The Medicines and Healthcare products Regulatory Agency works to ensure the drugs we're prescribed are safe enough, but it's failing the public in key areas

Professor Joe Collier: 'The MHRA made a terrible mistake'

Drugs watchdog fails public

After six volunteers were taken seriously ill when testing a treatment for arthritis, leukemia and multiple sclerosis at Northwick Park Hospital in London this March, the UK drugs regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), was asked to investigate.

Yet our research shows that in key aspects of its work as a drugs regulator, the MHRA, which is responsible for making sure that drugs are safe enough for GPs and hospitals to prescribe, is failing to effectively oversee the drugs industry and isn't working in the public interest.

Since the Northwick Park incident, there's been no independent inquiry into what happened. Instead the MHRA, which is responsible for authorising the conduct of UK drug trials, investigated itself. Its report found nothing wrong with the way the trial was run and said there was no evidence that the incident could have been avoided.

We disagree. We believe the investigation failed to address several issues and has done little to restore public confidence in clinical trials. For example, the trial broke the rules on good clinical practice and the MHRA said that the way the drug had been administered raised no safety issues. Yet the volunteers were injected in turn at just ten-minute intervals. Staff didn't wait to see whether there were any side effects after the first injection before continuing. This put the six men at an unacceptably high level of risk.

Some medical experts believe the trial was a disaster waiting to happen. Joe Collier, Professor of Medicines Policy at St George's Hospital, London, said that in his opinion: 'No new drug should be tested in this way. The trial should never have happened and the MHRA made a terrible mistake.'

Other cases

This is just one of many complaints levelled at the MHRA. *Which?* and our sister publication *Drug & Therapeutics Bulletin* (DTB) have been highly critical of the agency and similar charges were also made by the House of Commons Health Select Committee last year.

Clinical researcher Dr Aubrey Blumsohn believes that the agency has failed to look properly into allegations of research misconduct made by him against Procter & Gamble Pharmaceuticals (P&G).

Dr Blumsohn and his team at Sheffield University's Bone Metabolism Research Unit were commissioned by P&G to do research into its osteoporosis drug Actonel, which is already licensed for use. But a dispute arose when P&G published material in Dr Blumsohn's name without his permission based on the raw data his lab supplied.

'The MHRA reflects rather than leads'

Dr Blumsohn claimed that P&G refused him access to the data on which it based its conclusions, so couldn't compare the company's conclusions with his own. When he was finally given access, he believed the data did not back up the claims about Actonel made in the published research.

Following publicity surrounding the case, Dr Blumsohn was suspended from his post.

Then in December, the government announced that there would be an investigation by the MHRA into 'the alleged case of research misconduct' following the incident. Since then Dr Blumsohn believes he's been frozen out of the investigation.

The next March the MHRA told him it had 'interviewed all parties directly involved' but hadn't met with Dr Blumsohn or asked him to provide any evidence to back up his claims. And when he asked the MHRA to confirm that the evidence it had was the same as data he held, he was told he'd have to pay more than £600 to have this done because of the amount of work involved.

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So far no report has appeared, but in June the MHRA said that no 'regulations governing clinical trials' had been breached in the case. At the same time, it added that its remit didn't include looking into allegations about medical research misconduct after drugs have been licensed.

Dr Blumsohn told us: 'I wonder whether this organisation that is supposed to be safeguarding public health has any interest in doing so. The MHRA declined to accept my documentary evidence and I believe it conducted a sham inquiry.'

Watching adverts

Another role of the MHRA is to regulate pharmaceutical advertising and marketing, but the agency has failed repeatedly to protect the public from misleading and inappropriate adverts.

In April, DTB criticised claims being made about osteoporosis drug Protelos by drug company Servier. This prompted an investigation by the Prescription Medicines Code of Practice Authority, the pharmaceuticals industry self-regulator, which criticised Servier for implying its drug was better than other drugs in the field.

The authority took no further action but the findings were made known to the MHRA, which didn't investigate the claims. The agency told us it requires correction only when misleading claims pose a serious risk to the public and this didn't apply here.

Dr Ike Iheanacho, editor of DTB, is astonished at this decision: 'If Servier isn't asked to make a correction, doctors and the public will continue to believe that this drug has advantages over other drugs.'

This failure follows assurances from the MHRA that it would 'get tougher' on misleading adverts following criticisms by the select committee.

Drug warnings

The MHRA has also failed to rid itself of criticism that it has let drugs remain on the market without appropriate warnings.

It has fought a long-running battle against those who have accused it of being too slow to react to evidence of the dangers of anti-depressant drugs, such as Prozac and Seroxat. Since the 1990s there have been concerns that these drugs could induce suicidal behaviour and could lead to dependence. Yet in an article in the *British Medical Journal* (BMJ) this July Dr David Healy, Professor of Psychiatry at Cardiff University, said that even now the MHRA is lagging behind pharmaceutical companies in warning of the risks of these drugs.

Dr Healy told us that he believed the agency was too much in the pocket of drug manufacturers: 'The MHRA reflects rather than leads and its approach to licensing drugs doesn't involve the sort of close scrutiny which the public might expect.'

Questions have also been asked about the agency's close relationship with the drugs industry – the agency is funded by the industry through an annual service fee and fees for the licensing of drugs.

Just as damning are the comments by BMJ editor Dr Fiona Godlee in the same issue. She said the MHRA needed urgent reform as many see it as 'unaccountable, slow and lacking in the necessary expertise'.

The MHRA replied: 'Our role is not to protect industry interests. We have a responsibility to ensure that regulation is designed to enable rather than hinder the development of new products that would improve health.'

Future steps

Since the select committee report last year, the MHRA has said it will become more open and involve patients and the public in policy, publish more information on clinical trials and licensing, beef up its work on overseeing advertising, and add more lay representatives to its expert groups.

The time for an independent review is long overdue

However, the MHRA has failed to address many of the concerns of the select committee and there continues to be a conflict between promoting the drugs industry on one hand and protecting public health and safety on the other.

The time for an independent review of the agency's work is long overdue. Any reformed body should have greater transparency and more lay representation, while the responsibility for monitoring advertising and other promotions should be transferred to a new independent regulator.

In the meantime there should be more publicity from the MHRA to encourage the public to bring problems with medicines directly to its attention.

The regulator will be able to make better decisions about the health effects of medicines if the public gets more involved in reporting on side effects of drugs. Anyone can now report on this directly to the MHRA. If you have concerns about a drug you have taken, you can report it at www.yellowcard.gov.uk.

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