companies to control the use that is made of published data. If the data is not protected by IP rights but contains CCI, it will often lose its value upon publication.

[5] See for instance, the recent pharmaceutical industry program for providing access to clinical trial data for research purposes, which control access for the purposes of protecting both CCI and protecting personal data: PhRMA and EFPIA Principles for Responsible Clinical Trial Data Sharing Our Commitment to Patients and Researchers, 18 July 2013.

4. **Coherence.** Implementation of the Access to Documents Regulation (1049/2001) and the Aarhus Regulation (1367/2006) should be coherent with other parts of EU law and with international agreements concluded by the EU.

   - Such implementation should not undermine the protection of confidentiality provided in sector-specific EU legislation (*e.g.* Art. 118(2) and 119(2) REACH Regulation (1907/2006), Art. 63 Plant Protection Products Regulation (1107/2009) and Art. 66 of the Biocides Regulation (528/2012)). It should also stimulate self-regulatory schemes, such as the principles for responsible clinical data sharing in the pharmaceutical sector.

   - It should not compromise the purpose and benefits of EU competition law, by leading to disclosure of strategic data, *i.e.* data that reduces strategic uncertainty in the market, including technologies and R&D programs, production volumes and supply relationships.

   - Finally, it should be consistent with the TRIPS agreement, and in particular Art. 39(3) thereof, which requires the EU to protect the secrecy of undisclosed data subject to two exceptions: where disclosure is necessary to protect the public or where steps are taken to ensure the data is protected against unfair commercial use.

For further information, please contact:

Liesbeth Timmermans – Cefic (+32 2 676 7319, lti@cefic.be)
Euros Jones – ECPA (+32 2 663 1553, euros.jones@ecpa.eu)
Nathalie Moll – EuropaBio (+32 2 739 1175, n.moll@europabio.org)
Brendan Barnes – EFPIA (+32 2 626 2547, brendan.barnes@efpia.eu)
Maryse Hervé – ELC (+32 2 736 53 54, elc@ecco-eu.com)