

## ANNEX IV

### Elements to be submitted

1. A list of all the marketing authorisations affected by the notification or application.
2. A description of all the variations submitted, including:
  - (a) in the case of minor variations of type IA, the date of implementation for each variation described;
  - (b) in the case of minor variations of type IA which do not require immediate notification, a description of all minor variations of type IA made in the last 12 months to the terms of the concerned marketing authorisation(s) and which have not been already notified.
3. All necessary documents as listed in the guidelines referred to in point (b) of Article 4(1).
4. Where a variation leads to or is the consequence of other variations to the terms of the same marketing authorisation, a description of the relation between these variations.
5. In the case of variations to centralised marketing authorisations, the relevant fee provided for in Council Regulation (EC) No 297/95<sup>(1)</sup>.
6. In the case of variations to marketing authorisations granted by the competent authorities of Member States:
  - (a) a list of those Member States with an indication of the reference Member State if applicable;
  - (b) the relevant fees provided for in the applicable national rules in the Member States concerned.

---

**Status:** This is the original version (as it was originally adopted).

---

(1) OJ L 35, 15.2.1995, p. 1.