New rules on confidentiality of data and transparency of assessment under the EU regulatory regime for pharmaceuticals: a balancing act?

Abstract

An outline of the relevant provisions and philosophy, both under current law and in respect of the changes that will occur from the end of 2005 as a result of the implementation of Review 2001.

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Fulltext

The drug regulatory system in the EU has been reviewed extensively in the process of Review 2001 (the Review). In the Review the entire body of pharmaceutical legislation was revisited (European Council Regulation (EEC) No 2309/93 and Directive 2001/83/EC). One of the major changes in the outcome of the Review is the introduction of more transparency in the regulatory process. As a result, the Competent Authorities for marketing authorisations in the EU will become more accountable for their decisions and more information on use and characteristics of medicinal products will become available to users, for example patients, prescribers or pharmacists. This is generally accepted to be in the interest of public health.

However, increased transparency brings up questions on how to balance the need for transparency with principles of confidentiality that have long been part of the legal system. This chapter outlines the relevant provisions and philosophy, both under current law and in respect of the changes that will occur from the end of 2005 as a result of the implementation of the Review. Relevant legal principles in relation to protection of confidential data are also discussed and a conclusion is drawn on how the balance between transparency and confidentiality is likely to be achieved under the revised law. The chapter covers, in particular:

- Transparency and confidentiality under the current EU regulatory procedure.
- Transparency and confidentiality in the revision of the EU regulatory procedure (the Review).
- Role of the Competent Authorities in the context of ensuring confidentiality.
- Role of industry in the context of ensuring transparency.
- Transparency and data privacy.
- Transparency and the agreement on Trade-related aspects of Intellectual Property Rights (TRIPs).
- Where transparency stops and confidentiality starts.

Transparency and confidentiality under the current EU regulatory procedure

European perspective

The current regulatory system is governed by Regulation (EC) no. 2309/93, OJ L 214, 24.08.1993, 1 (the Regulation) and Directive 2001/83/EC (the Directive). The Regulation establishes the European Agency for the Evaluation of Medicinal Products (EMEA) and the centralised procedure, and the Directive is concerned with, among other topics, the national assessment of medicinal products and the procedure of Mutual Recognition (MRP). In the current legislation there is hardly any provision concerning either transparency or confidentiality. Before the last structural change of the regulatory system in 1993 there seemed to be an underlying understanding about confidentiality: without any specific legal basis, regulatory activities, as well as all documents underpinning applications for marketing authorisations, were believed to be strictly confidential. In 1993, presumably without anyone noticing the importance of the change, one new provision was introduced in the pharmaceutical acquis (paragraph 4, Article 12, Regulation 2309/93):

“Upon request from any interested person, the Agency shall make available the assessment report of the medicinal product by the Committee for Proprietary Medicinal Products and the reasons for its opinion in favour of granting authorization, after deletion of any information of a commercially confidential nature.”

When the EMEA started its activities, the provision was noticed and the avenue of transparency was started. Paragraph 4, Article 12 was implemented by the young agency through the publication of the European Public Assessment Report (EPAR) on the EMEA’s website. The content of the EPAR, as well as the timing of its publication, have developed considerably during the period between 1993 and today. Today, EPARs contain all information necessary to underpin, in a transparent way, the approval of the medicinal product in the Centralised Procedure.

The website contains information about the trials that have been submitted by the applicant to prove the safety and efficacy of the medicinal product, as well as information about the discussion that took place in the scientific committee (until 20 May 2004: Committee on Proprietary Medicinal Products (CPMP); since then: Committee on Medicinal Products for Human Use (CHMP)) before a positive opinion was given.

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at the EMEA, until 2005 conflicts between innovative and generic industry are not to be expected as, in 2005, data exclusivity will expire for the first products authorised through the centralised procedure (first authorisations were given in 1995, and the data exclusivity period for products authorised centrally is ten years).

Developments

In the last decade, since the introduction of the current system, a general tendency of openness and transparency has been in place. Following the lead of the Scandinavian countries, the other member states and the EU have been moving towards transparency. Legislation has been adopted to put the principles of freedom of information in place. Another important development has been the growth of the use of the internet as a major source of information. This has had consequences for the empowerment of consumers and is especially important in the pharmaceutical sector of patients. All these trends have led to an expectation and a wish for improvement of transparency. The secrecy with which decisions about medicinal products are taken, is not acceptable any more.

Transparency and confidentiality in the revision of the EU regulatory procedure (the Review)

The European Commission’s proposal

In the text establishing the current regulatory system it was suggested that an evaluation should take place five years after the adoption of the regulatory system. On the basis of this evaluation the European Commission drafted a proposal for the Review (26.11.2001, COM (2001) 404 final).

No revision proposals were made for transparency and confidentiality. However, there was one specific provision proposed for advertising that had wider repercussions. As the Commission explained, the intention was to promote better information to patients about medicinal products, but the provision was drafted as a derogation from the prohibition to promote prescription medicines to the public (paragraph 2, Article 98, 26.11.2001, COM (2001) 404 final). This proposal was not acceptable for the Council and the European Parliament (EP) (see below, Role of industry in the context of ensuring transparency).

It may have been the proposal for this new information channel that led to a revision of transparency philosophy. As a result, the EP, and to a lesser extent the Council, proposed other methods to inform the general public and concerned parties. Among the many hundreds of amendments the EP adopted many were directed at providing more (officially approved) information on all aspects of medicines.

The adopted texts

After fierce discussions in both the Council and EP, agreement was reached and the Review was adopted (Directive 2004/27/EC (amending Directive 2001/83/EC) and Regulation (EC) nr. 726/2004, OJ L 136, 30.4.2004). It is clear from the texts that have reached the Official Journal that there is a new approach to transparency. The "black box" model of drug regulatory procedures and the medicinal products in the EU has been left behind (see box, New provisions relevant to transparency).

The new provisions make the Competent Authorities more accountable when they take decisions about marketing authorisations. The provisions also mean that Competent Authorities can discuss regulatory decisions with academics and users (treating physicians and patients). This was previously hampered by lack of public information. For this reason Competent Authorities can and will have to deal with new groups of interested parties.

Role of the Competent Authorities in the context of ensuring confidentiality

As seen above, the extent to which research data are confidential to the company submitting them to the Competent Authorities in the context of an application for a marketing authorisation for a medicinal product has never been addressed directly in the Directive. However, it has always been assumed that those data would only be used by Competent Authorities to assess safety and efficacy of the medicinal product in the context of their duty to protect public health and not to make good “data gaps” in another person’s application "data exclusivity was introduced in Article 4.8(a)(iii) of Directive 65/65/EEC and is currently consolidated in Article 10.1(a)(iii) of Directive 10.1(a)(ii)).

The language of the data exclusivity law has given rise to a considerable body of case law that has been developed over the past few years by the ECJ as well as a number of cases which are still pending at the ECJ about the application of the data exclusivity provisions (Generica-case, Case C-369/96, 3 December 1998; AsfraZéneca-case, Case 223/01, 18 October 2003; Novartis-case, Case C-106/01, 29 April 2004; Eli Lilly-case, case C-36/03, GSK-case, Case C-74/03).

Although there has been considerable legal controversy about the interpretation of the law, the legal framework provides a defined period of protection in which the Competent Authorities cannot use the protected data to facilitate the market entry of second applicants. However, after expiration of this period, the data are still not publicly accessible, but can indirectly be benefited from by any applicant. However, since data that have been submitted to Competent Authorities are protected by data exclusivity, a regime of total confidentiality during the period of protection may not be necessary. A comparison could be made with patent systems, in which information about an invention is made publicly available on the condition that the patentee gets an exclusive right of commercial use of his invention.

If data underpinning a marketing authorisation are protected by data exclusivity, and disclosure could be in the interest of the protection of public health, this (partial) disclosure of the data should not lead to a breach of confidentiality.
The principle of confidentiality has been limited by the principle of data exclusivity, but these limits have been introduced in legislation in the context of protection of public health, while balancing various principles that serve public health. This balancing of interests is key to understanding various other limits and restrictions of the requirements of confidentiality and transparency.

Role of industry in the context of ensuring transparency

Now the need for transparency and correct and comprehensive information for the general public about the properties and use of medicinal products has been accepted and implemented, the question of the role of the industry in ensuring transparency arises. Should the public be dependent only on what the government wishes to and can disclose, or does industry have its own role? This becomes more relevant as patients’ own responsibility becomes a hot topic in various member states and in the context of national systems of reimbursement. Patients are supposed to take responsibility for cost-effectiveness of healthcare and to limit spending, sometimes at the “penalty” of co-payment (a legal provision in national laws on reimbursement that requires patients under certain circumstances to pay part of the price for the medicinal product themselves). If patients must take this responsibility, they have to be able to get correct and reliable information. These principles have been discussed in the context of the Review.

Current legislation

Article 88 of Directive 2001/83 prohibits advertising to the general public for medicinal products which are available only on prescription. Advertising of medicinal products is defined as any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products. The following information is not covered by the rules on advertising:

- The labelling and the accompanying package leaflets.
- Correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product.
- Factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they do not include product claims.
- Statements relating to human health or diseases, provided there is no reference, even indirect, to medicinal products.

The distinction between advertising and information is not always clear. Only the four exceptions above are forms of communication of information to patients on prescription drugs that are permitted.

The current practice is that European patients looking for information about their diseases and medicines are forced to rely on information produced by pharmaceutical companies outside the EU, usually through the internet. The availability of information on non-EU websites, in combination with the current restriction in the EU on providing information to consumers, has created a differentiation between patients who can go online and those who cannot and a differentiation between those who understand English and those who do not. In addition, often information from websites outside the EU is not accurate as products marketed elsewhere may be different from those marketed in the EU, even though they have the same name. Also, patients may be confronted with, for example, US websites containing direct-to-consumer advertising.

The purpose of the proposed amendment of paragraph 2, Article 88 was to address this situation, allowing all EU patients with specific serious conditions to get good, reliable and correct information in their own language and in an appropriate and well-controlled way (see above, Transparency and confidentiality in the revision of the EU regulatory procedure (the Review)). However, the new language was presented in the shape of a derogation from the ban on advertising to the general public. The EP subsequently rejected the proposed derogation on the grounds that this would be the first step towards consumer advertising of prescription medicines under the guise of “disease education”. The EP apparently regarded the industry as incapable of providing impartial information on its medicines and thought such information should therefore only come from independent sources.

Unfortunately, during the Review process the legislator did not resolve or clarify the borderline between advertising and information, and the responsibilities of the pharmaceutical industry and Competent Authorities in this respect. In practice this means that the evaluation of that division is left to the national courts and the ECJ. However, the legislator made a step towards clarification of the role of industry in this respect with the amendment to Article 88 of the Directive that was finally included in the revised law and is discussed below.


In the final version of Directive 2004/27/EC, Article 88 is amended with the insertion of a new Article 88a. The new article provides for a report by the Commission within three years of the Directive coming into force. This follows consultations with patients’ and consumers’ organisations, doctors’ and pharmacists’ organisations, member states and other interested parties, on current practice with regard to the provision of information (particularly on the internet) and its risks and benefits for patients. Following analysis of the above data, the Commission must, if appropriate, put forward proposals setting out an information strategy to ensure good quality, objective, reliable and non-promotional information on medicinal products and other treatments and must address the question of the information source’s liability.

As discussed above (see above, Transparency and confidentiality in the revision of the EU regulatory procedure (the Review)), under Regulation 726/2004 EMEA has the task of creating a database on medicinal products (to be accessible to the general public) and ensuring that it is updated, and managed independently of pharmaceutical companies. The database must facilitate the search for information already authorised for package leaflets and include a section on medicinal products authorised for the treatment of children. The information provided to the public must be worded in an appropriate and comprehensible manner.

Transparency and data privacy

The need for transparency also has to be balanced against the need for individuals’ privacy, which on the European level is regulated by Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995). This Directive had to be implemented in the national legislation of the member states by the end of 1998. The object of Directive 95/46/EC is to protect personal data, which is defined as any information relating to an identified or identifiable natural person. If information is not identifiable, Directive 95/46/EC does not apply. If information is identifiable, personal data must be:

- Processed fairly and lawfully; and
- Collected for a specified, explicit and legitimate purpose.

Directive 95/46/EC establishes that it is prohibited to process personal data revealing, among other things, data concerning health, unless the subject of the data has given his explicit consent to such processing. However, member states can provide that the data subject’s consent does not lift the prohibition. The prohibition does not apply where processing of the data is required for the purposes of:
The principle of confidentiality in the context of the use by Competent Authorities of confidential data submitted to them by companies that apply for a marketing authorisation has also been discussed in the context of Article 39 of TRIPS including trade in counterfeit goods. Companies can ensure that any privileged information they have at their rightful disposal is not disclosed without their permission, or acquired or used by third parties in any way that can be qualified as unfair commercial use. Privileged information included in the application dossier for market authorisation can be protected, because it is confidential, has commercial value and the companies have taken adequate steps to secure the confidential character of these data in their registration dossier (paragraph 2, Article 39, TRIPS). The disclosure or use of these data by the Competent Authorities without appropriate legal basis is unfair commercial use. Information in an application for marketing authorisation should be protected against unfair commercial use (paragraph 3, Article 39, TRIPS). The development and collection of these data for a market authorisation dossier takes considerable effort, so any relevant information that must be produced to support an application for marketing authorisation, must be protected from unfair competition.

Once the conditions of the provisions of Article 39 of TRIPS have been met, the protection granted is against "unfair commercial use". Use by a competitor could be deemed unfair if it gives a competitor an unlawful shortcut to obtaining a marketing approval. The practice of referral to the data of the innovator after expiry of the data exclusivity period has often been discussed in the context of this provision. The phrase "new chemical entity" (NCE) seems to limit the scope of the protection, because not all new medicinal products contain an NCE, but more important are the two exceptions to the requirement of confidentiality (paragraph 3, Article 39, TRIPS) where:

- The disclosure is necessary to protect the public; or
- Sufficient steps are taken to ensure that the data are protected against unfair commercial use.

Since 1987 legislation has been in place that balances the need to protect innovation with the prevention of repetitive testing, so it would seem that sufficient steps have been taken. The violation of data exclusivity by Competent Authorities will also mean a violation of these TRIPS provisions.

Where transparency stops and confidentiality starts

(This chapter does not address the exchange of information between Competent Authorities. The new Article 122 of Directive 2001/83/EC applies to such exchanges, obliging member states to mutually inform each other.)

Data of a commercially confidential nature

The most important challenge for EU regulators will be the decisions on the extent of transparency in the light of the protection of data submitted to Competent Authorities as commercially confidential. As discussed above, historically, confidentiality has been assumed for the entire content of applications of a marketing authorisation. It can be argued that knowing the exact content of a successful application is a valuable asset. However, Competent Authorities have been criticised for not having a critical view on the balance of interests of the applicant versus other interested parties. As far as confidentiality is concerned, patients and healthcare professionals take the position that the regulatory process is a "black box" and Competent Authorities refuse to be accountable for their decisions.

For the applicant it is best to have anything submitted to the Competent Authorities treated as strictly confidential. This strengthens data exclusivity. Companies can claim protection of the use of their submitted data and they can rely on the fact that competitors are not even familiar with the data subject. The right to object to the use of personal data for the purpose of obtaining a registration must be respected. Hence, the data subject must be provided with at least the following information:

- The identity of the controller and his representative (both as defined in the Directive).
- The purposes of the processing.
- Any further information such as:
  - the recipients or categories of recipients of the data;
  - whether replies to the questions are obligatory or voluntary, as well as the possible consequences of failure to reply;
  - the existence of the right of access to and the right to rectify the data concerning the data subject in so far as such further information is necessary, having regard to the specific circumstances in which the data are collected, to guarantee fair processing in respect of the data subject.

The data subject has the right to object at any time on compelling legitimate grounds relating to his particular situation to the processing of his data, except where otherwise provided by national legislation. Where there is a justified objection, the processing instigated by the controller may no longer involve his data. The identity of the controller and his representative (both as defined in the Directive).

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with the data. From a public health perspective many of the submitted data are relevant for use in medicinal products. It is therefore difficult to strike a balance.

**Transparency versus commercial interests**

The principle governing all systems advocating freedom of information is that all information that is used by the government for policy and decision-making should be available for anyone. This principle is based on the democratic right that citizens should be able to hold governments accountable for policies and decisions. An exception to this principle is made for confidential data as disclosure could harm the commercial interests of the company that submitted them. It can be argued that the general interest of transparency is not strong when set against the commercial interests of the pharmaceutical industry. However, the extent to which details of the research can be disclosed by Competent Authorities always hinges on the principle of “need to know”. In balancing the need for transparency and the need for confidentiality Competent Authorities should ask themselves which information is required to correctly inform the public. Any information that does not pass this test should always be kept confidential.

**Transparency versus public health**

In regulatory affairs the situation could be different because of the importance of information in the prevention of risks to public health. If saving lives of patients would slightly damage the commercial interests of the marketing authorisation holder, the balance of interests would tip over to transparency. Public health is a much stronger interest than the general principle of transparency and would often outweigh any commercial interest.

**Confidentiality: how will it work in practice?**

Initially, it seems impossible to give general rules about the best strategy for deciding on the balance of interests. A possible strategy could be to look separately at the different data that play a role in regulatory processes (see box, An overview of different types of information and considerations on how confidentiality issues could be approached).

**The new rules and the future**

It would seem that under the new rules, information on the testing on humans and animals will, to a large extent, be disclosed. Personal data may never be disclosed in the context of the Data Privacy Directive and TRIPs only provides additional protection if Competent Authorities use information contrary to the data exclusivity rules. It is unfortunate that no new rules have been provided under the Review which clarify the rights and responsibilities of industry in providing information of their own, with or without previous approval of the Competent Authorities. As far as the practical application of the new transparency rules is concerned, experience has to be built up by Competent Authorities and the pharmaceutical industry. It is likely that many questions concerning the balance between transparency and confidentiality will be submitted to national courts and the ECJ.

### New provisions relevant to transparency

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<th>Provision</th>
<th>Effect</th>
<th>Observation</th>
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<tr>
<td>Article 11, Regulation 726/2004</td>
<td>If an application is withdrawn, motivation for the withdrawal has to be given and the EMEA assessment report is published (in all provisions concerning assessment reports and other data it is stated that the published document will be published after deletion of all data of a commercially confidential nature)</td>
<td>Until now many applications were withdrawn before a negative opinion, which kept the procedure out of the public eye</td>
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<tr>
<td>Paragraph 3, Article 12, Regulation 726/2004</td>
<td>Information on refusal of a Marketing Authorisation (MA) is published</td>
<td>To prevent the (off-label) use of inefficacious medicines</td>
</tr>
<tr>
<td>Paragraph 3, Article 13, Regulation 726/2004</td>
<td>EMEA has to publish any adopted assessment report immediately</td>
<td>Until now, EPARs were published only if a new medicinal product was authorised and not until the marketing authorisation was granted</td>
</tr>
<tr>
<td>Paragraph 5, Article 24, Regulation 726/2004</td>
<td>MA holder is not allowed to present information on adverse drug reactions without prior notification to EMEA</td>
<td>Competent Authorities are to control companies in situations of pharmacovigilance crisis</td>
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<tr>
<td>Article 57, Regulation 726/2004</td>
<td>Publicly accessible databases are established, holding information on all medicinal products authorised in the EU. on all adverse drug reactions that have been reported and on all clinical trials that have been approved, and that have taken place, including the results</td>
<td>A lot of information that used to be treated as confidential will be made available to the public. There will of course be a system to protect trade secrets from being disclosed</td>
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<tr>
<td>Paragraph 4, Article 21, Directive 2001/83</td>
<td>National Public assessment report (PAR) is introduced</td>
<td>For every MA a PAR needs to explain to all concerned the reasons for accepting the medicine</td>
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## An overview of different types of information and considerations on how confidentiality issues could be approached

<table>
<thead>
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<th>Type of information</th>
<th>Considerations</th>
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| **Application of or variation on a marketing authorisation** (this box concerns the period between the date that the application has been submitted to the date the regulatory decision has been taken) | Information on facts of application:  
- Identity of applicant  
- Nature of the application/legal basis  
- Details (for example for generics: about the reference product)  

The application and details about the application would not be considered trade secrets, but, when disclosed early, could lead to useful information about competitor’s business. So information has to be treated as commercially confidential until marketing authorisation. The information an be made publicly accessible after authorisation |
| **The dossier** (this box concerns the content of the dossier from the moment the regulatory decision is taken. The content of the dossier is normally changed during the evaluation process) | Module 1 (general data)  
Administrative data is confidential until marketing authorisation and publicly accessible after authorisation  

Module 2 (regional data)  
Refers back to other parts of the dossier (summaries, overviews and expert reports) and therefore has a commercially confidential nature  

Module 3 (chemical pharmaceutical data)  
The most commercially confidential part. Never publicly accessible  

Module 4 (safety data)  
Results of pre-clinical testing could be considered commercially confidential to a certain extent  

Module 5 (clinical data)  
Results of clinical trials are pivotal to the evidence-based, rational use of a medicinal product. Therefore the content of Module 5 has to be made publicly available to a large extent |
| **Post-authorisation** | Adverse drug effect reports (ADRs) (for serious unexpected ADRs)  
Expedited reports and PSURs should first be analysed by Competent Authorities, but then be made available immediately because of their high relevance to the protection of public health  

Periodic Safety Update Reports (PSURs) |

## Article information

### Resource info
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### Jurisdiction
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### Section