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

Pharmaceutical Committee
11 July 2019
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

5. MAH(s) take(s) forward the data package, constructs a regulatory dossier and submits a variation/extension/marketing authorisation application to EMA or relevant NCA(s).

4. The Champion may share SA feedback. The development programme can be taken forward with or without the support of a specific MAH at this stage. The Champion should confirm compliance to Advice when pairing up with MAH.

3. A. Regulatory authority gives SA upon request from Champion and as applicable with other relevant stakeholders (MAHs, patient groups, HTA, other). Discussion on the proposals.

3 B. Regulators provide feedback, synopsis to relevant information about regulatory routes, Article 57 database etc.

2. Using identified data sources and/or own data, the Champion submits the proposal to enter the pathway to EMA or NCA for a repurposing regulatory scientific advice meeting using the relevant template.

1. Champion cross checks against the scope criteria

1. Champion proposes new indication

2. Regulatory guidance by web, TC, meeting

3. Champion assembles supporting data

6. Regulatory assessment

Approved indication

A champion is not a pharmaceutical company

MAA, variation, extension

MAH interaction

Champion assembles advised data package

Regulatory, Scientifico, HTA Advice EMA NCA
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: