Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Proposal for a framework to support not-for-profit organisations in drug repurposing

Reporting back from STAMP Working Group on repurposing

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TAGS: Research and Development Strategies | Regulation | Europe

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TAGS: Drug Review | Generic Drugs | Market Access

ASK THE ANALYST

‘Champions’ To Lead European Drug Repurposing Project

30 Oct 2018 | NEWS

by Ian Schofield

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Executive Summary

Work is under way on a new European procedure
uses. It would mainly be used for active substance
authorization holder and the relevant data were g

EU ‘Repurposing’ Project Plans Pilot Phase

05 Mar 2019 | NEWS

The Economist

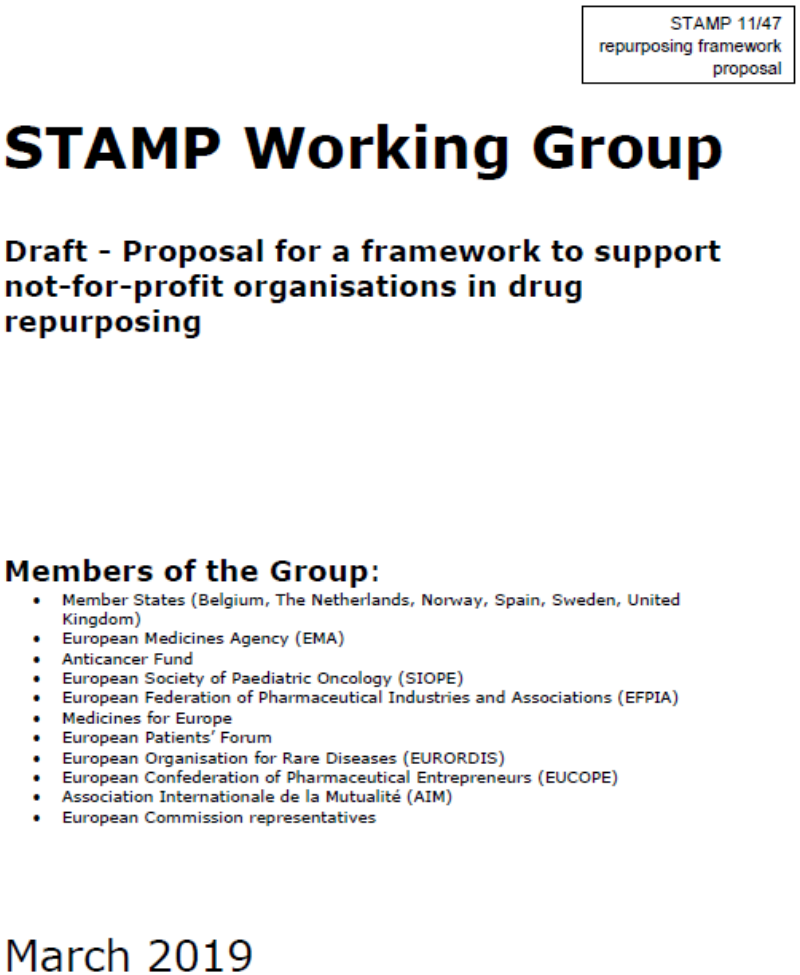
rma.com

g repurposing proposal originally devised by
ing the procedures to be used and running a

Cross purposes

“Repurposing” off-patent drugs offers big hopes of new treatments

STAMP: Repurposing working group – whitepaper sections



STAMP 11/47
repurposing framework
proposal

STAMP Working Group

Draft - Proposal for a framework to support not-for-profit organisations in drug repurposing

Members of the Group:

- Member States (Belgium, The Netherlands, Norway, Spain, Sweden, United Kingdom)
- European Medicines Agency (EMA)
- Anticancer Fund
- European Society of Paediatric Oncology (SIOPE)
- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- Medicines for Europe
- European Patients' Forum
- European Organisation for Rare Diseases (EURORDIS)
- European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
- Association Internationale de la Mutualité (AIM)
- European Commission representatives

March 2019

- Introduction
- Scope
- Key-features of repurposing framework
- Core components
- Regulatory engagement
- Industry engagement
- Incentives – disincentives
- Outline of key components proposed in the framework
- Repurposing schematic
- Summary conclusion/ next steps

- Proposal for a pilot
- Proposal for a monitoring board during the pilot
- Annex I: Useful resources, contacts and information on incentives in the EU

The framework – key principles

- 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

  - 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’

  - 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 MA exists which is out of protection periods

Champion engagement with regulators and industry

Regulatory engagement

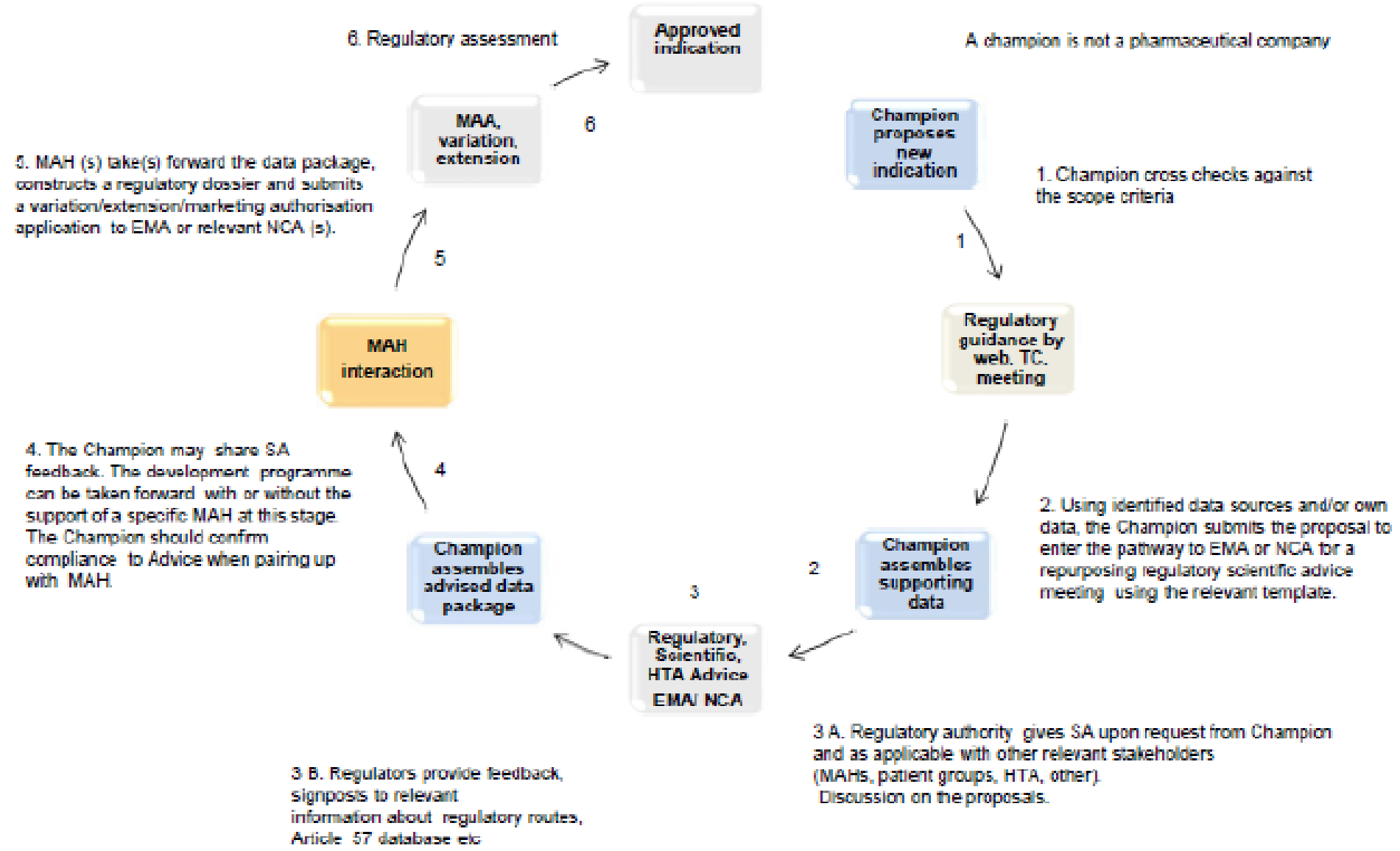
- Main tools are scientific and regulatory advice
- Scientific advice (SA) instrumental to discuss the data package in relation to regulatory requirements – current and future development plans
- Outcome of advice can be made available to MAH(s)

Industry engagement

- Before the Champion seeks SA in order to seek views or input
- Identification of MAH using EMA's Article 57 database
- MAH companies will be encouraged to create dedicated email addresses for repurposing queries on their webpages
- Input may range from none to data sharing or even collaboration

- After the Champion has sought SA – key engagement
- Champion to share output from SA with MAH(s)
- MAH will consider practical, economic and legal burdens, consider if interested in pursuing an MA variation
- Champion will need to provide relevant information for regulatory submissions

Repurposing of MP's out of patent & data protection



Summary

- The STAMP working group has finalised the whitepaper and agreed on a framework to support a Champion with a repurposing proposal
  - Broad alignment and agreement between multiple stakeholders
  - The STAMP repurposing project has generated much interest externally and has been mentioned in publications e.g. The Economist
- In order 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 a MAA for a 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
- The Anticancer Fund (Objective 2) will provide more details on these proposals in the next presentation