Reliance in MD regulation – MTIIR, IMoH

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Reliance in pre-market processes

- **Reliance is used for class I and II (IIa & IIb) products that have been registered and marketed in recognized countries**
- **Reliance pathways allow for shorter review time for:**
  - Market approval (MA)
  - Significant changes
  - Renewal and non-significant changes – declaration
- **The MD validity is registered in accordance with recognized country MA**
- **Labeling is approved in accordance with recognized country MA**

Reliance in post-market processes

- **In general, reliance is based on requirement for MA holder (MAH) to report of any incidents (e.g., FSN, FSCA, recall) that accord in a recognized country.**
- **Other PM Information sources:**
  - Reporting of local health organizations and patients
  - Public reporting of incidents from recognized countries
  - Specific RFIs from recognized countries

Key considerations with reliance

- **Multiple countries -> multiple regulatory schemes**
- **Requirements from MAH versus manufacturer**
- **Timing of reporting (initial signal or after full investigation)**


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