ESIP-MEDEV amendments
to the Revision of the EU general pharmaceutical legislation
Key messages

- **Robust and timely evidence generation:**
  - Demonstrate safety and efficacy by means of randomised controlled clinical trials with an active comparator using clinically meaningful endpoints;
  - Enforce binding quality and study design standards and increase transparency as to their methodology;
  - Define strict criteria and timeframes for post-authorisation safety and efficacy studies;
  - Enable conditional marketing authorisation and authorisation under exceptional circumstances only via the centralised procedure;
  - Introduce a timeframe (5 years) to complete studies within conditional marketing authorisation and authorisation under exceptional circumstances; revocation in case of non-compliance;
  - Restrict accelerated assessment procedures to products serving unmet medical needs;
  - Establish a database on on-going real-world data collection taking into account the ongoing work from DARWIN EU in combination with an obligation for marketing authorisation holders (MAH) to submit data, particularly for products with a conditional marketing authorisation (CMA).

- **Define data requirements** (study design, content, timeframe for evidence generation) **with HTA bodies and P&R authorities:** strengthen cooperation between decision-makers in order to ensure (1) that pre- and post-approval clinical trials are designed in such a way that data relevant for all stakeholders are generated (2) the highest possible level of evidence is ensured (3) and appropriate comparators are used.

- **Reinforce access and strengthen competition**:
  - Shorten regulatory protection periods (6+2+1);
  - Introduce an obligation to submit a P&R application across the EU27 for products addressing unmet medical and societal needs;
  - Shorten timeline (from three to two years) for ceasing marketing authorisation (i.e. sunset clause) for products addressing unmet medical and societal needs that are not placed on the market in all EU Member States, as well as for all products previously placed and later withdrawn from the market;
  - Expand the scope of the Bolar exemption and clarify its application;
  - Establish a database on the expiry of the respective, patent and SPCs protection periods;

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- Maintain flexibility for national competent authorities as to grant off-label use;
- Maintain the decentralised marketing authorisation and mutual recognition procedures for generics.

- **Introduce a harmonised and refined definition of unmet medical and societal needs** (life-threatening and seriously debilitating conditions) and establish an electronic database on unmet medical needs by the EMA, its respective committees and relevant stakeholders, to be regularly reviewed and updated.

- **Increase transparency** by publishing information on public funding received by MAH, ongoing post-authorisation efficacy studies, information on market launches, availability and justification for market launch delays, justification for the provision of conditional marketing authorisation and authorisation under exceptional circumstances.