

Minimum requirements for medical abortion package inserts

The International Planned Parenthood Federation (IPPF) and Gynuity Health Projects analysed package inserts for medical abortion commodities from 20 countries and found numerous inaccuracies and inconsistencies.* This simple checklist presents the minimum requirements to ensure a quality package insert, and should be used to guide insert reviews and improvements.

Regimens should reflect the current evidence

Inserts should be reviewed and revised to reflect changes in evidence-based guidance on medical abortion regimens, eligibility and contraindications. Regimens and eligibility must reflect scientific evidence and not cultural or social biases.



Clinical information should match stated indication/s

Inserts should be carefully checked after each revision to make sure the clinical information is aligned to the product's stated indication/s. For example, a product labelled for medical abortion should not list pregnancy as a contraindication.



Carefully check translations

It is essential to have inserts translated by a professional and checked by a native speaker with medical abortion knowledge. Translations should not lead to confusing phrases or inaccurate information.



Clearly state date of last revision

Having a date of last revision is essential. This will help providers and users to understand the extent to which the latest guidance has been included in the insert. It can also provide justification for review and renewal of inserts.



Avoid contradictory information

Inserts should be checked for contradictions and revised accordingly. For example, if an insert says that the product should not be used in lactating women, it should not then offer a protocol for how to use during lactation.



Clearly state accurate storage instructions

Inserts should state accurate storage instructions to ensure product quality is not compromised. Misoprostol and combipacks should be kept away from moisture, and stored below 25°C. Mifepristone should be stored below 30°C.

