Drug test rules ‘would eliminate biotechnology sector in UK’

MPs warned in evidence from Oxford professor and government adviser

April 21, 2013

by: Andrew Jack

British biotech companies would be throttled if proposals were passed to release full details of tests on patients of experimental medicines, a leading medical researcher and government adviser warns.

Sir John Bell, Regius professor of medicine at Oxford and one of the government’s life science advisers, said plans by the European Medicines Agency to publicise all data once it has assessed a new drug “would essentially eliminate the biotechnology sector in the UK”.

His warning came in written comments before hearings with the pharmaceutical industry scheduled for Monday afternoon by the House of Commons science and technology select committee, which is reviewing clinical trial legislation.

Sir John wrote in his evidence: “The extreme position of making all patient line data available to all comers has not been properly thought through … Many of the trials of interest for this sort of data release will be part of a set of global studies and a unilateral position of extreme data release in the UK would be certain to drive most of the important and interesting trials to other jurisdictions.”

Sir John is also a board member of Roche, the Swiss-based maker of Tamiflu, a blockbuster flu treatment whose efficacy has been questioned by academics.

The company says it has always fully co-operated with regulators, providing them with full clinical trial results, and that the efficacy of Tamiflu has been supported by reviews conducted by independent academics to whom it had released more details. Roche and GlaxoSmithKline, which will both testify to the committee, say they are willing to share “raw data” on the results of drug tests on individual patients, provided that it is made anonymous and channelled to authorised researchers.

But the companies and others say the main focus of transparency should be on providing summary results of trials rather than the underlying raw patient data, which they say could threaten patient confidentiality. They add that reanalysing underlying clinical data would be second-guessing regulators and could, if poorly conducted, create unnecessary public health scares over drugs.

Other drug companies remain still more concerned about the EMA's plans to release all information on drug applications after a decision on approval is made. AbbVie and InterMune, two US companies, are suing the agency to prevent public release of this data, arguing that it would undermine their competitive advantage.

Sir Kent Woods, chief executive of the Medicines and Healthcare Products Regulatory Agency, the UK body that approves medicines, said "commercial confidentiality" to maintain secrecy on drug trials had been too much of a catch-all excuse. "It's been sprayed on like black paint. That's not helpful," he said.

But he conceded that companies should be allowed to protect commercial knowhow about manufacturing processes from their competitors. He also cautioned over misinterpretation of data if it were made public. "There is a real downside to putting wrong information in the public domain. It carries morbidity and mortality implications," he said.