EDITORIAL

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Medicines agencies and transparency

Following publication of the new European legislative framework on medicinal products, it will be hard for medicines agencies to resist a strengthened obligation to become more transparent. And it applies to the European agency, as well as to the EU member states' agencies once the new Directive has been transposed.

In some countries, and notably in France, this obligation of transparency will represent nothing short of a cultural revolution, secrecy having been so firmly anchored in the administrative mind-set.

Yet many obstacles remain.

One that springs to mind is that public bodies tend to be secretive because they have conflicts of interest to hide. It is easy to see how medicines agencies whose budgets are largely dependent on drug companies can lose sight of the public health dimension of their work.

But direct influence from drug companies is only part of the story. Many other factors can encourage agencies to hide behind a veil of secrecy. In 1996, the Uppsala Statement on Transparency and Accountability in Drug Regulation listed a number of such factors (a):

– **"lack of legal obligation:** *in some countries, the law establishing official institutions does not impose on them any duty of providing information;*

– **lack of clarity in the law:** *agencies or their staff may consider it safer to apply confidentiality clauses broadly rather than narrowly; (…)*

– **lack of consistent policy:** *particularly in some developing countries there are (very) frequent changes in regulatory staff, and general policy matters such as the provision of information receive little attention;*

– **lack of explicit routines:** *within the agency, who is competent to release a particular type of information, to whom, and in what circumstances? (…)*

– **paternalism:** *the frequent belief that those outside of the agency do not need, could not cope with, or would misinterpret the information;*

– **embarrassment:** *an agency may hesitate to make fully public those decisions which are poorly documented or internally contested, papers that reflect poorly on the agency's performance, or matters on which it might be criticized for not yet having taken a decision; (…)*

– **over-caution:** *there may be an exaggerated fear of upsetting commercial sensitivities;*

– **bureaucratic habit and inertia:** *in agencies which are not subject to critical and transparent review, habits can form which discourage exchange of information".*

Agencies may need a slight push in the right direction.

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a- Extracts from The Uppsala Statement-1996. Full text available on www.isdbweb.org

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