Norwegian Medical Products Agency

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.).
- ☐ The material does not contain unnecessary text that dilutes the message.
- ☐ The language is comprehensible Norwegian and adjusted to relevant target groups.
- ☐ Pictures and illustrations shall only be used to increase understanding.
- ☐ Material shall not contain colour and graphics that are commercially related.
- ☐ As a general rule, company logos should be avoided. If included, it must be justified and only appear one place in each material.
- ☐ Title must include the product name with the active ingredient name in parentheses. The product name should be used as few times as possible in the rest of the material.
- ☐ There should not be a space for prescriber/patient signatures, unless 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.
- ☐ Standard text concerning reporting of adverse drug reactions to the NOMA can be found on guidance webpage.
- ☐ Version number and submission date in the format <month><year> should be included on all pages if possible. At a minimum, it must be included on the first and/or last page.
- ☐ Use the safety information logo from NOMA on material and any cover letter.
- ☐ It should be stated in the material where the educational material can be found online (Felleskatalogen, MAH webpage etc.).
- ☐ Contact information to MAH, e.g., email or phone number.
- ☐ If the material is to be distributed: A cover letter explaining the purpose of (or any changes to) the educational material.

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