RE: The Extraordinary meeting of the European Medicines Agency (EMEA) scientific committee, the Committee for Medicinal Products for Human use (CHMP) held on 8 December 2004 on selective serotonin re-uptake inhibitors (SSRIs) and serotonin and norepinephrine re-uptake inhibitors (SNRIs) and their use in children and adolescents.

The Medicines Authority (MA) participated at the latest extraordinary meeting of the Committee for Human Medicinal Products (CHMP) which is the Scientific Committee of the European Medicines Authority (EMEA), and is of the opinion that the advice provided for the SSRI and related anti-depressants is opportune and appropriate, with a positive benefit/risk profile in adults. However after a consensus agreed at the extraordinary meeting on the 8 December 2004 of the CHMP it has been decided that the Summary of Product Characteristics for Paroxetine needs to be modified to include safety measures on the use of Paroxetine in children and adolescents. Moreover, after review of the outcome of the UK's MHRA position on SSRI's issued of 6 December 2004, the MA agrees with the conclusions adopted by the CHMP, namely to have a class review on these medicines and their use in children and adolescents. The MA will await the outcome of the EU review and the Pharmacovigilance Working Party (PhWP) before implementing any further changes **(see press release by EMEA).**

In this connection the MA has taken the following measures:

1. **A "Dear Doctor" letter circulated to all doctors**
2. Press Release in the local media in **English** and **Maltese.**

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