PRODUCT ASSESSMENT FRAMEWORK TO GUIDE PRIORITISATION EXERCISE

medicines patent pool

The assessment framework proposed to be applied to each product has the following arborescence:

- Level 1 — PILLAR
- Level 2 — Sub pillar
- Level 3 — CRITERIA
- Level 4 — Sub criteria

Each sub-criteria is accompanied by an explanation of how the information gathered will likely be used in assessing the potential of an MPP intervention for the product in question. The final decision on product prioritisation is at the discretion of the MPP prioritisation committee.

ASSESSMENT FRAMEWORK

1. PUBLIC HEALTH CONSIDERATIONS

1.1. Disease burden

- 1.1.2. Prevalence & incidence
- 1.1.3. Treatment options
- 1.1.4. Disease severity
- 1.1.5. Epidemic risk

1.2. Clinical relevance

- 1.2.1. Safety
- 1.2.2. Efficacy
- 1.2.3. Posology & method of administration
- 1.2.4. Cross-disease impact

2. ACCESS CONSIDERATIONS

2.1. Intellectual property landscape

- 2.1.1. Years to patent expiry of API
- 2.1.2. Geographical coverage of patents
- 2.1.3. Secondary patents
- 2.1.4. Multiple patent owners

2.2. Service delivery enablers

- 2.2.1. Diagnostic
- 2.2.2. Companion drugs
- 2.2.3. Health system requirements

2.3. Manufacturing

- 2.3.1. Manufacturing simplicity
- 2.3.2. Presentation & storage

2.4. Regulatory

- 2.4.1. Regulatory pathway
- 2.4.2. Regulatory cost & complexities
- 2.4.3. Probability of biowaiver /Clinical trial waiver

2.5. Market

- 2.5.1. Affordability & Availability of candidate
- 2.5.2. Commercial potential for MPP Generics' network
- 2.5.3. Impact

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1. PUBLIC HEALTH CONSIDERATIONS

1.1. Disease burden

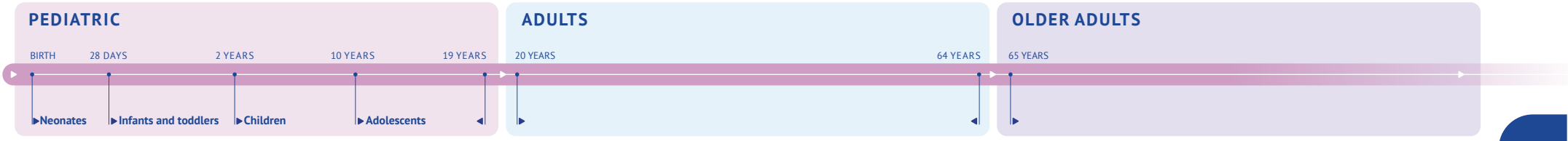
CRITERIA FOR PRODUCT'S ASSESSMENT			
N	CRITERIA	SUB-CRITERIA	EXPLANATION OF THE CRITERIA
1	Prevalence/incidence	**BURDEN OF DISEASE IN LMICS (GLOBAL OR LOCAL)**	The burden of the disease in LMICs (global) or in specific LMIC regions or countries (local).
2	Prevalence/incidence	**BURDEN OF DISEASE IN SPECIFIC POPULATIONS**	The burden of the condition in key populations (PLHIV, pregnant and lactating individuals, pediatric populations, and adolescents, people who inject drugs (PWID), incarcerated individuals, sex workers, and any other vulnerable groups).
3	Treatment options	**LACK OF ALTERNATIVE TREATMENTS**	Whether there is a lack of alternative treatment for the product-specific indication.
4	Disease severity	**DISABILITY-ADJUSTED LIFE YEARS (DALYs)**	Disability-adjusted life years (DALYs) as a measure of disease severity.
5	Disease severity	**NUMBER OF DEATHS**	Yearly estimated deaths linked directly or indirectly to the condition.
6	Epidemic risk	**EPIDEMIC/PANDEMIC RISK**	Whether there is a risk for imminent or future outbreaks of the disease.

1.2. Clinical relevance

CRITERIA FOR PRODUCT'S ASSESSMENT			
N	CRITERIA	SUB-CRITERIA	EXPLANATION OF THE CRITERIA
7	Safety	**SAFETY/TOLERABILITY**	Overall safety and tolerability profile of the product.
8	Safety	**DRUG-DRUG INTERACTIONS (DDI) WITH HIGH-BURDEN DISEASES REGIMENS**	Drug-drug interactions (DDI) with standard of care (SoC) for high-burden infectious diseases such as HIV, TB, and Hepatitis C, and other DDIs.
9	Safety	**PRODUCT-INDUCED ADVERSE EVENTS**	Whether the product causes adverse events (e.g. hepatotoxicity, nephrotoxicity, weight gain, hypertension).

CRITERIA FOR PRODUCT'S ASSESSMENT			
N	CRITERIA	SUB-CRITERIA	EXPLANATION OF THE CRITERIA
10	Safety	**SPECIAL ADMINISTRATION RESTRICTIONS**	Special administration restrictions such as fasting, or requirements for food intake.
11	Efficacy	**EFFICACY**	Overall efficacy compared to SoC. Efficacy should be ideally superior to the SoC. If the efficacy is comparable to SoC, then an additional advantage should be present. If the efficacy is inferior to the SoC, then product should be excluded from the evaluation.
12	Efficacy	**ADHERENCE**	Facilitated adherence to the product compared to SoC (from user/caregiver perspective).
13	Efficacy	**GENETIC BARRIER TO RESISTANCE**	When relevant. Whether there is a high genetic barrier to resistance, especially important for long/life treatment duration.
14	Efficacy	**KNOWN RESISTANCE MUTATIONS**	When relevant. Whether the product has known significant viral/bacterial resistance mutations of concern.
15	Efficacy	**SPECTRUM**	When relevant. Whether the product covers several diseases or all disease sub-types (e.g. Hepatitis C pan-genotypic treatment, multi-purpose technology, latent and active TB, several sexually transmitted infections (STIs), several cancers, etc.).
16	Efficacy	**INNOVATIVE PRODUCT**	Whether the product is innovative (such as a new promising mechanism of action, breakthrough therapy designation, orphan drug designation etc.).
17	Posology & method of administration	**DOSAGE**	Dosage for each indication (e.g. mg, mg/kg, mg/m2).
18	Posology & method of administration	**LENGTH OF THE TREATMENT**	Duration of the treatment for the main and secondary indications.
19	Posology & method of administration	**FREQUENCY OF ADMINISTRATION**	The frequency of dosing (e.g. once or twice daily or every 6 months).
20	Posology & method of administration	**AVAILABILITY OF A PEDIATRIC FORMULATION**	Whether a pediatric formulation/development program is available.
21	Posology & method of administration	**METHOD OF ADMINISTRATION**	Route of administration and concise instructions for correct administration and use.
22	Cross-disease impact	**CROSS-DISEASE IMPACT**	Synergies with other health areas i.e., whether the product could be used across several diseases.

We used the following age ranges:



2. ACCESS CONSIDERATIONS

2.1. Intellectual property landscape

CRITERIA FOR PRODUCT'S ASSESSMENT			
N	CRITERIA	SUB-CRITERIA	EXPLANATION OF THE CRITERIA
23	Years to patent expiry of API	YEARS TO PATENT EXPIRY OF API	Number of years of blocking patent protection left on the API.
24	Geographical coverage of patents	GEOGRAPHICAL COVERAGE OF PATENTS (INCLUDING SECONDARY PATENTS)	Country scope: how many LMICs are covered.
25	Secondary patents	SECONDARY PATENTS	Specific secondary patents (e.g. formulation, process, method of treatment, platforms) or patent thicket (e.g. biologics).
26	Multiple patent owners	MULTIPLE PATENT OWNERS	If multiple patent owners, might be lengthier to find an agreement with all the involved parties.

2.2. Service delivery enablers

CRITERIA FOR PRODUCT'S ASSESSMENT			
N	CRITERIA	SUB-CRITERIA	EXPLANATION OF THE CRITERIA
27	Diagnostic	REQUIREMENTS FOR DIAGNOSIS	Diagnostic requirements for the diagnosis of the disease.
28	Diagnostic	ACCESS TO DIAGNOSIS	It includes an evaluation on availability/ affordability/status awareness of the diagnosis. It also includes and info on whether the diagnosis is generally available in the public sector or only in the private one. A subset of countries is taken as a proxy.
29	Diagnostic	REQUIREMENTS FOR TREATMENT ELIGIBILITY/ TREATMENT MONITORING	Additional diagnostic requirements required to define eligibility to treatment candidate compared to SoC (e.g. sequencing) / requirement for treatment monitoring (e.g. viral testing).
30	Companion drugs	COMPANION DRUG REQUIREMENTS	Need of companion treatments.
31	Companion drugs	ACCESS TO COMPANION DRUGS	Access (availability and affordability) to companion treatment/s.
32	Health system requirements	HEALTH SYSTEM AND INFRASTRUCTURE NEEDS	Additional requirements for the proper and safe use of the candidate e.g. specific treatment efficacy and/or safety requirements/staff training/facilities.

2.3. Manufacturing

CRITERIA FOR PRODUCT'S ASSESSMENT			
N	CRITERIA	SUB-CRITERIA	EXPLANATION OF THE CRITERIA
33	Manufacturing simplicity	**MANUFACTURING**	This includes the simplicity of the manufacturing process generally for this class of molecules. Small molecules chemically manufactured are classified as "not particularly complex for manufacturing". Synthetic proteins or nucleic acids are considered as "partially complex manufacturing" as it is less standard process than small molecules and requires generally aseptic filling which demands specific competencies. Recombinant proteins are classified as "complex manufacturing" as these involve cell growth steps and precise characterization tools needing specific competencies, and it generally also requires aseptic filling. Any specificity of this product within its category is ranked in the criteria as "standard manufacturing operations".
34	Manufacturing simplicity	**MANUFACTURING OPERATIONS**	Compared to the general simplicity to manufacture this category of product, any complexity to manufacture this specific product is ranked here (e.g., non-standard manufacturing step requiring specific competency or investment).
35	Manufacturing simplicity	**MANUFACTURING FACILITY**	Special requirements in terms of manufacturing facilities are captured here. Higher value of MPP intervention is attributed to products with no specific facility requirement other than basic good manufacturing practices (GMP), for example non-sterile products. Medium rating is attributed to products which require some additional control in terms of facility, like requirement of grade C area for sterile products which can be sterilised by terminal sterilisation. Lower value of MPP intervention is attributed to products which would require aseptic processing (Grade A), or special containment like hormones or oncology products with occupational exposure limits (OEL) classification of 4 or 5, thus making likely more challenging the identification of manufacturers and potentially the implementation of the production.
36	Manufacturing simplicity	**EXCIPIENTS**	If the excipients are well known (pharmacopeia), neither costly nor difficult to supply, the MPP intervention would be considered of high value as the implementation would be facilitated. If the excipient is used only in a few medical products or its cost impacts significantly on the cost of goods or the low availability can hinder the supply of the medical product, it would likely result in more difficulties in supplying the excipients or in affecting the product pricing.
37	Presentation and storage	**SHELF-LIFE AND STORAGE CONDITIONS**	Higher value of MPP intervention is for products with a shelf-life of at least two years at room temperature. A more moderate value would be for products with a shelf-life between one year (excluded) and two years at non-controlled temperature or storage at controlled temperature (e.g. 2-8°C). Lower value for MPP intervention could be for products with a shelf-life lower than one year (included) or with storage in frozen conditions (e.g. -20°C) as it would likely complexify the product distribution.
38	Presentation and storage	**MEDICAL DEVICE**	Tablets, pills, and vials presentations are considered as standard and would be in principle facilitated by an MPP intervention. Pre-filled syringes (PFS) are considered a medium standard. Intranasal medical devices, insulin pens, or patches are considered non-standard as they require specific equipment, access to specific and potentially costly devices and could imply specific regulatory requirements. In such situations, the potential impact of an MPP intervention needs to be evaluated on a case-by-case basis. This classification could be revised based on the deeper impact of the different medical devices and other potential variables.

CRITERIA FOR PRODUCT'S ASSESSMENT			
N	CRITERIA	SUB-CRITERIA	EXPLANATION OF THE CRITERIA
39	Regulatory pathway	**REGULATORY PATHWAY FOR THE LICENSEES**	Probable regulatory pathway for the licensee. Higher rating is attributed to products where the originator product is already approved by SRA/WHO PQ, where the generics have regulatory pathways. Lower rating is attributed to products where the originator is not filed with any regulatory authority, where there is apparently no pathway for the licensee to file their product. Medium rating is attributed to products where the originator has approval in non-SRA countries, but no approval in SRA/WHO PQ. In such cases, potential sub-licensees would need to wait to have the originator product approved with SRA /WHO PQ to file their own product.
40	Regulatory cost and complexities	**COST AND COMPLEXITIES OF REGULATORY FILING**	The costs associated with regulatory filing are to be assessed separately here. This includes the cost of development, including possible studies (bioquivalence (BE), pre-clinical, clinical, etc.), cost of reference listed drug (RLD), etc. Simple generic products could be rated as high (since they have less complexities). Complex generic products like long-acting therapeutics, or complex dosage forms could be treated as with moderate complexity. Sometimes, simple generic products might need population studies which might add complexity to BE studies and could be included in this category. Biotherapeutics, which require a biosimilarity package, wherein a battery of preclinical and clinical studies are required, could be categorised as high level of complexity.
41	Probability of biowaiver / clinical trial waiver	**PROBABILITY OF BIOWAIVER /CLINICAL TRIAL WAIVER**	This aspect gets assessed in regulatory cost but needs to be understood separately if a biowaiver/clinical trial waiver is possible. High probability of biowaiver is there for oral solids of BCS Class I, or solutions. Moderate probability for biowaiver is where a molecule might have a probability of biowaiver/clinical trial waiver but there could be other studies/justifications required. For biotherapeutics, some less complex molecules with a PD marker might be included in this category. Low probability of biowaiver is applicable to BCS Class II /IV molecules. Complex biotherapeutics like mAbs would also fall in this category.

2.5. Market

CRITERIA FOR PRODUCT'S ASSESSMENT			
N	CRITERIA	SUB-CRITERIA	EXPLANATION OF THE CRITERIA
42	Affordability/availability of the candidate	**CANDIDATE-PRODUCT'S AVAILABILITY IN LMICS**	Availability of target product in LMICs to assess impact of voluntary licensing and business case.
43	Affordability/availability of the candidate	**CANDIDATE-PRODUCT'S AFFORDABILITY IN LMICS**	Affordability of target product in a sample of countries with reference to SoC, to assess impact of voluntary licensing and business case.
44	Commercial potential for MPP generic manufacturers' network	**COMPANY COMMERCIAL FOOTPRINT**	Commercial reach of company across the targeted MPP territories to understand if an in-house access program can reach people in need.
45	Commercial potential for MPP generic manufacturers' network	**MARKET SIZE**	Annual sales of the product globally and in a sample of territories to understand generic business case and impact on originator profit and loss.
46	Commercial potential for MPP generic manufacturers' network	**EXISTENCE, AVAILABILITY AND PRICE OF ALTERNATIVE OF MARKETED TREATMENTS**	To assess need and business case for originators.
47	Commercial potential for MPP generic manufacturers' network	**EXISTENCE AND AVAILABILITY OF ALTERNATIVE TREATMENTS IN PIPELINE**	Existence and availability of alternative therapies in development to focus our priorities and generic interest.
48	Commercial potential for MPP generic manufacturers' network	**PRODUCT ATTRACTIVENESS FOR THE LICENSEES**	Commercial attractiveness in terms of potential sales and volumes (which could be considered as a proxy for generic manufacturers potentially interested in developing the product).
49	Commercial potential for MPP generic manufacturers' network	**PROCUREMENT**	Whether there are any established procurement mechanisms available for this type of product.
50	Commercial potential for MPP generic manufacturers' network	**COMPETITIVE PRODUCTS (INCLUDING ALREADY EXISTING GENERIC VERSIONS OF THE CANDIDATE AND SAME CLASS PRODUCTS)**	Market share according to what is in the pipeline.
51	Impact	**POTENTIAL SAVING FOR PUBLIC HEALTH**	Commercial impact that generic manufacturers would create after MPP intervention. Whether MPP would be improving the *status quo* for patients and governments.