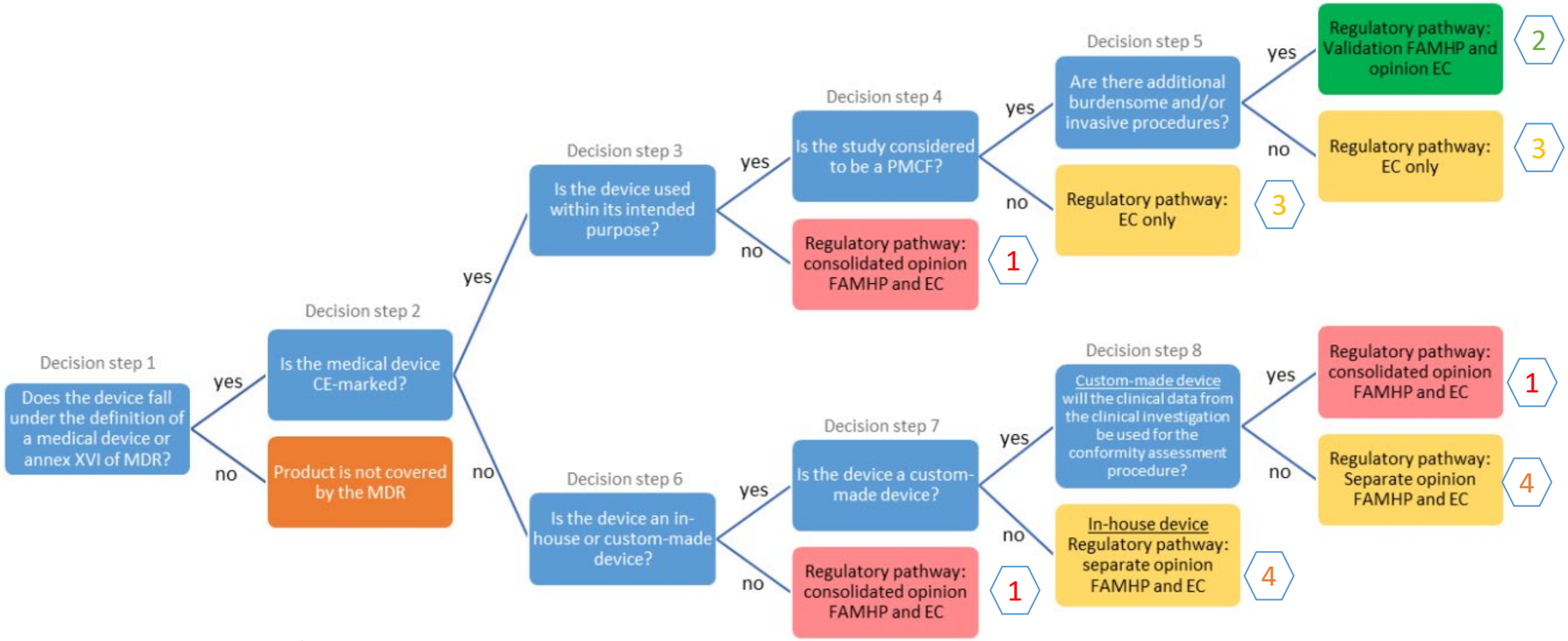
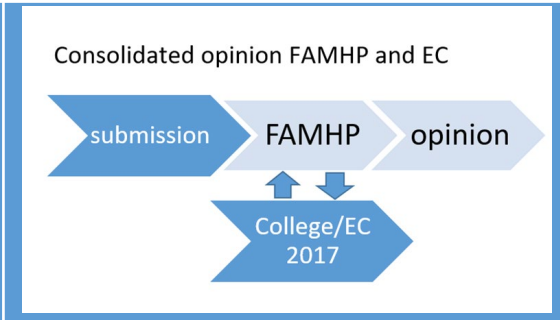
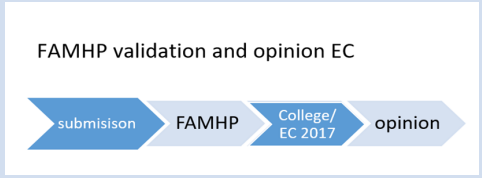
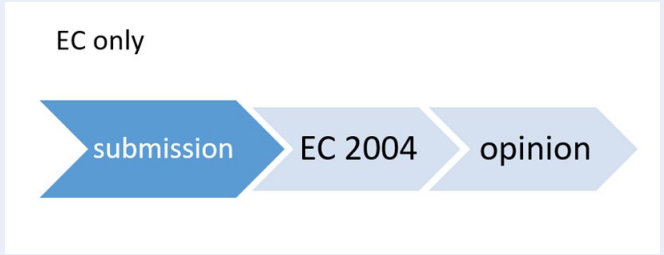
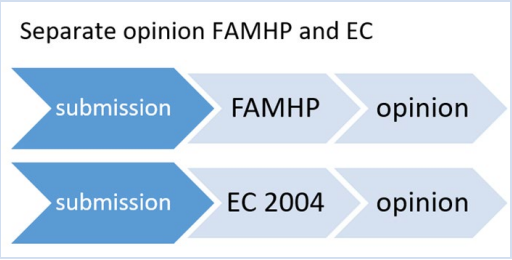


Figure 3. Decision tree

FAMHP guidance: https://www.famhp.be/sites/default/files/Guideline%20Submission%20of%20Clinical%20Investigation%20according%20to%20MDR_version%206.0_1.pdf

4 # flows

Flow 1: Consolidated opinion FAMHP and EC 2017 1		➔ clinical investigation **with CE-marked device** that is used **outside its intended purpose** ➔ clinical investigation **with device without CE marking** that is not a custom-made or in-house device ➔ clinical investigations involving **custom made devices** for which data **will be used for conformity assessment**
Flow 2: FAMHP validation and EC 2017 opinion 2		Post-Market Clinical Follow-up investigation (**PMCF**) **involving additional burdensome or invasive procedures**
Flow 3: EC 2004 only 3		➔ **PMCF without additional burdensome or invasive procedures** (Law on experiments) ➔ **other** clinical investigation **with CE-marked device** that is used for **its intended purpose** (RD on clinical investigations)
Flow 4: Separate opinion FAMHP and EC 2004 4		➔ clinical investigations involving **in-house medical devices** ➔ clinical investigations involving **custom made devices** for which data will **not be used for conformity assessment**