

Meeting with EMEA on Monday 19th April 2004 at 11.00a.m. until 1.00p.m.
7 Westferry Circus
Canary Wharf
London E14 4HB

Meeting arranged by Janice Simmons of
www.seroxatusergroup.org.uk.

The European Agency for the Evaluation of Medicinal Products (EMEA) is a decentralised body of the European Union. Its headquarters have been in London since 1995.

<http://www.emea.eu.int/htms/aboutus/emeaoverview.htm>

The EMEA work in conjunction with the CPMP) committee responsible for medicines for human use (CPMP) The meeting was arranged because the EMEA were holding a review into Paroxetine based medicines.

SUG Members attending the meeting:

Janice & John Simmons (SUG)

John Janyga (SUG)

Derek Scott (OSSG) - <http://www.seroxatusergroup.co.uk>

Faye & Peter Elliott (OSSG)

We were kindly accompanied by:

Dr Andrew Herxheimer

Millie Kieve (Chair of APRIL)

Richard Brook (CEO of MIND)

Members of EMEA/CPMP were:

Dr. Daniel Brasseur Chairman of CPMP

Dr Panos Tsintis Head of Sector Pharmacovigilance

Dr. Frances Rotblat UK member based as MHRA London

Dr Barbara van Zwieten-Boot

Johan Lindberg

Anthony Humphries MHRA

We arrived at Canary Wharf at 10.30a.m. Met up with Andrew Herxheimer, John Janyga, and Richard Brook. We all reported to ground floor reception desk where we were greeted by utter chaos because nobody seemed to be able to read or speak English. We were eventually allowed to go up to 4th floor where we met up with Millie. Dr Herxheimer asked Richard Brook what the relationship with the EMEA and Seroxat was and Richard said that Seroxat is EU licensed. So the UK cannot change the licence without Europe.

We were introduced to all members present from EMEA who quickly said their name we were therefore unable to remember who was who. The environment did not have a very friendly feel to it. I believe most of us felt very uneasy and it seemed that all EMEA members were bored before it began. In fact we were given a very cold welcome.

We were taken to a large boardroom at approximately 11.10. by Annabella, the Secretary of Dr Panos Tsintis. Each desk had a microphone in front of it and we had to switch these on or off every time we wished to speak. Nobody smiled as we entered the room and it felt more like a court in judgement than a meeting.

Dr Brasseur declared the meeting open by stating that they wished to be 'transparent' and said it was a very unusual procedure to have a meeting with groups such as SUG. He went on to say that as he was led to believe we may have information to give them that may assist them in their review, which they had not seen before. He stated that they would be willing to listen to us and we now had the floor.

Janice Simmons then introduced everyone present from the SUG/OSSG and their guests.

Derek Scott of OSSG (Online Seroxat Support Group) began by offering Dr Brasseur documents which were from the internal files of GSK asking if they had seen these before. These documents stated that in trials Seroxat showed no benefits to under 18's. They enquired as to whether the documents were those that were printed in the Canadian Journal. Derek said yes and they said they already knew about this documentation but could Derek summarise it for them.

Richard Brook said the document shows that 5 years ago GSK knew the results of trials and made a decision not to make it public for commercial reasons.

Derek asked "What is the EMEA going to do about this?" He was told in no uncertain terms that the purpose of the discussion today is to add any information to the EMEA review.

Janice Simmons asked if they were interested in personal experiences - is this important for your review. Janice offered to obtain questionnaires from all the Seroxat Group if necessary and hand them in to the EMEA. She was told that personal experiences were important to them but there would probably not be enough time to do this. Janice also stated that GP's were prescribing antidepressants and then had no idea how to wean patients off properly. She said that most GP's informed their patients to wean off by taking 1 x tablet every other day for 2 weeks and then stop. Janice said this did not work for many, many people and GP's mistook this for recurring depression instead of withdrawal symptoms.

John Janyga explained that he had made a suicide attempt when initially taking Seroxat and how quickly the feelings occurred. He stated that he had lost 6 years of his life and is very concerned about the thousands of people who are suffering.

Janice said the group represents over 10,000 people all of whom have suffered adverse effects/withdrawal symptoms of Seroxat. She said her husband John had been on Seroxat since 1991, had made a suicide attempt when initially prescribed the drug and was unable to get off it after 5 attempts. His 1st wife had committed suicide on the 3rd attempt, within 3 weeks of being prescribed Prozac. Janice stated that considering the size of the group present today they had first hand knowledge of 3 suicide attempts - what did that tell them? Janice also stated that she had been offered the drugs 4 times since her mothers death 2 years ago because she was feeling very sad, but she said she refused the drugs as it was part of life and the pain would ease in time.

John Janyga then enquired about safety concerns and Seroxat. He quoted the 'Mission Statement' from the EMEA web site about the high level of protection for the public and in light of the evidence that they had allowed an unsafe drug to be licensed how did they now judge their mission statement?

The answer to John was that they will not allude to the safety of the drug until after the review which involves many countries.

Tony Humphries of EMEA told us that in a month's time there would be 25 countries represented by the EMEA.

We were told that they were only interested in scientific data, several times, but when asked what they were considering in their review they would not or could not tell us.

Dr Tsintis told us that GSK and other drug companies give their opinions and information regarding their drugs to the EMEA on a regular basis.

Andrew Herxheimer asked if they could explain how the review is organised and what sources of information they have. If you tell us what you are doing then we can ask you the relevant questions.

There were no direct answers to Andrew's question.

We were then told again that it was a very rare event for them to listen to patient groups by Dr Brasseur.

Richard Brook enquired as to where they gained their sources of information for their review. Had they seen the FDA reports recently? Are they looking at SSRI's in general or just Paroxetine? He told them that consumer reporting was very important did they agree, Have you seen reports by Dr Healy. Have they seen BMJ article regarding random clinical trials which are suspect. Pharmacological working of Seroxat. Legislation. Consumer Protection is important.

Dr Tsintis stated that drug companies have to report any adverse effects to EMEA within weeks/months of drug being released. Richard Brook stated that it took two and a half years before GSK presented information that their drug was dangerous for children how did they get away with that. Look of surprise on his face/ I cannot answer that one. So he didn't.

Dr Brasseur shrugged his shoulders and said "the obligation is there!" and looked very helpless.

Faye Elliott spoke about her support group and how she had been affected by the drug. She stated that she had lost 9 years of her life to the drug. She stated that she had successfully withdrawn from the drug over the course of 1 year but only felt 50% of the person she was. She suffered from bad memory and lack of concentration.

Janice Simmons stated that the MHRA were found to have committee members on their review who had shares in GSK did they know whether their committee members had financial interests. Dr Brasseur said no they did not, as far as he knew. Janice said well Ian Hudson is a committee member and he has shares in GSK and used to work for them. Dr Frances Rotblat, member of EMEA jumped to his defence immediately, stating that he was instructed to leave the room if and when Seroxat was discussed. Janice stated that she did not think it could be a fair and just review with this going on.

Andrew stated that in the last 4-5 months he had personally been requested to write reports for people who have committed crimes during emotional turmoil while on these drugs. He said that none of these cases ever get into pharmacovigilance reports and he thinks this is the tip of the iceberg.

Andrew then held up two issues of "The Journal of Risk and Safety in Medicine" and asked if they had ever seen this journal. Did they have a library and were these journals in it? Nobody from EMEA seemed very sure about this.

Anthony Humphries eventually stated that yes, they did have a library but they were not aware of the journals. Dr Brasseur asked Andrew to give them the journals. He refused stating that he would send them copies.

Janice Simmons said that as the trials for Seroxat were only carried out for 1 year nobody knows what happens to people who have been on the drugs long term. She asked if they were concerned about this. All members of EMEA were unsure whether this was true. One said no it must be longer. Another said it was 3 years. Janice stated that she had heard the facts from Dr Benbow of GSK and it was definitely 1 year. They agreed that if it was a fact from GSK it must be true. There were a lot of notes written by EMEA regarding this item. Janice said she would like to see help for these people as nobody seemed to care.

Janice asked if they knew why GSK had taken out the statement 'this drug is not addictive' from their PIL last year. They could not answer this as they did not seem to know it had been changed. Janice said that Dr Benbow said the reason they had removed the statement was because the public did not understand it.

Janice stated that organisations such as EMEA, MHRA. GP's had had it their own way for far too long and now we the general public are on your tails. We want to know what is going on and what has been hidden behind the curtains over the years, we have the right to know as it is our lives that you are messing with. Anthony Humphries of EMEA asked if he could reply on this one. He said he totally agreed with Janice and it was a good thing that the general public could have access to this information as it had been a closed shop for far too long. But some information would still remain secret unfortunately.

He referred to pre 1995 licences which were impenetrable around EU and there was no way of finding out anything about licensing or why drug licences were suspended. Companies could file and withdraw information but now if the committee says a drug is not good the company must explain.

Richard Brook asked if the EMEA would tell us when the review was to be concluded. They said they could not tell us but there was a legal time frame and it would be concluded very soon.

Richard Brook asked if they had looked at the FDA hearings and how people in authority had changed their minds after one day of listening to people's experiences. He also said there is some evidence as to why Seroxat works the way it does although it may not yet have been peer reviewed - it is cutting edge stuff. He also mentioned the class action in the UK to which some of the EMEA members looked very puzzled. Richard Brook also stated that when he was on the MHRA review committee the MHRA reports of the EU work was quite disturbing.

Richard Brook said that he had met with the German regulator at the FDA meeting and he had informed Richard that he would vote against, whatever the evidence, due to generic commercial interests.

Andrew Herxheimer stated that reports from patients were totally different from Yellow Card Reports completed by doctors. He said suicidal ideation where a doctor is the judge will probably be linked to depression and not the drug and therefore would not be reported.

John Janyga added that in his own experience the speed at which the suicidal ideation took over was very sudden and happened within a very short space of time. He said it is very important that this should be looked at in detail as it is a very serious subject. Survival instinct is taken from you and he said he could not emphasize this strongly enough how quickly it takes over.

Richard Brook stated that in the USA GlaxoSmithKline are settling out of court suicide claims for 4-5million dollars a claim and not contesting in court due to the belief that they would lose the cases in court.

John Janyga said that he could not help but get the feeling that transparency and openness is a little distant and that we had come along today for this meeting in the hopes of everybody being just that. John also stated that the public's trust in the government regulatory system is not confident at the moment.

Dr Brasseur said the purpose is to find a better way out and asked 'You say you are not trusting?' He then said the point is to take the right decision not just the popular decision. He said 'we have a legal framework and there are limitations set. We are doing our best.'

John Janyga said that he could not believe the standard of GP prescribing over the past 5 years. There has been a dramatic increase in prescribing due to other services not being available. He said that mental health services, resources and funding had been appalling for the last 30 years.

Dr Barbara van Zwieten-Boot stated 'you should realise who we are as an organisation, we cannot instruct doctors on how to prescribe.'

Dr Frances Rotblat said 'we are frustrated about what we can/cannot do. The UK are behind and are limited by law in what they can do'.

Millie Kieve stated 'You can't regulate what the doctor prescribes but you can regulate what influences the doctor to prescribe. She then went on to say 'is the working party on PIL's aware that if working with patient groups that are funded by pharmaceutical companies or even set up by them, they may not get a true picture of the drugs adverse effects?' Dr Brasseur concluded the meeting by saying he is aware that the system is far from perfect and the more countries that are involved in the EU the more challenging it becomes.

Janice Simmons then thanked the Chairman, Dr Brasseur for allowing us to attend the meeting with them and we all left the room.