

## **Seroxat User Group Meeting**

**18<sup>th</sup> June 2007. 11.00a.m.**

### **Present:**

Lord Hunt

Members of MHRA: Sarah Wark, Paul Brice, Michael Deats, Emma Hall

Janice and John Simmons

Patricia Martin (Solicitor at Field Martin Solicitors, working on pro-bono basis)

Paul Duckett (Psychologist at Manchester University, working on pro-bono basis)

Victoria Conway (on behalf of Jonathan Djanogly MP)

### **The Problem:**

Hits to the Seroxat User Group Website:

56,037 in 2005

Just over 86,000 in 2006

36,736 to date 2007

### **GPs require better training**

Necessary help not available from GPs as they are unaware of severity of withdrawal symptoms.

Difficult to withdraw from drugs.

GPs need more training in mental health and the drugs they prescribe.

GPs need to be more aware of the negative effects. Listen to those who have suffered them and can describe severity.

MHRA send information to GPs but is it absorbed? No way of checking that they have read and understood.

Some GPs unaware of Yellow Card System.

Two questions:

Is information correct and reliable?

Is information read?

## **Issues**

MHRA is funded by the pharmaceutical industry, therefore their research cannot be seen to be truly independent/transparant.

What has been done to implement recommendations of House of Commons Health Committee 2005?

LH confirmed that notwithstanding the Select Committee recommendation, the 2 roles of the Health Ministry – safeguarding the public and promoting the pharma industry – be split. This is not going to happen.

LH promised to write and explain why he believes it is in the interest of the public for the Health Ministry to retain its sponsorship/promotional role rather than seeing this function devolved to the Dept. of Trade and Industry.

What is being carried out to review drug licencing, which should be continuous?

## **Influence of pharmaceutical companies**

Pharmaceutical companies sponsor academia. Therefore they can control what is released.

GSK have been known to use ghost writers on many medical research documents.

There have been issues already with GSK and problems concerning corporate social responsibility.

LH endorsed the need for transparency and publicity of results.

LH noted that there was a move away from self-regulation to proportionate regulation in the UK.

## **Effects of Seroxat**

Can cause violence, self harm, vivid hallucinatory dreams, great emotional turmoil etc.

GPs cannot test for clinical depression in the same way they can test for diabetes, therefore many people may be prescribed SSRIs unnecessarily.

Patients with normal serotonin levels prescribed SSRIs could experience serotonin syndrome/akathisia.

### **Coroners**

The same information that is sent to GPs should also be made available to Coroners. Enabling Inquest Reports on whether the person was taking SSRI medication, whether the dose was changed etc. This information to be collated in the same way as Yellow Card Reports on adverse reactions.

### **Support Groups**

Need for support groups in various strategic locations throughout the country. Possible meetings at doctors' surgeries once a month.

Self help groups have been proven to be more useful than seeing a GP.

Difficult to fund this work.

LH will look into this, but there must be some sort of formal structure to the Seroxat User Group in order to qualify for funding.

### **Following the Meeting Lord Hunt Promised to:**

Look into the possibility of funding support groups.

Write a comprehensive note as to why the Select Committee's recommendations have not been implemented.

Raise the issue relating to Coroners with colleagues at the Justice Ministry.

LH did not want to comment on the criminal investigation presently being undertaken into GSK, but said the finding would be made public.

Seroxat User Group Meeting with Lord Hunt and Members of the MHRA 18<sup>th</sup> June 2007

JS began by talking about the large number of hits to the group website (87,000 in 2006) and said this demonstrates that there is a real need for people to receive help. She continued that GP's do not recognise the severity of side effects/adverse reactions/withdrawal symptoms and require more training/information. They do not listen to the patient.

PM stated that patients with no history of depression or other psychiatric symptoms have been prescribed Seroxat/SSRIs for ailments and have experienced suicidal thoughts and some have committed suicide.

LH suggest that perhaps part of the MHRAs work on this could be to encourage engagement with GPs.

SW said that information has been sent to GPs via the CSM's public health link. She added that the CSM working group had led to information being updated.

JS went on to ask why the MHRA is funded by the pharma industry and whether this was a conflict of interest.

LH assured her that the MHRA is an independent body.

PM asked what has been done to implement the recommendations of the Health Select Committee in 2005 and spoke of the need for transparency.

SW said that CSM was a new independent scientific committee and that none of the commissioners have any interests in the pharmaceutical industry, whereas previously they could have interests but had to declare them. She added that there are also lay members on every expert working group.

PM asked what is being done to review the licencing of Seroxat.

LH assured her that if new evidence were to come to light it would be reviewed. He also spoke of the fact that the MHRA is regarded as one of the top regulators in the world and that the MHRAs current advice on Seroxat has been endorsed by other member states and also recently by the FDA.

SW said they they are working on promoting the patient reporting scheme so that patients have more of a voice.

JS presented LH with a pack of emails the User Group has received and SW and LH said these would be looked at.

128 emails taken at random – 98 mention suicide or self harm.

JS said the Government should be concerned at the cost of this problem. GPs prescribe to easily and unnecessarily.

Many patients had lost their jobs, homes, and had suffered significant financial losses, and some had lost their lives. Many are unable to work due to the severity of withdrawal symptoms.

PD said he appreciated what the MHRA was doing for patient voice but that he was still concerned that the industry has too much power in what research is being conducted in the country.

LH said that he would endorse openness and transparency, but that there was always going to be a certain amount of partnership with industry. He added that he felt one of the reasons that industry to invest in R&D in this country is that there is such a strong regulatory approach.

JS said that the EWG had recommended that SSRIs be used only for severe depression but that only 3% of users were severely depressed.

LH asked how the User Group would try to ensure appropriate prescribing.

JS suggested more training and information would help. GPs should consider other reasons for depression such as thyroid problems, vitamin deficiencies, hormonal problems etc before prescribing.

PD stated that he felt the problem of violence caused by SSRIs was not recognised.

LH said if the SUG could provide evidence of this it would be considered.

JS also asked if the letters of information that are sent to GPs, such as the GSK letter of May 2006, are also sent to Coroners, as we will never know the true suicide figures until Coroners recognise the SSRI suicide risks.

LH said he thought this a good question. Said that with all the reforms taking place as a result of the Shipman enquiry, they were trying to encourage a closer relationship between Coroners and professionals. He said he would try to find out the answer to her specific question.

JS continued that the User Group does not receive any funding and they would welcome some government support (non pharma).

LH said he would look into this.

JS asked about the current investigation by the MHRA into GSK considering it has been ongoing for over 3 years.

LH said it would not be appropriate for him to go into detail but that he understands from Paul Brice that an outcome should be forthcoming in the very near future.

PB stated that the outcome will definitely be released to the public.

LH summarised by saying that he would look into the funding of support groups, the information issued on Seroxat, recommendations of the Select Committee and also the role of GPs.