For years the Government has known Seroxat anti-depressants can be dangerous. When one expert was asked to hide the truth, he quit. Here he reveals why

by RICHARD BROOK

CHIEF EXECUTIVE OF MIND

LAST week I resigned from the Government's watchdog on anti-depressants after it tried to cover up its own ten-year failure to identify serious side-effects of the –controversial drug Seroxat.

The Medicines and Healthcare Products Regulation Agency found from information that had been in its possession for more than a decade that high doses of the anti-depressant can lead to aggression and thoughts of suicide.

But instead of revealing the truth to the 17,000 people taking high doses and the other half-million Britons on a safer dose, the MHRA sat on its findings.

Astonishingly, I was actually threatened with legal action by Professor Kent Woods, chief executive of the MHRA, if I revealed this.

Mind, the mental health charity, has been tracking Seroxat for a decade and found it to be the most problematic anti-depressant. Side-effects include nervousness, aggression, irrational thoughts and, in some cases, feelings of suicide.

Although Seroxat has been effective for thousands suffering from severe depression, there are many who blame tragic events, including murders and suicide, on it.

Last year, BBC's Panorama showed that — despite denials from the manufacturer — people can get hooked on Seroxat and suffer terrible withdrawal symptoms when trying to come off it.

The drug's manufacturer, GlaxoSmithKline, has sought to play down its side-effects, denying until last year that it could be addictive.

Mind — along with dozens of people suffering the drug's side-effects — held a demonstration last June outside MHRA's headquarters in London, calling for the drug regulator to take action.

BY THE end of that week, I had been invited to join its expert panel to look at the effectiveness of the so-called 'happy pills', selective serotonin re-uptake inhibitors (SSRIs) — drugs prescribed to tackle depression, anxiety and other psychological problems. They include Prozac and Seroxat.

I hoped we could issue clear guidance to doctors on how to prescribe SSRIs safely. But my colleagues at the regulator, all from the medical establishment — doctors, academics and psychiatrists — had different ideas.

They appeared more interested in putting their reputations, and those of drugs companies, before the safety of patients.

In October, the MHRA reviewed data from the earliest trials of Seroxat. The information was supplied by GlaxoSmithKline in the late Eighties, and it was the MHRA's responsibility to analyse the statistics to inform its decisions.

In four reviews of these statistics over ten years, the regulator had failed to pick up the vital information that any dose of Seroxat above 20mg a day doesn't work any better but significantly increases the side-effects. Some 17,000 people were prescribed more than 20mg of Seroxat last year.

But the panel wanted to kick the findings into the long grass, passing it to European regulators. It would take months. In that time, hundreds would be prescribed dangerous levels of Seroxat.

It was then that Professor Woods made clear I faced prosecution if I revealed what the regulator had found, citing the need to protect the 'commercial confidentiality' of drugs firms.

On the MHRA website, Professor Woods defends the watchdog, saying its advice is backed by clinical data.

A few days later, I went to see Health Minister Lord Warner to tell him of my concerns. He said he would speak to the regulator, and soon after they reluctantly published the findings.

Their statement 'reminded' doctors not to prescribe more than 20mg, as if it had been common practice all along. Previously, the MHRA's recommended 'safe' dose was 20mg to 50mg a day.

I resigned. If a regulator will not own up to its mistakes, who knows if data about other drugs has not also been overlooked, with potentially fatal results.

Regulators are supposed to be a stop-check for safety issues. But at the MHRA, many of the people who work there or advise it have ties to drugs firms. Some have shares in the companies, research departments funded by them or receive fees for advice.

The only protection is a musical chairs system where you leave the room if you have an interest in the drug being discussed or its manufacturer, or you can stay but not vote.

THERE is an urgent need for an independent inquiry into the MHRA. The Government must also change its culture of secrecy.

Seroxat is far too extensively prescribed, especially for mild and moderate depression. But anti-depressants — including SSRIs — do work, and can prevent suicides in severe cases. However, they are not wonder drugs.

GPs should clearly outline all the options to sufferers and anti-depressants shouldn't be the automatic answer. If vital information such as that the MHRA tried to cover up is not released, these decisions cannot be fully informed.

Likewise, patients on Seroxat concerned by my findings should consult their doctor before adjusting their medication.

Mind does a lot of work with the Government, and we have a good relationship. But I am very concerned that I was put under such pressure not to reveal the regulator's findings.

My only hope in speaking out is that the regulator will change. It must listen to people suffering negative side-effects of drugs and to be more accountable to patients rather than to pharmaceutical companies.

Dr Alastair Benbow, European medical director at GlaxoSmithKline, says: 'We remain fully confident in the effectiveness of Seroxat, an important medicine that has helped many millions around the world lead fuller lives.'

■ *RICHARD BROOK is chief executive of Mind.*

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