Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Home Affairs FDHA

Federal Department of Foreign Affairs FDFA

BILL & MELINDA GATES *foundation*

Memorandum of Understanding between The Bill & Melinda Gates Foundation, The Federal Department of Home Affairs and The Federal Department of Foreign Affairs of the Swiss Confederation

This Memorandum of Understanding (the "MOU") is hereby established by and between the **Federal Department of Home Affairs (FDHA)** and the **Federal Department of Foreign Affairs (FDFA)** at the Swiss Confederation and the **Bill & Melinda Gates Foundation (the "Foundation")**. FDHA, FDFA and the Foundation are each hereinafter referred to as a "Side" and are jointly referred to as the "Sides".

This MOU is not legally binding and any obligations or commitment of funding for projects or as otherwise contemplated by this MOU will be affected through separate agreements between the Sides and/or potential funding recipients.

WHEREAS, the Foundation is an independent, private, charitable foundation which is headquartered in Seattle, Washington, U.S.A., which has as one of its missions the reduction of global health inequities by accelerating the development, deployment, and sustainability of health interventions that will save lives and dramatically reduce the disease burden in developing countries.

WHEREAS, the FDFA hosts the **Swiss Agency for Development and Cooperation (SDC)** whose fundamental aims are to:

- Preventing and overcoming crises, conflicts and catastrophes
- Creating access for all to resources and services
- Promoting sustainable economic growth
- Supporting the transition to democratic, free-market systems
- Helping to shape pro-development, environmentally friendly and socially responsible globalization
- Fighting against poverty

WHEREAS, the FDHA hosts Swissmedic, the **Swiss Agency for Therapeutic Products (Swissmedic)** whose fundamental tasks include:

- Authorization of medicinal products
- Market surveillance of medicinal products and medical devices
- Inspection and licensing of companies
- Authorization and inspection of clinical trials

WHEREAS, the Sides see great potential in a close partnership and wish to coordinate and leverage their respective financial, human, technical and other resources in a cooperation for the purpose of strengthening regulatory systems in resource-constraint countries and increase efficiency in the global health regulatory system in order to accelerate access to important health interventions for diseases that disproportionately affect populations living in these countries.

NOW, THEREFORE, the Sides have elected to memorialize certain mutual understandings and guiding principles for such anticipated cooperation.

I. Objectives of this Memorandum of Understanding

The Sides endeavor to work in concert as partners to achieve the following objectives:

Identify and support opportunities for common projects in the area of regulatory systems strengthening and optimization that will have a meaningful impact for resource-constrained developing countries.

Encourage relevant stakeholders to address the need for strengthening and improve efficiency in regulatory systems as important components in order to improve and accelerate access to health interventions and therapeutic products in developing countries.

Maximize the impact of each Side's funding and activities through coordination and close partnership as well as information and technical data sharing to avoid unnecessary duplication and to yield mutual benefits.

Perform any other activities on which the Sides would agree throughout the timeframe of this agreement.

II. Principles of Cooperation

The Sides decide to cooperate in accordance with the following principles:

Mutual respect. The Sides will cooperate with each other on the basis of their common intention and respect in furtherance of the Objectives as set forth in this MOU.

Common objectives. The Sides will work to ensure a conducive environment for mutual cooperation and common development in furtherance of their shared global health objectives and to have a meaningful impact - focusing on improving access to important health interventions through strengthening and optimization of regulatory systems.

Strategic coordination. The Sides will cooperate with each other on areas of mutual interest, as will be agreed upon by the Sides from time to time and will seek regular opportunities including an annual strategic meeting between the leadership of the Sides, to share and exchange views and objectives through periodic meetings and other communications.

Global access. The Sides intend that the knowledge and information gained from their cooperation be promptly and broadly disseminated and made publically available. The Sides will not share any knowledge or information that would be considered confidential or classified with each other without first discussing appropriate uses for such material, as nothing in this Memorandum should be construed as creating any legal requirements around nondisclosure of confidential or classified material.

III. Areas of Cooperation

The Sides decide to cooperate in their shared global health objectives and anticipate that the following may be areas of particular interest in seeking collaborative opportunities:

- (in the case of BMGF) support a) the development of studies to inform strategies and priorities to optimize the global health regulatory landscape, support b) policy and advocacy efforts to secure engagement and alignment from key stakeholders, facilitate c) partnerships with product developers to accelerate product introduction in priority countries, facilitate d) the collaboration with national regulatory authorities from low- and middle- income countries, and develop e) funding grants to catalyze impact.

- (in the case of SDC) contribute a) in the area of facilitation of political processes and dialogue on country and on global level, and b) with technical support and expertise through its partners on country and global / international level.

- (in the case of Swissmedic) contribute a) scientific expertise in the area of authorization and surveillance of therapeutic products / medical products, and b) expertise in developing and implementing strategic approaches for small and medium sized regulatory authorities.

IV. Miscellaneous

No Partnership, no Agency. Nothing in this MOU establishes or will be deemed to establish a principal-agent relationship, employee-employer relationship, a representative, or joint partnership between the Sides, and neither Side will enter into any contract or commitment on behalf of the other Side.

Compliance with law. Each Side intends to conduct all activities conducted under the MOU in accordance with all applicable laws, regulations and other legal standards, including ethical standards.

Non-Binding MOU; No Commitment of Funds. The proposed cooperation under this non-binding MOU is non-exclusive. All activities within this cooperation framework will be carried out depending on the availability of financial and human resources. Nothing in this MOU will be construed to constitute an obligation or commitment of funds from either Side. This MOU is not legally binding. Any obligation or commitment of funding of Projects or as otherwise contemplated by this MOU will be affected through separate agreements between the Sides.

Use of Name and Press Releases. If either Side wishes to issue a press release announcing this MOU, the subject matter hereof and/or the relationship established hereunder or otherwise recognize and acknowledge the terms hereof, the Side wishing to do so will first contact the other Sides at least fourteen days in advance (unless the Sides decide on a shorter period) to obtain the other Sides' approval of the timing and contents of the press release or announcement before any such announcement is made.

Amendments. This MOU may be amended at any time and from time to time upon the mutual written agreement between the Sides.

Notices. Any notice or request required or permitted to be given or made under this MOU will be in writing. Such notice or request will be deemed to have been duly given or made when it will have been delivered by electronic mail or by overnight courier to the Side to which it is required to be given or made at the address specified below or such other addresses as hereafter notified.

For the BMGF, the FDHA and the FDFA of the Swiss Confederation

Trevor Mundel	Lukas Bruhin	Benno Bättig
President, Global Health	Secretary General	Secretary General
BMGF	FDHA	FDFA

Berne, 22 January 2014