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

Pharmaceutical Committee
1 April 2019
STAMP – Repurposing discussions

• Since March 2016 repurposing of medicines discussed in STAMP
• June 2018 proposal for a framework on repurposing discussed and further developed
• December 2018 principles of framework agreed
• Pilot to test and monitor the framework
Framework

• 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
Repurposing of MP’s out of patent & data protection

6. Regulatory assessment

MAA, variation, extension

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).

Approved indication

A champion is not a pharmaceutical company

1. Champion cross checks against the scope criteria

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.

3. Champion assembles supporting data

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.

Regulatory guidance by web, TC, meeting

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

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

Health and Food Safety
Proposed pilot

• To test the framework a pilot is proposed with a monitoring board

• Aim of a pilot is to assess whether the proposed framework is able to facilitate an application for new indication(s)

• In order to provide support to potential Champions, provide a governance role and to conclude on the pilot, proposed to create a voluntary virtual monitoring board
Thank you for your attention

More information: