

Drug Repurposing Guidebook

Building Block E140

This document defines the content of the FACT SHEET to be created for each identified tool, incentives, initiative or practice (the Building Block) introduced by public bodies or used by developers to expedite drug repurposing in Rare Diseases (RDs).

ITEM	DESCRIPTION
Building Block (BB) Title	STAMP initiative
References	<p>1 - https://health.ec.europa.eu/medicinal-products/pharmaceutical-committee-veterinary-pharmaceutical-committee-and-expert-groups/commission-expert-group-safe-and-timely-access-medicines-patients-stamp_en</p> <p>2 - Asker-Hagelberg C, Boran T, Bouygues C, Eskola SM, Helmle L, Hernández C, Houyez F, Lee H, Lingri DD, Louette L, Meheus L, Penninckx W and Stepniewska B (2022) Repurposing of Medicines in the EU: Launch of a Pilot Framework. <i>Front. Med.</i> 8:817663. doi: 10.3389/fmed.2021.817663 - https://www.frontiersin.org/articles/10.3389/fmed.2021.817663/full</p>
Description	<p>The STAMP (Safe and Timely Access to Medicines for Patients) expert group is set up to provide advice and expertise to the Commission services in relation to the implementation of the EU Pharmaceutical legislation, as well as programmes and policies in this field. The STAMP expert members exchange views and information about the experience of Member States, examine national initiatives and identify ways to use more effectively the existing EU regulatory tools with the aim to further improve safe and timely access and availability of medicines for patients.</p> <p>STAMP has a work stream to support not-for-profit and academic stakeholders in Repurposing, which is the purpose of this BB</p>
Category	Regulatory and HTA engagement

ITEM	DESCRIPTION
Type of BB	Regulatory
Geographical scope	Europe
Availability	Through EMA and the Heads of Medicines Agencies
Scope of use	Follow-up of STAMP activities in the field (think-tank) + see BB on 'EMA pilot project to support academia' for the implementation
Stakeholders involved	European Commission, Members States, Regulators (EMA and HMA), Developers of medicines (the proposed framework is dedicated to non-for-profit organisations and academia), patients.
Enablers/ Requirements	<p>In June 2019, STAMP, with the European Medicines Agency (EMA) and stakeholders, developed a proposal for a framework to support not-for-profit organisations and academia in drug repurposing. The proposed framework will be tested through a pilot project launched by EMA and the Heads of Medicines Agencies on 28 October 2021.</p> <p>The aim of the pilot is to support not-for-profit organisations and academia to gather or generate sufficient evidence on the use of an established medicine in a new indication to have this new use formally authorised by a regulatory authority. This is a way of making affordable new treatment options available to patients. Further information is available in a question-and-answer document.</p> <p>The pilot is open to not-for-profit stakeholders and academia (institutions and individuals) who have a particular interest in repurposing an authorised medicine for a new indication in an area of public health interest, have a scientific rationale for their repurposing programme and would like to seek scientific advice with a regulatory authority. They should apply to EMA or national authorities: European Medicines Agency: Scientific advice and protocol assistance (see under 'Scientific advice on medicine repurposing') or Heads of Medicines Agencies</p> <p>The pilot is one of the actions highlighted in the Pharmaceutical Strategy for Europe to inform the review of the pharmaceutical legislation. For more details of the strategy see: A pharmaceutical strategy for Europe.</p> <p>Previous activities of the STAMP expert group: Overview of the activities of the STAMP expert Group in 2015 – 2016.</p>

ITEM	DESCRIPTION
Output	<p>Proposal for a framework to support not-for-profit organisations and academia (institutions and individuals) in drug repurposing - https://health.ec.europa.eu/system/files/2021-10/pharm773_repurposing_annex_en_0.pdf</p>
Best time to apply and time window	<p>Not applicable for STAMP – see BB on ‘EMA pilot project to support academia’</p>
Expert tips	<p>STAMP acts as a think-tank.</p> <p>Please see BB on ‘EMA pilot project to support academia’ which is related to the implementation of the aforementioned framework.</p>