Statens legemiddelverk

Checklist for the development of educational material and educational material for pregnancy prevention programs

- ☐ The material **contains all the parts** described in the RMP part V* (patient card, material for healthcare professionals etc.).
- ☐ Each part contains **only the required information** from RMA part V* (key messages).
- ☐ The **language** must be clear and comprehensible norwegian and adjusted to relevant target groups.
- ☐ **Pictures and illustrations** shall only be used to increase understanding of key messages.
- ☐ Material shall not **contain colour and graphics** that are commercially related.
- ☐ The **company logo** shall only be used one place in each element.
- ☐ There should not be a space for **prescriber/patient signatures**, unless this is decided by EMA.
- ☐ Material shall contain a **black triangle** in one place on all documents when the drug is on EMA's list of medicines under additional monitoring (except for patient cards).
- ☐ Text concerning **reporting of adverse drug reactions** to the Norwegian Medicines Agency can be found on www.legemiddelverket.no/english/pharmacovigilance/educational-material-guidance-for-submission-and-distribution
- ☐ **Version number** must be visible on all material.
- ☐ Use the **safety information logo** from NoMA on material and possibly on cover letter.
- ☐ It should be stated in the material **where the educational material can be found online** (Felleskatalogen).
- ☐ MAH should enclose a **cover letter** if relevant.

*For products in central procedure requirements are also given in Annex IID in the summary of product characteristics (SmPC)