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Heart attacks and suicides... yet the dangers were all kept so quiet. So how CAN you trust your medicine?

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A dose of bad medicine? Critics say drugs watchdogs are failing

Few of us would think to question the safety of our prescription drugs. After all, they've been developed to make us better.

But just how safe are they really — and is the official drug watchdog doing enough to protect us?

Last month, for instance, it was revealed that the number of powerful anti-psychotic drugs being prescribed to children had almost doubled in past six years.

Yet despite the growing evidence that these drugs can seriously harm children — causing excessive weight gain, a rise in blood pressure, severe lethargy and even lactation — the Medicines and Healthcare Products Regulatory Agency is powerless to limit their use.

The problem is that these drugs aren't officially licensed for use on children — they are given on doctors' own authority and the MHRA is not able to interfere.

In other areas where the MHRA does have power to act, it turns out to be a watchdog with rubber teeth. Critics say it simply isn't robust enough.

Over the past four years, there has been a string of disturbing reports suggesting that, with some major drugs, the watchdog and doctors were not told the whole story.

As a result, patients were prescribed medicine thought to be safe and effective but which actually put them at risk of dangerous side effects, including heart attack and suicide.

Information about these risks simply hadn't been passed on to the regulators.

This has prompted some experts to ask if our drug watchdog is up to the task. The best-known of these drugs is the antidepressant Seroxat.

Specialists had been warning for years that it raised the risk of suicide in children.

But the MHRA, relying on evidence it had from the manufacturer (GlaxoSmithKline), issued assurances that there was no suicide link.

Then, in 2003, following two BBC Panorama programmes, the drug watchdog mounted its own investigation and discovered the company had hidden information about the suicide link.

More recently, an American academic who looked at more than 60 trials found that other manufacturers had concealed data about the effects of their antidepressant drugs on adults.

Half of the studies were positive and all of these had been published; virtually none of the negative ones had.

When the results of both the published and 'concealed' trials were combined, the drugs were shown to be no better than a placebo for mild to moderate depression.

There were similar revelations about the anti-inflammatory drug Vioxx. This was withdrawn from the market in the UK four years ago after a U.S. study found it doubled the risk of heart disease.

Leading cardiologists had been flagging up the risks for years. After Vioxx's withdrawal it emerged that data from clinical trials had been 'fudged'. An article published in the prestigious Journal of the American Medical Association recently revealed how this was done.

The conclusion for one study was that the drug was ‘well tolerated’; in fact the study’s raw data (which emerged during a court case) showed that twice as many people who took Vioxx died compared with the placebo.

And yet the study was used to promote the drug. It was also said that the company used ‘ghost-writing’ — paying top academics to put their names to favourable articles written by the drug company’s employees — to make Vioxx appear more effective.

‘The manipulation is disgusting,’ wrote the journal editor. (The manufacturer, Merck, has since dismissed the journal’s article as ‘false and misleading’.)

Given drug companies’ readiness to produce evidence that puts their products in a good light, it seems curious our drug watchdog should be willing to rely so heavily on them. And yet it continued to do so.

Take the case of Strattera, the drug used to treat hyperactivity in children.

There have been concerns it could cause psychosis — hallucinations, delusional thinking, or mania — in some children. Three years ago, the American drug watchdog, the Food and Drug Administration, highlighted the risks and, as a result, the warnings on the

label were changed. Instead of issuing a similar warning, the UK drug watchdog contacted Eli Lilly and asked them to review the evidence.

The drug firm came to a rather different conclusion, including doubting whether the reports of hallucinations in children were genuine.

‘Asking a drug company to review its own product is crazy, but it goes on quite a lot,’ says Andrew Herxheimer, editor of the Drug And Therapeutics Bulletin, and emeritus fellow of the Cochrane Centre (the organisation which gathers and assesses information about drug effectiveness and safety).

‘The problem is that the MHRA has always been far too trusting of drug companies. They almost never look at the raw data from trials when licensing drugs. Instead, they rely on summaries provided by the companies.’

Critics also say our drug watchdog isn’t robust enough about investigating drugs when problems come up. Last year, a study linked the diabetes drug Avandia to a raised risk of heart problems.

The drug watchdog’s reaction has been to point out that the link between the drug and heart disease has been in the list of side effects since the drug was first licensed.

‘That kind of advice is just useless,’ says Dr Aubrey Blumsohn, a researcher at Sheffield University until he became embroiled in a very public dispute with a drug company when it refused to allow him to see all the data from his research.

‘It doesn’t tell you anything useful about who is likely to get it, how high the risk is and so on.’

So is our drug watchdog really up to the business of protecting us?

Labour MP Paul Flynn believes it's not. He was one of the members of the Parliamentary committee which produced a report on pharmaceutical drugs and the drug watchdog in 2005, just after Vioxx had been withdrawn.

It called for investigations; it said the drug watchdog 'lacked competence', and criticised it for a 'passive process of drug surveillance'.

Professor Kent Woods, the chief executive of the drug watchdog, says at the time it was still a new agency. 'It had only been set up in

2004. Much of the criticism was directed at the UK's previous medicine sanctioning body, the Medicine's Control Agency.

'Today's MHRA is very different; we have been much expanded and have new responsibilities.'

Evidence of this more robust approach is seen in the Agency's lengthy investigation into the way evidence about Seroxat had been concealed.

This included pursuing interviews with employees of GlaxoSmithKline. The MHRA made more than 100 requests, but not one employee would talk.

So how confident is Professor Woods now that the Agency won't be lied to again?

'There have been positive gains from the exercise on both sides,' he says. 'We have learnt there needs to be greater clarity about the laws — and loopholes will be closed.'

Indeed, in March ministers announced that the laws requiring drug firms to release data from clinical trials would be tightened.

As for the question of whether we can be sure we're told the truth about a drug's safety, he says: 'You are certainly being told the truth. But it is important to realise there aren't any safe medicines.'

'There is always the potential for adverse side effects in a minority of patients. It is a matter of balancing risks and benefits. Our job is to give people the most up-to-date information about that balance.'

Paul Flynn is not convinced that the MHRA is doing enough. 'For too long the British authorities have just followed the American lead in issuing warnings about drug safety.'

'When there is clear evidence that data about a drug has been concealed, there is never a full investigation. Other regulators like Ofwat fine companies for failing to meet targets and giving false information.'

'The MHRA never does.'

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