Request for Proposal

Objective

To create a database for regulatory requirements of generic pharmaceutical products in different low-income countries (LICs), lower-middle-income countries (LMICs) and upper-middle-income countries (UMICs); covered by MPP licences

Background on MPP

The Medicines Patent Pool (MPP) is a United Nations-backed public health organisation working to increase access to, and facilitate the development of, life-saving medicines for low- and middle-income countries.

Through its innovative business model, MPP partners with civil society, governments, international organisations, industry, patient groups and other stakeholders, to prioritise and license needed medicines and pool intellectual property to encourage generic manufacture and the development of new formulations.

To date, MPP has signed agreements with eleven patent holders for thirteen HIV antiretrovirals, one HIV technology platform, three hepatitis C direct-acting antivirals, a tuberculosis treatment, and a licence for long-acting technologies.

In 2020, MPP's mandate was temporarily expanded to include COVID-19 treatments. In 2021 it was expanded further to include the licensing of technology with an initial focus on COVID-19 vaccines and pandemic preparedness. MPP was founded by Unitaid, which continues to be MPP's main funder. MPP's work on access to essential medicines is also funded by the Swiss Agency for Development and Cooperation (SDC).

Consultancy purpose

Through this database, MPP intends to have a clear understanding of the following aspects related to registration of pharmaceutical products in different low-income countries (LICs), lower-middle-income countries (LMICs) and upper-middle-income countries (UMICs); covered by MPP licences

- The general requirements for registration and /or import of products in the countries of interest
- The different pathways for registering generics, complex generics, biosimilars, vaccines, and in vitro diagnostics (specific classes)
- The requirements of data package support required from originators
- The acceptability of SRA originators/dossiers for different national regulatory authorities
- The different regulatory bodies that the country is a part of
- The possible bioequivalence and biowaiver opportunities in the country

- Any country specific requirements regarding originators, bioequivalence, clinical trials etc
- The requirements for new formulations of existing molecules like long acting, new strength, new dosage form, fixed dose combination, multipurpose combinations, paediatric formulation etc

Scope:

The scope of the project would include a list of LICs, LMICs and UMICs as per Annexure. Scope would include registration and/or import requirements of pharmaceutical products in the country of interest. Pharmaceutical products would include generics, complex generics, biosimilars, follow on vaccines, and In vitro diagnostics (specific classes).

Key Steps:

Stage 1

Conduct a mapping exercise to segregate the list of countries into two broad categories:

- Countries which do not have an internal assessment procedure for generics and rely on assessment by other regulatory bodies: Group 1
- Countries which have an internal assessment procedure for generics: Group 2

Conduct similar exercise for other categories like biosimilars, follow on vaccines, in vitro diagnostics

Stage 2

Database to be created for the companies in Group 1 and 2 to cover the following topics as enumerated below.

Group 1: Countries which do not have an internal assessment procedure

Database should focus on understanding the requirements of procurement procedure and import of pharmaceutical products. It should also identify the country's inclusion into any regulatory body/group for filing. The database should provide answers to the following questions:

1. What are the different Stringent Regulatory Authorities (SRAs) which are recognised by the country?
2. Does the country participate in any other regulatory processes (WHO CRP, ASEAN, SADC, ZAZIBONA, CARICOM, AMRH, EAEU etc) through which a registration can be done?
3. What are the documents required for import and registration of drug products (CoPP, GMP certifications etc)?
4. Can any drug product be imported or there are any specific criteria, for eg inclusion in National Essential Medicines list?
5. What are the stability data requirements for drug product?

6. Is it necessary to have a local presence or can any manufacturer register their products in the country?
7. Are there any special requirements with respect to local language usage for labelling?
8. Are there any legislative timelines for registration of products?
9. What are the fees for registration?

Conduct similar exercise for other categories like biosimilars, follow on vaccines, in vitro diagnostics.

Group 2: Countries which have an internal assessment procedure

In addition to the questions for group 1, database should also focus on understanding the local requirements for registration of pharmaceutical products. It should identify the regulatory guidance documents related to development and registration of generic pharmaceutical products. The database should provide answers to the following additional questions:

For generics/complex generics

1. What is the regulatory guidance available for development and registration of generics? Are they available in English?
2. Is there any specific requirement for choice of originator product?
3. What are the additional data required if the originator is not present in the country?
4. Is there any specific bioequivalence requirement (Choice of originator product, inclusion of local population etc)?
5. Is BCS based biowaiver as per ICH M9 applicable? Apart from ICH, is there any additional data requirements?
6. Is biowaiver applicable based on dose weight proportionality? What is the data package required for submission?
7. Is there any specific guidance for establishing bioequivalence of complex generic products (Long acting injectables including microarray patches, device-based inhalation products, implants, vaginal rings etc)?
8. What are the additional data required for new formulation/dosage/strength of existing molecule?
9. What are the additional data required for new formulation /dosage form of existing molecules in paediatric population?
10. What is the additional data requirement for multipurpose use combinations of existing molecules?
11. Are there any specific requirements for raw materials like APIMF, excipients, packaging material etc?
12. Is there any requirement of in-country QC release, testing or samples?
13. Is there any requirement of separate GMP inspection?
14. Are there any legislative timelines for registration of products?
15. What are the fees for registration?

For biosimilars

1. What are the regulatory pathways available for registration of biosimilars?
2. What is the regulatory guidance available for development and registration of biosimilars? Are they available in English?
3. Are there any special criteria for establishing biosimilarity apart from the guidelines from WHO and EMA?
4. Is there any specific requirement for choice of originator product?
5. What are the additional data required if the originator is not present in the country?
6. Is there any specific clinical trial requirement (Choice of originator product, inclusion of local population etc)?
7. Are there any specific requirements for raw materials like APIMF, excipients, packaging material etc?
8. Is there any requirement of in-country QC release, testing or sample?
9. Is there any requirement of separate GMP inspection?
10. Are there any legislative timelines for registration of products?
11. What are the fees for registration?

Conduct similar exercise for other categories like follow on vaccines, in vitro diagnostics.

Stage 3

In this stage, all guidance documents identified in stage 2 will be reviewed. Any critical guidance, which is not available in English language will have to be translated. For some guidance documents, a summary of key points can be provided instead of translating the whole guidance.

Outputs

Stage 1

Classification of the countries based on their capabilities on assessment of generic medicines.

Stage 2

Comprehensive report on the Group 1 and Group 2 countries to cover the questions enumerated in the earlier section. Any critical information with respect to any typical local requirement (other than those covered in the questions) needs to be highlighted.

References for the information, including links to websites, documents and transcripts of interviews conducted with local agents/ authorities (if any) will have to be appended to the report.

Stage 3

English translation/regulatory summary of the selected guidance to be provided.

Project Timelines

- Last date to receive quotes: 15th Nov 2021
- Kick-off meeting: By 3rd Dec 2021
- Project Start date: By 6th Dec 2021
- Draft submission: By 6th June 2022
- Project End date: By 6th July 2022

Submission of Proposal:

The proposal should contain the following:

- Profile of the consultant, including details about experience in similar projects
- Methodology and work plan for the project, including a tentative schedule
- Proposed quote for the proposal

All proposals should be submitted by email to Aditi Das, Business Development Manager, Technical and Regulatory at adas@medicinespatentpool.org with the subject RFP: MPP Regulatory Project. Please feel free to write to us in case any additional information or clarification is required.

Annexure

List of countries

S.No	Country	Income Status	Geographic Region
1	Afghanistan	LIC	South Asia
2	Albania	UMIC	Europe & Central Asia
3	Algeria	LMIC	Middle East & North Africa
4	Angola	LMIC	Sub-Saharan Africa
5	Argentina	UMIC	Latin America & Caribbean
6	Armenia	UMIC	Europe & Central Asia
7	Azerbaijan	UMIC	Europe & Central Asia
8	Bangladesh	LMIC	South Asia
9	Belarus	UMIC	Europe & Central Asia
10	Belize	LMIC	Latin America & Caribbean
11	Benin	LMIC	Sub-Saharan Africa
12	Bhutan	LMIC	South Asia
13	Bolivia (Plurinational State of)	LMIC	Latin America & Caribbean
14	Bosnia and Herzegovina	UMIC	Europe & Central Asia
15	Botswana	UMIC	Sub-Saharan Africa
16	Brazil	UMIC	Latin America & Caribbean
17	Bulgaria	UMIC	Europe & Central Asia
18	Burkina Faso	LIC	Sub-Saharan Africa
19	Burundi	LIC	Sub-Saharan Africa
20	Cabo Verde	LMIC	Sub-Saharan Africa
21	Cambodia	LMIC	East Asia & Pacific
22	Cameroon	LMIC	Sub-Saharan Africa
23	Central African Republic	LIC	Sub-Saharan Africa
24	Chad	LIC	Sub-Saharan Africa
25	China	UMIC	East Asia & Pacific
26	Colombia	UMIC	Latin America & Caribbean
27	Comoros	LMIC	Sub-Saharan Africa
28	Congo	LMIC	Sub-Saharan Africa
29	Congo, democratic Republic of the	LIC	Sub-Saharan Africa
30	Costa Rica	UMIC	Latin America & Caribbean
31	Côte d'Ivoire	LMIC	Sub-Saharan Africa

S.No	Country	Income Status	Geographic Region
32	Cuba	UMIC	Latin America & Caribbean
33	Djibouti	LMIC	Middle East & North Africa
34	Dominica	UMIC	Latin America & Caribbean
35	Dominican Republic	UMIC	Latin America & Caribbean
36	Ecuador	UMIC	Latin America & Caribbean
37	Egypt	LMIC	Middle East & North Africa
38	El Salvador	LMIC	Latin America & Caribbean
39	Equatorial Guinea	UMIC	Sub-Saharan Africa
40	Eritrea	LIC	Sub-Saharan Africa
41	Eswatini	LMIC	Sub-Saharan Africa
42	Ethiopia	LIC	Sub-Saharan Africa
43	Fiji	UMIC	East Asia & Pacific
44	Gabon	UMIC	Sub-Saharan Africa
45	Gambia (the)	LIC	Sub-Saharan Africa
46	Georgia	UMIC	Europe & Central Asia
47	Ghana	LMIC	Sub-Saharan Africa
48	Grenada	UMIC	Latin America & Caribbean
49	Guatemala	UMIC	Latin America & Caribbean
50	Guinea	LIC	Sub-Saharan Africa
51	Guinea-Bissau	LIC	Sub-Saharan Africa
52	Guyana	UMIC	Latin America & Caribbean
53	Haiti	LMIC	Latin America & Caribbean
54	Honduras	LMIC	Latin America & Caribbean
55	India	LMIC	South Asia
56	Indonesia	LMIC	East Asia & Pacific
57	Iran (Islamic Republic of)	LMIC	Middle East & North Africa
58	Iraq	UMIC	Middle East & North Africa
59	Jamaica	UMIC	Latin America & Caribbean
60	Jordan	UMIC	Middle East & North Africa
61	Kazakhstan	UMIC	Europe & Central Asia
62	Kenya	LMIC	Sub-Saharan Africa
63	Kiribati	LMIC	East Asia & Pacific
64	Korea (Democratic People's Republic of)	LIC	East Asia & Pacific
65	Kosovo	UMIC	Europe & Central Asia
66	Kyrgyzstan	LMIC	Europe & Central Asia
67	Lao People's Democratic Republic (the)	LMIC	East Asia & Pacific
68	Lebanon	UMIC	Middle East & North Africa

S.No	Country	Income Status	Geographic Region
69	Lesotho	LMIC	Sub-Saharan Africa
70	Liberia	LIC	Sub-Saharan Africa
71	Libya	UMIC	Middle East & North Africa
72	Madagascar	LIC	Sub-Saharan Africa
73	Malawi	LIC	Sub-Saharan Africa
74	Malaysia	UMIC	East Asia & Pacific
75	Maldives	UMIC	South Asia
76	Mali	LIC	Sub-Saharan Africa
77	Marshall Islands	UMIC	East Asia & Pacific
78	Mauritania	LMIC	Sub-Saharan Africa
79	Mauritius	UMIC	Sub-Saharan Africa
80	Mexico	UMIC	Latin America & Caribbean
81	Micronesia (Federated States of)	LMIC	East Asia & Pacific
82	Moldova, Republic of	UMIC	Europe & Central Asia
83	Mongolia	LMIC	East Asia & Pacific
84	Montenegro	UMIC	Europe & Central Asia
85	Morocco	LMIC	Middle East & North Africa
86	Mozambique	LIC	Sub-Saharan Africa
87	Myanmar	LMIC	East Asia & Pacific
88	Namibia	UMIC	Sub-Saharan Africa
89	Nepal	LMIC	South Asia
90	Nicaragua	LMIC	Latin America & Caribbean
91	Niger	LIC	Sub-Saharan Africa
92	Nigeria	LMIC	Sub-Saharan Africa
93	North Macedonia	UMIC	Europe & Central Asia
94	Pakistan	LMIC	South Asia
95	Panama	UMIC	Latin America & Caribbean
96	Papua New Guinea	LMIC	East Asia & Pacific
97	Paraguay	UMIC	Latin America & Caribbean
98	Peru	UMIC	Latin America & Caribbean
99	Philippines	LMIC	East Asia & Pacific
100	Romania	UMIC	Europe & Central Asia
101	Russian Federation	UMIC	Europe & Central Asia
102	Rwanda	LIC	Sub-Saharan Africa
103	Saint Lucia	UMIC	Latin America & Caribbean
104	Saint Vincent and the Grenadines	UMIC	Latin America & Caribbean
105	Samoa	LMIC	East Asia & Pacific

S.No	Country	Income Status	Geographic Region
106	Sao Tome and Principe	LMIC	Sub-Saharan Africa
107	Senegal	LMIC	Sub-Saharan Africa
108	Serbia	UMIC	Europe & Central Asia
109	Sierra Leone	LIC	Sub-Saharan Africa
110	Solomon Islands	LMIC	East Asia & Pacific
111	Somalia	LIC	Sub-Saharan Africa
112	South Africa	UMIC	Sub-Saharan Africa
113	South Sudan	LIC	Sub-Saharan Africa
114	Sri Lanka	LMIC	South Asia
115	State of Palestine	LMIC	Middle East & North Africa
116	Sudan	LIC	Sub-Saharan Africa
117	Suriname	UMIC	Latin America & Caribbean
118	Syrian Arab Republic	LIC	Middle East & North Africa
119	Tajikistan	LMIC	Europe & Central Asia
120	Tanzania, United Republic of	LMIC	Sub-Saharan Africa
121	Thailand	UMIC	East Asia & Pacific
122	Timor-Leste	LMIC	East Asia & Pacific
123	Togo	LIC	Sub-Saharan Africa
124	Tonga	UMIC	East Asia & Pacific
125	Tunisia	LMIC	Middle East & North Africa
126	Turkey	UMIC	Europe & Central Asia
127	Turkmenistan	UMIC	Europe & Central Asia
128	Tuvalu	UMIC	East Asia & Pacific
129	Uganda	LIC	Sub-Saharan Africa
130	Ukraine	LMIC	Europe & Central Asia
131	Uzbekistan	LMIC	Europe & Central Asia
132	Vanuatu	LMIC	East Asia & Pacific
133	Venezuela (Bolivarian Republic of)	UMIC	Latin America & Caribbean
134	Viet Nam	LMIC	East Asia & Pacific
135	Western Sahara	LMIC	Middle East & North Africa
136	Yemen	LIC	Middle East & North Africa
137	Zambia	LMIC	Sub-Saharan Africa
138	Zimbabwe	LMIC	Sub-Saharan Africa