Public Policy Statement: Social Licensing Approach for Research Development Partnerships for Neglected Tropical Diseases (NTDs)

Scope

This Policy applies to all out-licensed discoveries deemed by Merck Research Labs for the development of medicines and vaccines for neglected tropical diseases (NTDs) for use in least developed countries (LDCs).

Merck has a long history of both in-house research and engagement with external researchers on diseases that are prevalent in low- and middle-income countries.

Merck recognizes that new methods and a broader scope of collaborating—with both public and private entities—are critical to continuing innovation for disease areas where there is limited commercial incentive to motivate adequate investment by the private sector alone – most notably neglected tropical diseases (NTDs) [1]. Merck will continue its interactions with public-private research partnerships in order to understand key research priorities and opportunities and to provide Merck's relevant expertise.

With respect to out-licensing efforts related to discoveries resulting from NTD-related research with external research partners, Merck will adhere generally to the following licensing principles to help ensure equitable access to resulting discoveries:

1. Grant users[2] non-exclusive, royalty-free licenses to relevant intellectual property for the research, development and manufacture of products, technologies or services, for the sole purpose of addressing public health needs for NTDs in least developed countries (LDC)[3].

2. Grant users non-exclusive, royalty-free licenses to such intellectual property to make or have made such products, technologies or services for the sole purpose of commercializing said products in LDCs.

For products resulting from such licenses provided by Merck, Merck will:

1. Consider in good faith the issue of access to these products for other developing countries, which do not qualify as LDCs. This includes considering in good faith the granting of a license under any relevant intellectual property on a case-by-case basis, taking into account the economic development of the countries and the need to facilitate access to disadvantaged populations.

2. Encourage any partners to whom Merck may license a resulting product in LDCs to make it available through donation or at pricing levels commensurate with a nation's level of economic development and to ensure sustainable access.

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[1] See Appendix I for list of NTDs covered by this policy.
[2] "Users" are research partners that have entered into license agreements with Merck to use our intellectual property and/or materials and/or services.
[3] See Appendix II for list of LDCs covered by this policy.

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Appendix I

The neglected tropical diseases and conditions covered by this policy are:

1. Buruli Ulcer
2. Chagas disease (American trypanosomiasis)
3. Cysticercosis,
4. Dengue/dengue hemorrhagic fever
5. Dracunculiasis (guinea-worm disease)
6. Echinococcosis,
7. Endemic treponematoses (Yaws)
8. Foodborne trematode infections
9. Human African trypanosomiasis
10. Leishmaniasis
11. Leprosy
12. Lymphatic filariasis
13. Onchocerciasis
14. Rabies
15. Schistosomiasis
16. Soil transmitted helminthiasis
17. Trachoma
18. Podoconiosis
19. Snakebite
20. Malaria
21. Tuberculosis

Appendix II

Least Developed Countries (LDCs)
LDCs, as defined by the United Nations Office of the High Representative for the Least Developed Countries, Landlocked Developing Countries and the Small Island Developing States (UN-OHRLLS), as of August 6, 2013:

Africa (34)

Angola	Madagascar
Benin	Malawi Mali
Burkina Faso	Mauritania
Burundi	Mozambique
Central African Republic	Niger
Chad	Rwanda
Comoros	Sao Tome and Principe
Democratic Republic of the Congo	Senegal
Djibouti	Sierra Leone
Equatorial Guinea	Somalia
Eritrea	South Sudan
Ethiopia	Sudan
Gambia	Togo
Guinea	Uganda
Guinea-Bissau	United Republic of
Lesotho	Tanzania
Liberia	Zambia

Asia (14)

Afghanistan	Nepal
Bangladesh	Samoa
Bhutan	Solomon Islands
Cambodia	Timor-Leste
Kiribati	Tuvalu
Lao People's Democratic	Vanuatu
Republic	Yemen
Myanmar	

Latin America and the Caribbean (1)

Haiti