

European Paediatric Formulary

Criteria for maintenance and vigilance of monographs

It is essential to re-evaluate all monographs published in the European Paediatric Formulary to keep them up-to-date with current clinical, scientific and regulatory developments.

Active monitoring by the group

The following should be monitored regularly and revision or suppression of a published monograph considered:

- EMA PRAC recommendations concerning active substances,
- new European guidelines on excipients,
- authorisation of age-appropriate dosage form via centralised procedure.

Follow-up and evaluation of information received

A revision or suppression should be considered when information regarding the following cases is received:

- safety signals other than from EMA PRAC,
- quality issues,
- New drugs for first-line treatment marketed,
- Authorisation of age-appropriate dosage form, e.g. via national or decentralised procedures,
- new formulations,
- new evidence-based clinical use,
- follow-up from questions received by the EDQM.

Stakeholders may request changes based on information known to them (e.g. published literature, changes in clinical practice).

Periodical re-evaluation

All monographs should be reviewed at the latest after 5 years.

A periodical re-evaluation should include

- a check, if current clinical/therapeutic criteria for inclusion of a monograph in the formulary are still met.

Criteria for inclusion in the formulary may change in the future. Older monographs need to be updated in view of these changes. There may have been a change in the therapeutic guidelines, so that the recommended use (e.g. indication, type of use, age) of the product differs, a new first-line treatment may be available or the treatment of the disease has changed (e.g. inclusion of younger age groups).

- 1 - A check, if current quality criteria for inclusion are still met.
- 2 *State-of-the-art production, tests and assay of extemporaneous preparations may change.*
- 3 *Monographs published should keep track with these developments.*
- 4 - A review of relevant feedback on the monograph received by the EDQM.
- 5 - Looking for changes in other existing formularies that were used as basis for the elaboration.
- 6 - Checking in other formularies for changes that have been developed and would be of higher
- 7 quality.