

Drug Repurposing Guidebook

Building Block I452

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	Generics
References	<p>[1] US FDA: https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-generic-drugs https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs</p> <p>[2] US database https://purplebooksearch.fda.gov/ https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals</p> <p>[3] EMA 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 https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation/generic-hybrid-medicines</p> <p>[4] EMA database: https://www.ema.europa.eu/en/medicines/download-medicine-data</p> <p>[5] Australia database https://www.pbs.gov.au/browse/medicine-listing</p> <p>[6] Latin America https://gabionline.net/</p> <p>[8] Publications https://chemistry-europe.onlinelibrary.wiley.com/doi/10.1002/cmdc.201200552</p> <p>[9] Worldwide consortium:</p>

ITEM	DESCRIPTION
	https://www.iprp.global/home [10] Worldwide database: https://www.drugs.com/availability/ https://druginfo.nlm.nih.gov/drugportal/jsp/drugportal/DrugNameGenericStems.jsp
Description	<p>Generic drugs are medicinal products that can be manufactured and marketed by others than the innovator company after the original patents have expired. Bioequivalence is the main regulatory principle for generic drug approval in European Union and the United States. For two drugs to be bioequivalent, they must contain identical amounts of the same active ingredient in the same strength and dosage form and their bioavailabilities must be similar in such a degree that their effects can be expected to be essentially the same.</p> <p>Repurposing generic drugs could offer a cheaper and faster way to develop new treatments. Since patents allow drug suppliers to have a monopoly over sales for a span of time, there is less opportunity for profit with generics than with new drugs. Researchers have been collecting these “failed” compounds for further testing, trawling through research papers, patents and clinical trial databases to find repurposing candidates. Some labs have used artificial intelligence to automate this process.</p>
Category	Availability of data
Type of BB	Development resource
Geographical scope	International
Availability	Most generics are manufactured in developing countries where production costs are cheaper- e.g. China, India, Brazil
Scope of use	<ul style="list-style-type: none"> • Basic Research investigations • Drug development • Clinical studies • Market studies
Stakeholders involved	<ul style="list-style-type: none"> • Researchers, bioinformaticians, data scientists, AI scientists, chemists • From academia to industry • Policy makers • Manufactured companies (India and China for most of them) • Distributors

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Enablers/ Requirements	<p>To be considered as generic: the drug must contain identical amounts of the same active ingredient in the same strength and dosage form and their bioavailabilities must be similar in such a degree that their effects can be expected to be essentially the same as the brand name.</p> <p>Regulators, Generic manufacturers, policy makers</p>
Output	<p>New knowledge to faster drug development</p> <ul style="list-style-type: none"> • Discovery of new treatment for a RD • Discovery of new applications for a drug
Best time to apply and time window	<p>From the beginning of the project since it is a strategic approach to define early on</p>
Expert tips	<p>PROs: in cancer, it was shown that a drug development took 10 years for a novel drug and only 5 for a generic one since the pre-clinical studies and first stage of the clinical trials could be skipped</p> <p>CONs: if the initiator of the project is looking for a return on investment, this strategy cannot be chosen, and it cannot be a back-up plan as it is better to go for it from the start and decide not to make any money in the patients' best interest.</p>