

## **PLAN B<sup>a</sup> SAFETY REVIEW**

An important component of the evaluation of a product for switch from prescription to over the counter (OTC) status is the acceptability of its safety profile and whether the benefits clearly outweigh the known risks associated with the product. This section summarizes the safety review conducted for the assessment of Plan B for OTC marketing. The safety review contains the following components:

### **Subsection A – Medical Officer Review**

1. Background
2. Safety Data that were the Basis of Approval of Plan B for Marketing as a Prescription Drug Product.
3. Post-Marketing Safety and Distribution
4. Evaluation of Misuse and Abuse Potential
5. Contraindication Assessment
6. Safety of Advanced Provision and Pharmacy Provision
7. Overall Safety Conclusions
8. Labeling Recommendations Based on this Safety Review
9. Efficacy Impact of Timing of Plan B Doses

### **Subsection B – Office of Drug Safety, Division of Drug Risk Evaluation Review**

### **Subsection C – Review of Teratogenic Risk of Hormonal Products for Contraception**