Repurposing of medicines European Commission Expert Group on Safe and Timely Access to Medicines for Patients (STAMP)

Pharmaceutical Committee
11 July 2019

Health and Food Safety

Repurposing Framework - Aim

- Aim to provide a visible supportive framework to not-for-profit stakeholders who have the data and scientific rationale for a new indication, and who have the aim to see this new use on-label

Key principles (1)

- Promotes a process for facilitating data generation in accordance with regulatory standards, described as voluntary steps within the existing regulatory framework

- Elements of the framework cover only one possible scenario, some key milestones are not regulatory activities

- Applicable to both EMA and NCA activities, and driven by 'Champions'

Key principles (2)

- A Champion is not a pharmaceutical company, is able to coordinate, transparent, files initial request for scientific advice, provides information to MAH

- Core components: new indication in areas of public health benefit / Union interests, valid out of protection marketing authorisation exists

Champion engagement with regulators

- Main tools are scientific and regulatory advice
- Scientific advice instrumental to discuss the data package in relation to regulatory requirements – current and future development plans
- Outcome of advice can be made available to marketing authorisation holders

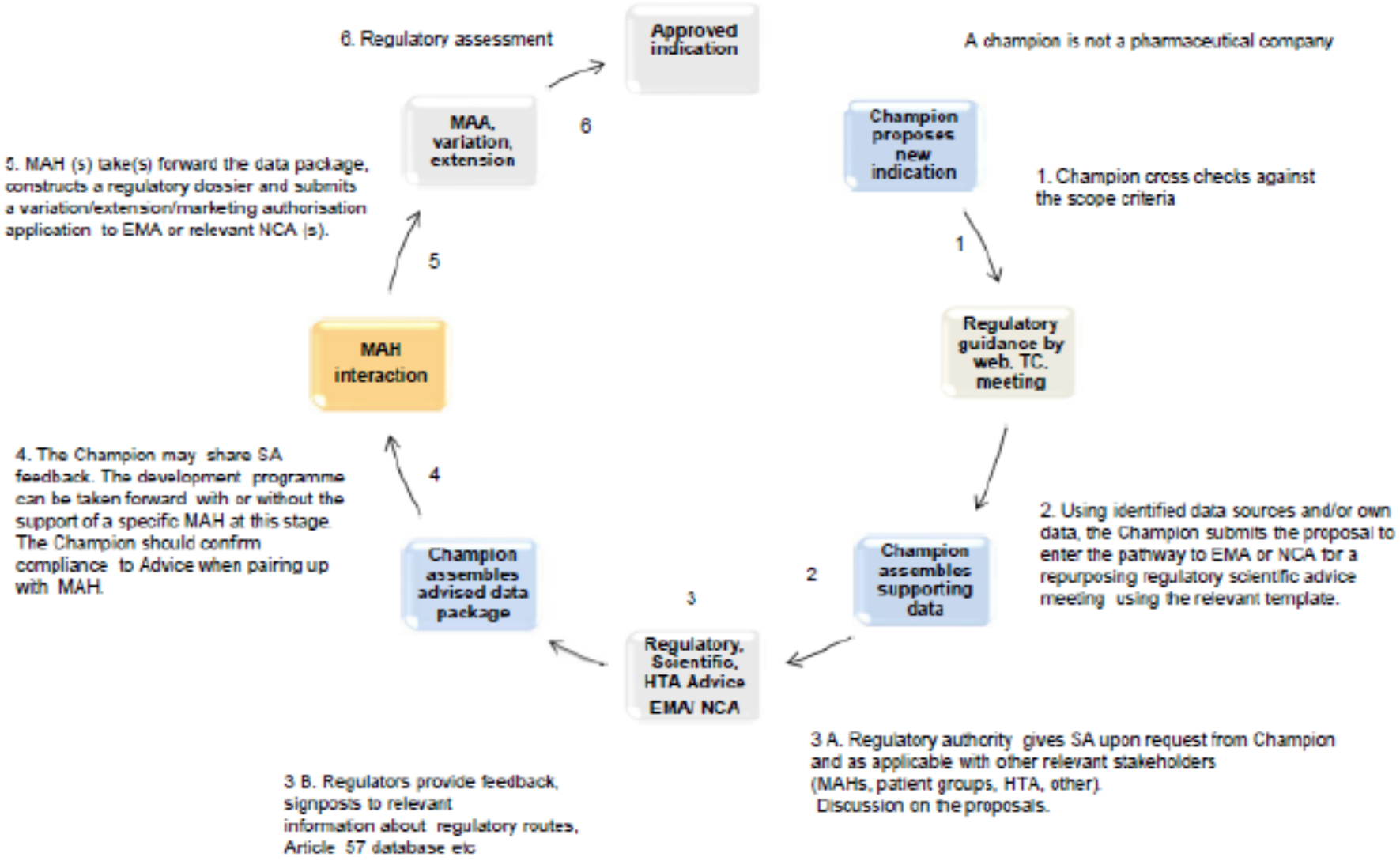
Champion engagement with industry – before scientific advice

- Before the Champion seeks scientific advice in order to seek views or input
- Identification of marketing authorisation holder using the European Medicines Agency's Article 57 database
- Companies will be encouraged to create dedicated email addresses for repurposing queries
- Input may range from none to data sharing or even collaboration

Champion engagement with industry – after scientific advice

- After the Champion has sought scientific advice – key engagement
- Champion to share output from scientific advice with marketing authorisation holders (MAH)
- MAH consider if interested in varying their marketing authorisation
- Champion to be ready to provide relevant information for regulatory submissions

Repurposing of MP's out of patent & data protection



Pilot to test framework

- assess whether the proposed framework is able to facilitate an application for a new indication for an unprotected off-patent medicinal product

- learn from the practical applications of candidates within the framework and build on the concepts identified

Repurposing Observatory Group – voluntary group led by Spain

- Objectives:
  - conclude on the practical aspects of the implementation
  - promote interaction
  - report on the challenges, successes and opportunities
  - make recommendations to facilitate the cooperation between parties
- Contact point for regulatory authorities and other stakeholders
- **not involved** in selecting Champions or medicines for the pilot nor any individual assessment or decision making role for the individual pilot projects

Next steps

- Repurposing Observatory Group
  - reach out to other groups
  - prepare supporting documentation (Q&A etc.)
  - dissemination plan
- Communication and start of pilot in Q4

Thank you

More information:

http://ec.europa.eu/health/documents/pharmaceutical-committee/stamp/index_en.htm