BMJ

BMJ 2013;347:f5390 doi: 10.1136/bmj.f5390 (Published 3 September 2013)

NEWS

Industry and drug regulators disagree on which data should remain confidential

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Sharp differences of opinion have emerged over how much clinical trial data some drug companies are willing to release as the clock ticks down to the transparency deadline of 1 January 2014 set by the European Medicines Agency (EMA).

A meeting in Brussels late last month showed that the industry itself is split, despite the publication of a draft policy by the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Pharmaceutical Research and Manufacturers of America (PhRMA) which outlined the principles their members should follow.[1]

At the meeting one drug company representative, Neal Parker, of the US company AbbVie, broke ranks by asserting that some data on adverse drug reactions should be treated as commercially confidential.

AbbVie, a research based biopharmaceutical company which split off from Abbott at the beginning of this year, has already taken action in the courts to prevent the European Medicines Agency from releasing to a rival, the Belgian company UCB, data on AbbVie's rheumatoid arthritis drug adalimumab (Humira). It won an interim judgment preventing release of this data on 30 April this year.[2]

At the Brussels meeting, Parker shocked data transparency campaigners and drug regulators by detailing a range of information AbbVie considered commercially confidential because its release would help competitors to make copies of its drugs.

These included "internal tactical decisions on how we are going to run a study, engage with regulators, and confront and solve problems and challenges we have uncovered during clinical trials," he said, according to *Scrip Intelligence*.[3] "This information cannot be patented nor have exclusivity, but can give other companies a tremendous competitive advantage by revealing our strategic thinking for proving safety and efficacy of our products." This could include adverse drug reactions, he added.

Hans Georg Eichler, the EMA's senior medical officer, responded by saying, "I have been a regulator for many years and I am totally flabbergasted."

Did Parker mean, he asked, that if there was a healthcare concern and your company was asked to give an explanation you would consider your reply commercially confidential?

Aginus Kalis, head of the Dutch Medicines Evaluation Board, said, "Are you aware you are working in the healthcare industry, with patients and human beings?"

The director general of EFPIA, Richard Bergström, intervened to say that "most of our members are quite relaxed" about data disclosure. For most products there would be no issues, though for highly competitive fields such as biological there might be. "You might get companies from South Korea or China breathing down your neck trying to copy your technology, then you get extra sensitive," he said.

Ben Goldacre, who campaigns for data transparency, told the meeting that the EFPIA/PhRMA guidelines did not go far enough, falling short of the promise made by the European Medicines Agency to publish almost all the clinical study reports that accompany applications for a licence. The "huge loopholes" in the industry document included the omission of all trials conducted before the 1 January 2014 deadline, meaning that it would do nothing to improve the evidence base for prescribing decisions being taken on drugs available today.

He questioned whether the review panels to be set up by companies to consider requests for data would be truly independent. In addition, there was no provision for routine public audit of who asked for access to data, who was refused, and why.

As the Brussels meeting demonstrated, there is a wide range of views within the industry. While GlaxoSmithKline, for example, has agreed to publish past clinical study reports, the industry as a whole has not. The companies that have been exposed to the worst publicity for past misdemeanours, such as GSK, are generally more supportive of transparency than those that have not.

The European regulator, given little choice by a decision of the European Ombudsman, is for disclosure and believes it should be the arbiter of what should be excluded on grounds of commercial confidentiality. The industry believes it should have this job and is itself split over the extent of transparency between the likes of GSK and, at the other extreme, AbbVie and InterMune, a California based company that has also taken legal action against the EMA to prevent its data being released.

The extent of the disagreements within industry should be clearer by the end of this month, when a consultation on the draft EFPIA/PhRMA guidelines closes. A failure to reach consensus would leave decisions on what to release and how in the hands of the EMA, though subject to what the European Courts decide.

1 O'Dowd A. Drug industry pledge on access to trial data is met with scepticism. *BMJ* 2013;347:f4829.

2 Kmietowicz Z. European regulator is ordered not to release clinical study documents. *BMJ* 2013;346:f2846.
3 Schofield I. Industry and regulators clash in debate over trial data disclosure. *Scrip Intelligence* , 29 Aug 2013. www.scripintelligence.com/home/Industry-and-regulators-clash-in-debate-over-trial-data-disclosure-346093.

Cite this as: *BMJ* 2013;347:f5390