PEAG minutes: 12th January 2011

Item: Fluoxetine and Persistent Sexual Dysfunction

The EAG was presented with the data from a cumulative review of all data relevant to the issue of persistent post SSRI sexual dysfunction that had been submitted by the MAH and its advice sought on the implications for the product information.

The EAG noted that the available was not particularly robust as it consisted of confounded spontaneous case reports, non validated reports from the Internet and clinical trial data from relatively small studies on persistence of effect of several SSRIs on premature ejaculation and some preclinical evidence of an effect of SSRIs on the reproductive system in rats. The EAG commented that the data would appear to be similar for several of the members of the SSRI class with even more cases recorded in the yellow card database of sexual dysfunction with paroxetine.

The EAG considered that a major hurdle to the further assessment of the issue is the lack of a clear definition for persistent post SSRI sexual dysfunction. It was proposed that the MAH should be requested to gather expert opinion to aim to formalise such a definition .

The EAG also recommended that the MAH should be requested to explore what further studies might be appropriate. A comparison of the effects of CBT and SSRIs on sexual function outcomes was suggested to eliminate the confounding of the underlying condition.

The EAG concluded that there was insufficient evidence to warrant an update to the fluoxetine product information, particularly given that without frequency or an idea of the persistence or permanence of the effect, any proposed labelling would not be helpful.