N. HALL/REUTERS

GlaxoSmithKline chief executive Andrew Witty, who announced the firm's commitment to openness.

BIOMEDICINE

Drug firm to share raw trial data

Full disclosure could improve health care and restore trust.

BY DECLAN BUTLER

The secrecy that has long surrounded drug-industry trials is crumbling. Scientists are applauding drug giant GlaxoSmithKline (GSK) for its announcement last week that it will make the trove of detailed raw data underlying its clinical trials systematically available to researchers. And GSK's move — the first such commitment for a big player in the industry — is just the beginning. Starting next year, the European Medicines Agency (EMA) intends to open up access to all new clinical-trial data sets it receives from industry for product registration.

The decisions represent a sea change in clinical science. Whereas data sharing is taken for granted in fields from genomics to particle physics, data from clinical trials are rarely shared fully with other scientists, says Joseph Ross, a researcher at Yale School of Medicine in New Haven, Connecticut. This means that doctors, health officials and researchers are forced to make important decisions about patients and health care on the basis of incomplete, and sometimes biased, information. GSK's decision acknowledges the wide value of raw trial data to investigators and public-health officials, says Ross, who says that "the move by GSK is a great public step forward".

Greater openness about clinical-trial data should help to speed up drug development, provide independent assessments of drug safety and efficacy and increase trust in industry science. It could also put an end to the scandals that, over the past few years, have seen almost every major drug company fined hundreds of millions of dollars for putting profits before patient safety and welfare, often through selective data reporting. In July, GSK itself reached a US$3-billion settlement with the US authorities for fraud, including publishing "false and misleading" accounts of trials, and for hiding data on safety concerns (see *Nature* **487,** 139–140; 2012). The settlement covered the antidepressants Paxil (paroxetine) and Wellbutrin (bupropion), and the diabetes drug Avandia (rosiglitazone).

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GSK now intends to make available anonymized patient-level data for all the trials it has carried out since 2007 for both approved and abandoned drugs (the company says that only post-2007 data is in formats suitable for sharing). It will also set up an expert panel at arm's length from the company to review requests to access data for scientific merit, a restriction that some researchers dislike.

James Shannon, chief medical officer of GSK, justifies the restriction as a way to stop people from trawling through the data without a solid scientific question or hypothesis. Such fishing trips could lead to flawed analyses that could alarm the public unnecessarily and damage public health, he says.

WAIT AND SEE

Peter Gøtzsche, director of the Nordic Cochrane Centre in Copenhagen, says that he has "huge problems" with the restrictions, however. He argues that they could lead to arbitrary decisions about data release, which might favour the company rather than the public interest. Any risk of scares is outweighed by having more eyeballs on the data, he says, arguing that the lack of sharing of trial data by industry has been "far more harmful".

Kay Dickersin, director of the Center for Clinical Trials at the Johns Hopkins Bloomberg School of Public Health in Baltimore, Maryland, agrees with GSK that some access restrictions can be helpful. She cautions that the value of GSK's new openness will ultimately depend on how much detail it supplies in the patient-level data and, crucially, on the extent of documentation about how the trials were designed and data were collected, processed and analysed. "Let's wait and see," she says.

Openness will take another step forward next year, when the EMA begins to make public the clinical-trial data sets submitted to it. Although most companies might view the data as confidential, the EMA was empowered by a 2010 ruling by the European Ombudsman that the public-health interest of trial data overrides commercial interests, says Hans-Georg Eichler, a senior medical officer at the EMA.

The EMA's plans are "a phenomenal step in the right direction, a total game changer", adds Ross. The US Food and Drug Administration, by contrast, considers raw data from trials to be commercially confidential, he notes.

Alluding to the scandals that have rocked the drug world, Shannon says that the transparency his company is pioneering is the only way forward for the industry, and that he hopes other companies will follow GSK's lead. To maintain a 'licence to operate' from society, he says, the pharmaceutical industry has to move towards full disclosure. Many within GSK's rank and file have long been gunning for greater sharing of clinical data, he says, and last week's announcement was met with "much internal celebration", and hailed by some GSK scientists as a "dream come true". ■