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WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property: the Contribution of Switzerland

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Disclaimer

The views and ideas expressed herein do not necessarily imply or reflect the opinion of the authors. This report is a consolidation of activities described by different stakeholders, with each stakeholder having contributed to the description of activities of his/her own sector. This information could not be systematically verified by the authors and thus they cannot be held accountable.

Foreword

The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) is a comprehensive framework for addressing issues related to innovation and access to essential health technologies for developing countries. It aims to promote innovation, improve access, and build capacities in relevant areas and mobilize resources for these purposes.

Comprising 8 elements, sub-elements and specific actions, the GSPA-PHI identifies a number of stakeholders against each specific action and specifies lead stakeholders within each group. The most important stakeholders are Member States.

To facilitate the implementation of GSPA-PHI, WHO collaborates with many external stakeholders. Internally, work is shared across several departments in headquarters, as well as with regional and country offices. As part of the WHO implementation plan the Department of Public Health, Innovation and Intellectual Property seeks to capture and document national efforts and approaches to implementing the GSPA-PHI and to make information and lessons learned available to other stakeholders.

WHO appreciates this publication by Switzerland which analyses the current and potential contribution of the Swiss institutions involved in the implementation of GSPA-PHI. Switzerland has been an active advocate and promoter of GSPA-PHI during its development. WHO looks forward to the next steps and acknowledges the endeavors of the Swiss Institutions behind this effort.

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Preface

The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) adopted in May 2008 (WHA 61.21) takes up in a comprehensive way actions needed in the area of research and development (R&D), transfer of technology, intellectual property (IP), health system strengthening and financing. The strategy has not only succeeded in integrating the notion of IP as an incentive for R&D, but also in addressing those aspects where such incentives are not sufficient to cover the need for the development of new products to fight diseases which disproportionately affect developing countries and where the potential paying market is small or uncertain. Numerous Swiss actors are active since a long time in the topics covered by GSPA-PHI.

As a prime location of scientific research, Switzerland is home to a major pharmaceutical industry, internationally recognized public health and medical research institutions and non governmental organizations with a broad expertise in international health. Switzerland is committed to providing the best possible conditions for research, adequate protection of intellectual property and access to essential drugs for developing countries. The Swiss public sector is taking into account its responsibility to contribute to publicly finance research institutions, as well as to orient and organize research in order to address the needs of public health also globally. In spite of potentially conflicting policy goals there is a common will to act. Therefore the Swiss federal administration has established in 2005 an expert group on public health and intellectual property, where officials from all concerned federal entities work together towards a coherent position of Switzerland in all fora where these issues are dealt with. This group includes the Federal Office of Public Health, the Swiss Federal Institute of Intellectual Property, the Swiss Agency for Development and Cooperation, the Directorate of Political Affairs of the Foreign Ministry, the State Secretariat for Economic Affairs, the State Secretariat for Education and Research, the Swiss Agency for Therapeutic Products (Swissmedic).

This inter-ministerial group of experts accompanied the negotiation process in WHO towards a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. The issue of the link between public health and intellectual property was first brought to international attention by a South African court case on the price of HIV drugs from 1997 to 2001. This was followed in 2001 by the Doha Ministerial Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health. This Ministerial Declaration, while remaining fully committed to the TRIPS Agreement, called for an implementation of the Agreement that should respect the rights of the World Trade Organization (WTO) Member States regarding public health protection and access to medicines for all.

Since then, Switzerland has been an active player in the various rounds of negotiations that led to the adoption of the GSPA-PHI. In 2003 the World Health Assembly Resolution WHA 56.27 mandated WHO to establish the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), which was chaired by former Swiss President Mrs Ruth Dreifuss and financially supported by Switzerland. The CIPIH report showed the broad challenge and the complexity of the full innovation cycle: access to medicine needs basic research, applied research, drug development, production capacities, regulatory capacity and a health system able to deliver the right medicines at the right time to the right patients. This is linked to research policy and incentives, questions of intellectual property, commerce, pricing, regulation and strengthening of the health system. The CIPIH report was welcomed by resolution WHA59.24 drafted under a Swiss chair, which established the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) with the mandate to negotiate a “soft law” instrument to implement recommendations of the CIPIH report. This IGWG negotiated from December 2006 to May 2008. The GSPA-PHI was adopted by the World Health Assemblies 2008 and 2009 in resolutions WHA 61.24 and 62.16. As the GSPA-PHI states, advances in biomedical science have provided opportunities to develop new, affordable, safe and effective health products and medical devices, particularly those that meet public health needs, and urgent efforts must be made to make these advances more affordable, accessible and widely available in developing countries.

We are convinced that negotiating international instruments is not a goal per se. Instruments such as the GSPA-PHI are only useful if they are implemented and ultimately lead to concrete access of people to medicines. In view of the complexity of the subject and the fact that many actions are already under way, we have decided that our contribution in the initial phase of the implementation of the GSPA-PHI would be to establish a descriptive

overview of the actions taken so far by Swiss actors, both public and private. We have therefore jointly commissioned research on the contribution of five different sectors (the Swiss federal public administration, the academic sector, the NGOs, the private for profit sector and the public private partnerships) towards achieving the elements and objectives of the GSPA-PHI. The mandate was given to the Swiss Tropical and Public Health Institute (Swiss TPH) to provide an overview on how Switzerland is contributing to the GSPA-PHI. Aimed at improving synergies across and within sectors, the report reveals many interesting aspects of the implementation of the GSPA-PHI, and illustrates the comparative advantages and responsibilities of all the implicated Swiss private and public actors for the further commitment of Switzerland in the implementation of the GSPA-PHI. The Swiss TPH mandate has been supervised by the inter-ministerial expert group on public health and intellectual property.

While this publication is primarily to show the Swiss involvement in GSPA-PHI, it is also part of a deliberate effort to improve coherence through the Swiss Health Foreign Policy, the first formal agreement between a ministry of health and a ministry of foreign affairs on a national global health policy adopted in 2006¹. The implementation of the GSPA-PHI is an excellent illustration of the challenges of and need for coherence in a global health policy of a country. Questions of domestic law, where Switzerland has implemented the possibility of compulsory licensing for the manufacturing and export of patented pharmaceutical products in its patent law, national research policy, technical cooperation with emerging economies, development cooperation to strengthen national health systems and Switzerland's position in negotiations such as those in WHO, are closely interlinked. Each of these subjects falls under the responsibility of a different ministry. This requires a close and open minded collaboration between them.

The Swiss contribution to the GSPA-PHI needs also to be put into the specific national context. First, the federal structure provides political autonomy to the cantons with consequent heterogeneity in terms of planning of services, including educational and scientific institutions, which are decentralized. Second, the Swiss political system is characterized by the consensus democracy and multiparty government with proportional representation and changing coalitions. Third, as a consequence of the subsidiary role of the Confederation, cantons are responsible for many services, including certain education policies. Fourth, as a result of this, Switzerland has a clear bottom-up approach on setting priorities for the allocation of government funding for research, where the scientifically most promising and best project will be funded. It is therefore difficult to impose a top-down approach, but it can make an important difference to make researchers aware of the challenge posed by the GSPA-PHI and invite them to address the research needs of developing countries through existing funding channels. Thus, many of the activities described in this report result from the public sector being an important partner in R&D, and from private initiatives (public private partnerships, private for profit or NGOs).

Providing a comprehensive overview of the results achieved so far in implementing the GSPA-PHI by the various Swiss stakeholders has been a complex undertaking. It is however worth noting that, as a first consequence of this report on Swiss implementation of GSPA-PHI, awareness of the importance of further coordination among all the involved stakeholders has been raised. Effective information sharing has started and efforts to increase policy coherence have been initiated. We foresee further progress in this area and are confident that this report, from a Swiss perspective, will contribute to achieve the goals of the GSPA-PHI.

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¹ <http://www.bag.admin.ch/themen/internationales/11103/11523/index.html?lang=en>

Swiss Health Foreign Policy: an instrument to enhance coordination and coherence

An agreement on Swiss health foreign policy objectives was adopted by the Federal Department of Foreign Affairs and the Federal Department of Home Affairs (9 October 2006). The main goals of the Swiss health foreign policy have been (i) to protect the health interests of the Swiss population, (ii) to harmonise national and international health policies, (iii) to improve the effectiveness of international collaboration in the health areas, (iv) to improve the global health situation, and (v) to safeguard Switzerland's role as a host country to international organizations and a base for major companies working in the health sector. Should such interests contain certain conflicting elements, the health foreign policy is meant to reconcile divergences. The complex issues at stake in the GSPA-PHI call for coordination among the different governmental authorities in charge of public health, development cooperation, research promotion, intellectual property protection, economic questions and foreign policy in order to reach maximum coherence on two different levels: one where national priorities must be checked against international developments, and one where specific interests of public or private actors are balanced with those of other actors involved. The necessary level of coherence – not to be confused with complete alignment of position – is achieved through the coordinating efforts of the interdepartmental (inter-ministerial) expert group on public health and intellectual property. The mandate of this expert group, whose members represent all interested government bodies, is to contribute to the implementation of several medium-term goals and priorities defined by the Swiss health foreign policy. The following three (out of a total of 18) goals are particularly relevant in this context:

- "Improve international access to essential drugs – both recognized and newly developed" (goal 9).
- "Promote research to strengthen the empirical basis for effective health interventions. Influence the dialogue on global research priorities in the health field in order to reduce the disproportionate burden of disease in the southern hemisphere in a sustainable way" (goal 12).
- "Ensure appropriate protection for intellectual property as an essential incentive for research into, and development of new drugs and vaccines" (goal 18).

Abbreviations

AAI	Accelerating Access Initiative
ACT	Artemisinin Combination Therapy
AEMRN	Afro-European Medical and Research Network
AMFm	Affordable Medicine Facility for malaria
ARCEAU	Alliance for Clinical Research & Clinical Epidemiology
ARV	AntiRetroViral (drug)
AT	Antenna Technologies
BD	Berne Declaration
BuruliVac	Buruli Vaccine Research Project
CERN	European Organisation for Nuclear Research
CIPIH	Commission on Intellectual Property, Innovation and Public Health
COHRED	Council on Health Research for Development
COMPITCH	Mexico based umbrella organisation for indigenous healers and midwives in Chiapas
CPDD	Consortium for Parasitic Drug Development
CRO	Contract Research Organisation
DNDi	Drugs for Neglected Diseases initiative
DRC	Democratic Republic of Congo
EANETT	Eastern African Network on Trypanosomiasis
EDCTP	European and Developing Countries Clinical Trials Partnership
EMVDA	European Malaria Vaccine Development Association
EPFL	Federal Institute of Technology Lausanne
ETHZ	Swiss Federal Institute of Technology Zurich
FDFA	Federal Department of Foreign Affairs
FDJP	Federal Department of Justice and Police
FIND	Foundation for Innovative New Diagnostics
FOPH	Federal Office of Public Health
FORS	Swiss Foundation for Research in Social Sciences
FRIND	Fund for Research and Development in Neglected Diseases
GAVI	Global Alliance for Vaccines and Immunization
GFATM	Global Fund to fight AIDS, Tuberculosis and Malaria
GFHR	Global Forum on Health Research
GHI	Global Health Institute
GIPAP	Glivec® International Patient Assistance Program
GMP	Good Manufacturing Practice
GSPA-PHI	WHO Global Strategy on Public Health, Innovation and Intellectual Property
HRP	Special Programme on Human Reproductive Health Research
HR	Human Resources
HUG	University hospital of Geneva
IAEA	International Atomic Energy Agency
ICDRA	International Conference of Drug Regulatory Authorities
IGWG	Intergovernmental Working Group on public health, innovation and intellectual property
IMCI	Integrated Management of Childhood Illness
IP	Intellectual Property
IPI	Swiss Federal Institute of Intellectual Property
ITN	Insecticide Treated Net
KFPE	Commission for Research Partnerships with Developing Countries
LDC	Least Developed Country
LPRI	Federal Law to Promote Research and Innovation
MMS	Medicus Mundi Switzerland
MMV	Medicine for Malaria Venture
MoH	Ministry of Health
MoU	Memorandum of Understanding
MSF	Médecins Sans Frontières

NCCR	National Centres of Competence in Research
NEPAD	New Partnership for Africa's Development
NFSD	Novartis Foundation for Sustainable Development
NGO	Non-Governmental Organisation
NITD	Novartis Institute for Tropical Diseases
NVGH	Novartis Vaccine Institute for Global Health
ODA	Official Development Assistance
PDP	Product Development Partnership
PMI	President's Malaria Initiative
PPP	Public Private Partnership
R&D	Research & Development
RAFT	le Réseau en Afrique Francophone pour la Télémédecine
RPDC	Research Partnership with Developing Countries
SAMS	Swiss Academy for Medical Sciences
SCNAT	Swiss Academy of Sciences
SCIH	Swiss Centre for International Health
SCOPEs	Scientific Cooperation between Eastern Europe and Switzerland
SDC	Swiss Agency for Development and Cooperation
SECO	State Secretariat for Economic Affairs
SER	State Secretariat for Education and Research
SMIH	Service de Médecine Internationale et Humanitaire
SNIS	Swiss Network of International Studies
SNSF	Swiss National Science Foundation
SRC	Swiss Red Cross
Swiss TPH	Swiss Tropical and Public Health Institute
TB	Tuberculosis
TDR	UNDP/World Bank/WHO's Special Programme for Research and Training in Tropical Diseases
TTCIH	Tanzanian Training Centre for International Health (TTCIH)
UNAIDS	Joint United Nation Programme on HIV/AIDS
UNCTA	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNFPA	United Nations Population Fund
UNICEF	United Nations' Children Fund
UNIDO	United Nations Industrial Development Organization
VCT	Voluntary Counselling and Testing
WFP	World Food Programme
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WIRE	Web for Interdisciplinary Research and Expertise
WTO	World Trade Organization
ZHUAS	Zurich University of Applied Sciences

Table of Contents

Foreword	II
Preface	III
Executive Summary	1
1 Introduction	2
1.1 The different elements of the GSPA-PHI	2
1.2 The policy background for the implementation of the GSPA-PHI	3
2 Aims and Objectives	4
3 Methodology	5
4 Contributions of the Different Sectors to the GSPA-PHI	6
4.1 Swiss Federal Offices	6
4.1.1 The State Secretariat for Education and Research (SER)	6
4.1.2 The Swiss Agency for Development and Cooperation (SDC)	7
4.1.3 The State Secretariat for Economic Affairs (SECO)	8
4.1.4 The Swiss Federal Office of Public Health (FOPH)	9
4.1.5 The Swiss Federal Institute of Intellectual Property (IPI)	10
4.1.6 Swissmedic	11
4.1.7 Contributions of the Federal Offices to the different elements of the GSPA-PHI	11
4.2 The Academic Sector	11
4.2.1 The NCCR North–South Programme	12
4.2.2 Programme “Research partnerships with developing countries” (RPDC)	12
4.2.3 Research in Development and Cooperation of Swiss Universities for Applied Science	13
4.2.4 Programme “Scientific Cooperation between Eastern Europe and Switzerland” (SCOPEs)	13
4.2.5 Capacity development of SDC in the scientific sector	13
4.2.6 Swiss Network for International Studies (SNIS)	14
4.2.7 Swiss Commission for Research Partnerships with Developing Countries (KFPE)	14
4.2.8 Bilateral research partnerships with priority countries	14
4.2.9 Other projects of the academic sector	15
4.2.10 The contribution of the academic sector to the elements of the GSPA-PHI	16
4.3 Non-Governmental Organisations	17
4.3.1 Médecins Sans Frontières (MSF) Switzerland	17
4.3.2 Swiss Red Cross (SRC)	18
4.3.3 Novartis Foundation for Sustainable Development (NFSD)	19
4.3.4 Afro-European Medical and Research Network (AEMRN)	20
4.3.5 Antenna Technologies (AT)	20
4.3.6 Esperanza Medicines Foundation	20
4.3.7 mediCuba-Suisse	20
4.3.8 mission 21	21
4.3.9 medico international schweiz	21
4.3.10 Berne Declaration (BD)	21
4.3.11 Swiss Aids Care International	22
4.3.12 SolidarMed	22
4.3.13 NGO contribution to the elements of the GSPA-PHI	22

4.4	The Private For-profit Sector	23
4.4.1	Novartis	23
4.4.2	Roche	25
4.4.3	The contribution of the private for-profit sector to the elements of the GSPA-PHI	27
4.5	The Private–Public Partnerships	28
4.5.1	Global/International PPPs	28
4.5.2	Local PPPs	30
4.5.3	Contributions of the PPPs to the different elements of the GSPA-PHI	31
5	Discussion	33
5.1	Limitation of the current assessment	33
5.2	Conscious effort and systematic approach needed	33
5.3	Trends in the contribution and identified gaps	33
5.4	The current policy environment in Switzerland related to the implementation of the GSPA-PHI	34
5.5	The issue of sustainable financing	35
6	Conclusions	35
7	References	36
	Epilog Swiss TPH, the mandated authors of the study	38
	Appendix	39
	Table 2: WHO Global plan of action on public health, innovation and intellectual property - Swiss federal offices interested	39

Executive Summary

After more than six years of negotiations, the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) was endorsed by the sixty-first World Health Assembly in May 2008. The GSPA-PHI promotes new thinking on innovation and access to medicines. It provides a framework with more than 100 specific activities for needs-driven research, rather than purely market-driven research, focusing on target diseases that disproportionately affect people in developing countries. The framework is structured into eight key elements: (1) prioritising research and development needs, (2) promoting research and development, (3) building and improving innovative capacity, (4) transfer of technology, (5) application and management of intellectual property to contribute to innovation and to promote public health, (6) improving delivery and access, (7) promoting sustainable financing mechanisms, and (8) establishing monitoring and reporting systems.

The Swiss government has been heavily engaged in the different phases of the negotiation process, and after the endorsement of the action plan, the focus lies now on its implementation.

The aim of this assessment is to explore the contribution of Switzerland regarding the implementation of the GSPA-PHI, with the following specific objectives:

- to identify the chief actors contributing to the strategy;
- to describe the contribution and activities of five major sectors in relation to the WHO strategy; and
- to describe existing approaches to implementing the WHO strategy.

The contribution of Switzerland regarding the implementation of the GSPA-PHI was assessed in two steps. In a first step, an individual assessment of activities contributing to the implementation of the GSPA-PHI was done by five major actors, namely by the Federal Office of Public Health (FOPH) and the Swiss Federal Institute of Intellectual Property (IPI) for the Federal Offices, by the Swiss Academy of Medical Sciences (SAMS) for the academic sector, by Medicus Mundi Switzerland (MMS) for the non-governmental organisations (NGOs), by Interpharma for the private for-profit sector, and by the Swiss Tropical and Public Health Institute (Swiss TPH) for the public-private partnerships

(PPPs). In a second step, the five individual assessments were consolidated into one report. This step required the addition of further information about activities contributing to the implementation of the action plan because of the partly incomplete individual reports. The additional information was mostly extracted from information available on the Internet but was also obtained through contacts with experts in the field.

The current assessment shows that the Swiss sectors assessed in this report have proactively implemented all eight elements of the GSPA-PHI, although only the government has addressed all of them because element 8 involves only WHO and the government. It is noteworthy that there is a gap in the limited or dispersed interventions of the PPPs and the private for-profit sector in the domain of traditional medicine.

Moreover, while the list of Swiss activities is quite comprehensive, it was beyond the scope of the assessment to determine the weight of the described activities, their resulting effects, or which activities should be sustained in the future.

Furthermore, the assessment has a number of limitations, among others, the lack of a common methodology, shortcomings of the reporting tool, and to a certain extent, incompleteness in the reports submitted by different sectors. However, even taking the limitations into account, a voluntary coordination in terms of exchange of information and communication among different actors could enhance the synergies in respect to implementation of the GSPA-PHI.

1 Introduction

After more than six years of negotiations, the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI) of the World Health Organization (WHO) was endorsed in May 2008 by the sixty-first World Health Assembly. The GSPA-PHI outlines more than 100 specific actions across eight elements. The elements are described in more detail below in section 1.1. This global strategy and plan of action aims at providing a medium-term framework to secure an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries, proposing clear objectives and priorities for research and development, and estimating funding needs in this area [1].

The Swiss government has been heavily engaged in the different phases of the negotiation process. Through the Swiss chairmanship of the Commission on Intellectual Property, Innovation and Public Health (CIPIH), Switzerland has provided crucial contributions to better understanding the determinants and challenges of innovation as an essential element for improving the health status of the most deprived populations. In the subsequent negotiating process of the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (commonly referred to as IGWG), the Swiss government played the important role of facilitating an exchange of views and informal as well as formal discussions among WHO Member States, particularly involving industrialised countries and emerging economies and developing countries. The Swiss government has thus contributed to finding a delicate balance between the protection of intellectual property rights as an incentive for innovation and the necessity of making research results and new medical products accessible to low-income countries.

Now, as the negotiation process is over and the GSPA-PHI is endorsed, the focus lies on implementing the action plan. With the mapping of already existing activities that are contributing to implementation of the GSPA-PHI, the Swiss government would like to identify the contribution of Switzerland.

1.1 The different elements of the GSPA-PHI

Adopted by the World Health Assembly, the GSPA-PHI promotes new thinking on innovation and access to medicines. It provides a framework for needs-driven research, rather than purely market-

driven research, focusing on target diseases that disproportionately affect people in developing countries. It defines research and development (R&D) objectives and priorities and attempts to identify sustainable funding sources and mechanisms.

The GSPA-PHI is grouped into eight key elements, which are further divided into sub-elements with specific activities (see Appendix 1). The eight key elements are as follows:

(1) Prioritising research and development needs (3 sub-elements, 13 specific activities)

Element 1 highlights that the health research and development policies of developed countries need to reflect adequately the health needs of developing countries. Gaps in research on Type II and Type III diseases and on the specific R&D needs of developing countries in relation to Type I diseases shall be identified². Prioritising R&D according to public health needs in developing countries, including health-system strengthening activities, support of South–South partnerships and a focus on traditional medicine, are regarded as very important.

(2) Promoting research and development (5 sub-elements, 22 specific activities)

This element encourages the promotion of national health research programs that take into consideration human resources and the implementation of research networks and initiatives at the national, regional, and international levels to increase research coordination. It stresses the need to increase developing countries' capacities to analyse and manage clinical trial data, to access publication and information related to research knowledge, results, and technology, and to publish peer-reviewed papers.

(3) Building and improving innovative capacity (5 sub-elements, 18 specific activities)

Element 3, which is related to capacity building, especially in developing countries, represents an essential component in the realisation of the GSPA-PHI. Related investments in human resources (HR), knowledge sources, and regional centres of excellence shall be promoted. Associated policy support shall be provided to support effective policies for HR strengthening and development of innovative approaches toward safe, high-quality,

² *Type I diseases* are incident in both rich and poor countries, with large numbers of vulnerable populations in each. *Type II diseases* are incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries. *Type III diseases* are those that are overwhelmingly or exclusively incident in developing countries. The prevalence of diseases and thus their categorisation in the typology can evolve over time.

and good manufacturing practices for traditional medicine.

(4) Transfer of technology

(3 sub-elements, 9 specific activities)

Element 4 highlights the need to support North–South and South–South development cooperation, partnerships, and networks to build and improve transfer of technology related to health innovation.

Of particular importance is technology that considers public health aspects. A feasibility analysis is envisaged to assess the advantages and disadvantages of innovative approaches such as voluntary patent pools.

(5) Application and management of IP to contribute to innovation and to promote public health

(3 sub-elements, 14 specific activities)

Element 5 addresses relevant aspects of the current international regime on intellectual property that are related to the promotion of innovation capacity in developing countries and the protection of public health. Management and application of intellectual property rights with regard to public health, however, also include other aspects, such as how to negotiate license or material transfer agreements, how to read, analyse, and examine patent claims, and how to draft patenting strategies for research institutes or pharmaceutical companies.

(6) Improving delivery and access (3 sub-elements, 21 specific activities)

Element 6 refers to improved delivery and access that shall be achieved through increased investments into the health delivery infrastructure and financing health products. The development of sustainable financing mechanisms as well as the promotion of human resources development are hereby emphasised. Furthermore, the quality, safety, and efficacy of health products and procedures shall be promoted through the following: strengthened national health authorities, developed country poverty reduction strategies, compliance with good manufacturing practices, compliance with ethical principles for clinical trials, and strengthened regional networks for clinical trial implementation. A competitive market environment shall also be created to improve availability and affordability of health products in line with public health policies and needs, e.g., through generic drug production, elimination of import tariffs, and monitoring of prices.

(7) Promoting sustainable financing mechanisms

(2 sub-elements and 6 specific activities)

The importance of identifying, securing, and ensuring sustainable financing mechanisms for R&D represents a key element. A focus is placed on establishing an expert group for organisational

purposes, setting up a database for financing sources, disbursing enough funds for further R&D, promoting best practices in public–private partnerships for research and product development, especially in developing countries, and monitoring their performance.

(8) Establishing monitoring and reporting systems

(2 sub-elements, 5 specific activities)

A system shall be put in place to monitor performance and progress of the overall global strategy as well as of each element. A monitoring of investments in R&D in developing countries, of incentive mechanisms, and of the effect of intellectual property rights laws on development and access to medicine products shall also be ensured. A progress report will be submitted to the Health Assembly through the Executive Board every two years. A comprehensive evaluation of the strategy will be undertaken after four years.

The WHO has taken on a guiding role and has the goal of supporting member states in developing and harmonising national R&D plans and coordinating joint efforts. Several stakeholders are or will be implementing the eight elements and 108 corresponding activities³ defined in the GSPA-PHI. These stakeholders include: the WHO, WHO Member States, non-governmental organisations (NGOs), the pharmaceutical industry, academia, civil society organisations, the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO), the United Nations Conference on Trade and Development (UNCTAD), and the United Nations Industrial Development Organization (UNIDO).

1.2 The policy background for the implementation of the GSPA-PHI

In any country, activities undertaken to implement the GSPA-PHI will take place in a given environment, more or less conducive to effective and efficient interventions aimed at improving needs-driven innovation and access to essential medical products for those in greatest need. Therefore, it is critical to consider the existing set of national policies because they are a key determinant of the implementation process. It is beyond the scope of the present exercise to explore all the existing policies and regulations affecting the complex elements of the GSPA-PHI. However, the following elements were taken into account:

Switzerland is an industrialised democratic country with an important trade sector, a long tradition of diplomacy and development aid, and strong

³ See Appendix 1.

scientific and research institutions. These activities are supported and regulated by a wide array of policy and legal instruments in the respective domains of health, education, research and development, innovation and technology, and industry and trade, to name only a few of the most relevant sectors for the GSPA-PHI.

The Swiss government has developed and adopted laws and policies at the federal level that frame many interventions of relevance for the GSPA-PHI, including:

- The Federal Council's Message on the Continuation of Technical Cooperation and Financial Aid for Developing Countries 2009–2012 presents a unified strategy for the development cooperation of the Swiss government that aims, among other things, to help improve access of developing countries to basic resources in education, health, and hygiene and to develop knowledge and technologies in these countries [2].
- The “SDC Health Policy” of the Swiss Agency for Development and Cooperation (SDC) highlights the principles of equal partnerships with developing countries, policy and technical support based on these countries' self-defined needs, and a comprehensive approach to health and its determinants [3].
- The “Federal Law to Promote Research and Innovation (LPRI)”⁴ determines the principles of the promotion of scientific research and innovation and the support of the evaluation and application of research results, of the control of the coordination of research organs, and of the efficient use of federal funds for research and innovation [4].
- The recent amendment (July 2008) of the Patent Act makes provision for research exemption and compulsory licensing for the manufacturing and export of patented pharmaceutical products and thus facilitates access of the least developed countries to production capacities in Switzerland in order to procure medicines of utmost public health importance to them, to name only a few [5].

While the existence, relevance, and potential positive or negative interactions of Swiss policies in various sectors are not explored here, it is important to keep the Swiss legislative and regulatory background in mind when reading the report and for further qualifying the analysis.

⁴ Forschungs- und Innovationsförderungsgesetz (FIGG) / Loi fédérale sur l'encouragement de la recherche et de l'innovation (LERI) / Legge federale sulla promozione della ricerca e dell'innovazione (LPRI), SR 240.1

2 Aims and Objectives

The aim of this assessment is to explore the contribution of Switzerland regarding the implementation of the GSPA-PHI.

The specific objectives are as follows:

- to identify the chief actors contributing to the strategy;
- to describe the contribution and activities of five major sectors in relation to the WHO strategy; and
- to describe existing approaches to implementing the WHO strategy.



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3 Methodology

The approach to assessing the contribution of Switzerland regarding the implementation of the GSPA-PHI has been made in two steps.

1. Step one included an individual assessment of activities contributing to the implementation of the GSPA-PHI done by five major sectors, namely the Federal Office of Public Health (FOPH) and the Swiss Federal Institute of Intellectual Property (IPI) for the Federal Offices, by the Swiss Academy of Medical Sciences (SAMS) for the academic sector, by Medicus Mundi Switzerland (MMS) for the NGOs, by Interpharma for the private for-profit sector, and by the Swiss Tropical and Public Health Institute (Swiss TPH) for the public-private partnerships (PPPs).
2. Step two included the consolidation of the five individual assessments into one final report. Because the information provided by the individual assessments was partly incomplete, further information on activities contributing to the implementation of the action plan was added during the process of consolidating the different contributions. The additional information was mostly extracted from information available on the Internet but was also obtained through contacts with experts in the field.

The following experts were contacted:

- Martine Berger, MD, specialised in international public health and policy advice on research for health, and involved in the development of the WHO Health Research Strategy and of the GSPA-PHI;
- Professor Matthias Hamburger, Head of the Institute of Pharmaceutical Biology, University of Basel;
- Slim Slama, MD, MPH, Programme Director of the Geneva Health Forum, Geneva University Hospitals; and
- Laurent Miéville, Vice-President ASTP and Director of Unitec, Office of Technology Transfer, University of Geneva.

The assessment describes current activities only. However, relevant past activities that are still actualised (e.g., the amendment of the Patent Act, SR 232.14) were also included. Another inclusion criterion is related to the actors having Swiss roots. For the private for-profit sector, only Roche and Novartis were included while other companies such as Pfizer, Merck, GlaxoSmithKline, etc., were



excluded for not having Swiss roots. The same criterion was chosen for the selection of the PPPs. Some well-known international PPPs such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), UNITAID, and the Global Alliance for Vaccine and Immunization (GAVI), although registered and having their headquarters in Switzerland, were excluded for this assessment because the Swiss component concerns only location in Switzerland and their activities cannot be regarded as a Swiss contribution to the implementation of the WHO plan of action.

4 Contributions of the Different Sectors to the GSPA-PHI

The following overview describes briefly the key activities of the Swiss Federal Offices, of the academic sector, of the NGOs, of the private for-profit sector, and of the PPPs contributing to the implementation of the GSPA-PHI. The activities are outlined and framed according to these sectors; however, to a certain extent, overlaps are inherent to the activities of the strategy. Details of the contribution of each actor to the GSPA-PHI are given in Appendix 1.

4.1 Swiss Federal Offices

In Switzerland, the Federal Administration is composed of seven departments, the Federal Chancellery, and roughly 90 offices. Each department has a member of the Federal Council as its head and is divided into different units.

Four out of the seven departments have at least one unit that runs different activities contributing to the implementation of the GSPA-PHI, as follows:

- the Federal Department of Home Affairs comprises the Federal Office of Public Health and the State Secretariat for Education and Research;
- the Federal Department of Foreign Affairs comprises the Swiss Agency for Development and Cooperation;
- the Federal Department of Economic Affairs comprises the State Secretariat for Economic Affairs;
- the Swiss Federal Institute of Intellectual Property has a service agreement with the Federal Department of Justice and Police; and
- Swissmedic, the Swiss Agency for Therapeutic Products, has a service agreement with the Federal Department of Home Affairs [6].

In the following subsection, the different contributions of each of these units are described more in detail.

4.1.1 The State Secretariat for Education and Research (SER)

SER is the federal government's specialised agency for drawing up and implementing policy in the area of science, research, university, and space policy in Switzerland. It coordinates related activities within the Federal Administration and ensures cooperation with the cantons [7].



SER offers support to different programmes and institutes that run activities that fall within the scope of the WHO action plan, as follows:

- supporting the Swiss TPH, which has a strong research focus on diseases that are prevalent in the South and in Eastern Europe and which is involved in capacity building within health systems of developing countries;
- supporting two high-level research centres, the Centre Suisse de Recherches Scientifiques in Côte d'Ivoire and the Ifakara Health Institute in Tanzania;
- supporting the Swiss Vaccine Research Institute in Lausanne, which is active in the search for a vaccine against HIV, through the international "Collaboration for AIDS Vaccine Discovery";
- supporting the Global Health Institute (GHI) of the Federal Institute of Technology Lausanne (EPFL), which is contributing to the understanding, diagnosis, prevention, and treatment of infectious diseases. The GHI comprises eight groups, all engaged in different facets of research linked to human health but with a strong emphasis on diseases of global importance such as HIV/AIDS, tuberculosis (TB), and malaria;
- supporting the Swiss Network for International Studies (SNIS, which promotes academic research on phenomena that transcend traditional nation–state boundaries. The SNIS strongly encourages pluri-disciplinary research and fosters collaboration among Swiss organisations of higher education, international organisations, and NGOs.
- taking part in the "European and Developing Countries Clinical Trials Partnership" (EDCTP), which aims to develop new clinical trials and to strengthen regional capacities to combat HIV

and AIDS, malaria, and TB in developing countries, in particular in sub-Saharan Africa;

- participating in several COST research programmes (COST - European cooperation in the field of scientific and technical research); WHO is also a member of some COST research programmes;
- participating in the 7th EU Framework Programme on Research and Development. This programme finances, among others, projects in the fields of cardiovascular diseases, diabetes, cancers, chronic respiratory diseases, and public health issues (e.g., tobacco use, physical inactivity, unhealthy diets, and the harmful use of alcohol) in Southern and Eastern countries and in international cooperation; and
- signing bilateral research partnerships for fostering scientific collaboration with different priority countries, such as India and China. Some of these partnerships cover health topics as well. Because Swiss academic institutions coordinate these programs, these partnerships are described in more detail in section 4.2.8.
- providing the funds for and mandating the Swiss national Science Foundation (SNSF) that established the NCCR programme North South

The SER also commissioned the Web for Interdisciplinary Research and Expertise (WIRE) - a think tank of Bank Sarasin & Co Ltd and Collegium Helveticum of the Swiss Federal Institute of Technology Zurich (ETHZ) and the University of Zurich - to deliver a preliminary study of "open source in pharmaceutical research and the health service".

With these different activities, the SER is contributing to elements 1, 2, 3, 4, and 6 of the action plan.

4.1.2 The Swiss Agency for Development and Cooperation (SDC)

SDC is Switzerland's international cooperation agency within the Federal Department of Foreign Affairs. In collaboration with other concerned federal offices, SDC is responsible for the overall coordination of development activities and cooperation with Southern countries and Eastern Europe, as well as for the humanitarian aid delivered by the Swiss Confederation [8].

SDC supports health projects in bilateral cooperation with the following focus countries: Chad, Mozambique, Tanzania, Mali, Benin, Burundi, Rwanda, Democratic Republic of Congo (DRC), Bosnia-Herzegovina, Ukraine, Tajikistan, Moldova,



and Kyrgyzstan. Most of the projects focus on strengthening health systems and health reform and are thus supporting governments in implementing the recommendations of the WHO plan of action.

Furthermore, SDC is supporting governments in implementing the GSPA-PHI through financial and intellectual contributions and policy dialogue with the following multilateral organisations: United Nations Development Programme (UNDP), United Nations Population Fund (UNFPA), Joint United Nations Programme on HIV/AIDS (UNAIDS), the GFATM, United Nations' Children Fund (UNICEF), WHO, the Special Programme for Research & Training in Tropical Diseases (TDR), the Special Programme on Human Reproductive Health Research (HRP), the African Development Bank, the World Bank, and the World Food Programme (WFP).

Against that background, the SDC role as part of the Swiss contribution involves a focus on the following elements of the WHO plan of action:

- contributing to the National Centre of Competence in Research (NCCR) North-South with health, planning, and sanitation as one research focus;
- supporting various research institutions in some focus countries such as the Ifakara Health Research and Development Centre in Tanzania, which has the mission to develop and sustain district-based health research and development capable of generating new knowledge and relevant information for public health policy and action;
- supporting national health programmes in countries such as Tanzania, Mozambique, Rwanda, Burundi, Bosnia-Herzegovina, and Kyrgyzstan;
- supporting Primary Health Care Programmes (including social protection), e.g., in the East and Southern Africa region in Tanzania, Mozambique, Rwanda, DRC, Burundi, Chad, Mali, and Benin;

- partnering with and/or supporting different PPPs such as Medecins for Malaria Venture (MMV), Drugs for Neglected Diseases initiative (DNDi), NATNETS in Tanzania, and the Tanzanian Training Centre for International Health (TTCIH) in Ifakara;
- piloting and capitalising on experiences with new aid modalities, fostering aid coordination among all stakeholders involved, with a sector-wide approach in selected partner countries such as Tanzania, Mozambique, Rwanda, Burundi, and Kyrgyzstan and contribution to Health Sector Budget Support in Mozambique, Tanzania, and Kyrgyzstan; in addition, supporting the planning of human resource development, investment, and financing.
- through facilitation, technical, and financial support, contributing to the prioritisation of health care in national agendas, especially in countries where health is a sector focus in the SDC cooperation strategy: Mozambique, Tanzania, Mali, Benin, Burundi, Rwanda, DRC, Bosnia-Herzegovina, Ukraine, Tajikistan, Moldova, and Kyrgyzstan;
- providing support to the institutional building of traditional medicine associations to improve their efficiency, their lobbying ability, and their complementarities with the "modern" system (Tanzania, Mali);
- providing a core contribution and board membership in TDR, a special programme co-sponsored by UNICEF, UNDP, World Bank, and WHO that funds research in infectious tropical diseases and provides support and training to researchers and institutions in the countries where these diseases occur; TDR has developed its own strategy for implementing the parts of the GSPA-PHI most relevant to its expertise and focus; and
- supporting the Council on Health Research for Development (COHRED) and the Global Forum on Health Research (GFHR). COHRED is specialised in supporting countries in areas such as health research system assessment and development, policy development, priority setting, and research



communication/knowledge translation. In recent years, it has developed a new line of activity to support pharmaceutical innovation and access to essential medical products in Africa, in collaboration with New Partnership for Africa's Development (NEPAD) and the WHO/Public Health and Innovation Secretariat, thus contributing to early implementation of the GSPA-PHI. The GFHR is committed to demonstrating the essential role of research and innovation for health and health equity, benefiting poor and marginalised populations. In November 2010, COHRED and the GFHR agreed to organisational integration.

SDC is contributing to elements 1, 2, 3, 4, and 6 of the action plan.

4.1.3 The State Secretariat for Economic Affairs (SECO)

SECO is the federal government's centre of expertise for all core issues relating to economic policy. Its aim is to ensure sustainable economic growth by putting in place the necessary regulatory and economic policy conditions. In terms of foreign trade policy, SECO is active in formulating efficient, fair, and transparent rules for the world economy [9].

SECO is working with specialists from the Institute of Intellectual Property as well as international and local experts on various bilateral projects aimed at improving and increasing the use of intellectual property (also in the area of public health and intellectual property) in developing countries as part of its economic development co-operation efforts. The overarching goal of the projects is to support developing countries in the development and implementation of an up-to-date system geared to their needs to protect intellectual property rights and, through that, to strengthen national development strategies, such as the fight against poverty and the encouragement of commerce, while upholding the provisions of the WTO/TRIPS agreement. SECO supports different projects in Vietnam, Laos, Azerbaijan, Ghana, Egypt, and Serbia.

In Vietnam, for example, Switzerland was able to aid in the legal structuring of its new national legislation on intellectual property within the framework of the "Swiss Vietnamese Intellectual Property Project" and its predecessor project. The project included presenting various workshops on the topic of public health and intellectual property such as the protection of clinical test data and intellectual property legislation in the areas of biotechnology, pharmaceuticals, and agro technology.

WEIN (Economic Cooperation and Development Infrastructure Financing), SECO's infrastructure support programme, is carrying out public health projects within the framework of mixed financing in Vietnam, Jordan, and Egypt. It involves technology transfer accompanied by technical assistance. In Jordan, projects are related to health care waste management in hospitals and ambulances for the international airports. In Egypt, projects target restructuring the blood transfusion system and upgrading radiology services in the hospitals of the Ministry of Health and Population.

SECO is mainly contributing to elements 3 and 4 of the action plan.

4.1.4 The Swiss Federal Office of Public Health (FOPH)

As the national authority in health matters, the FOPH represents Switzerland in international organisations and in dealings with other countries. Within Switzerland, it is responsible—together with the cantons—for public health and the development of national health policy [10].

FOPH is also supporting activities on the international level that contribute to the implementation of the GSPA-PHI.

For an initial period of two years, FOPH is financing the secondment of an intellectual property expert of



the Federal Administration at the secretariat of WHO. This expert will advise and coordinate the implementation of the GSPA-PHI with regard to its intellectual property aspects.

In 2005, the FOPH and the Federal Institute of Intellectual Property jointly created a core group of experts to coordinate the position of Switzerland on all issues concerning public health and intellectual property. This group brings together representatives of the ministries and offices responsible for health, intellectual property, development cooperation, research, economy and commerce, human rights, drug approval, and foreign affairs.

At the Graduate Institute in Geneva, the FOPH supports the global health program organising courses on 'health diplomacy'. Additionally, it has also foreseen integration of a course on 'health and intellectual property'.

In 2005, Switzerland and China concluded a Memorandum of Understanding (MoU) aimed at strengthening their relations and cooperation in the health sector. The MoU provides a framework for mutual exchanges on infectious diseases, health personnel, traditional Chinese medicine, and non-communicable diseases. The intense cooperation led to two courses on global health diplomacy organised by the FOPH in China in 2009 and in 2010, respectively. In addition, there will be partnerships between various Swiss cantons and Chinese cities on hospital planning.

FOPH is competent to fix the maximal price at which a new drug (proved to be efficient, appropriate, and economical) can be reimbursed by the federal health insurance. Thus, it generally includes a financial incentive (premium for innovation) to promote innovation of new drugs (about 10–20% of the manufacturing price).

The draft Federal Law relating to human research—which will be submitted to the Swiss Parliament for adoption in autumn 2011⁵—is based on ethical principles recognised at the international level. This national law will also regulate clinical trials in the future and assure that they are carried out in accordance with these ethical principles.

With these different activities, the FOPH is contributing to elements 1, 3, 5, 6, and 8 of the action plan.

⁵ Expected to come into force on January 1, 2013.

4.1.5 The Swiss Federal Institute of Intellectual Property (IPI)

The IPI is the federal agency for matters concerning intellectual property (IP) in Switzerland. It has a service agreement with the Federal Department of Justice and Police by which it is charged with the tasks of drafting legislation in the field of intellectual property, acting in an advisory capacity to the Federal Council and other federal administrators, and representing Switzerland at the international level [11].

Switzerland implemented numerous recommendations from the CIPIH and the WHO global strategy and action plan when it put the amended Patent Act (SR 232.14) into force on July 1, 2008. The act brings patent law up to date with the technological advancements and international developments of recent years.

In the area of biotechnology inventions, a new amendment allows a license to be granted for using a patented invention as an instrument for further research. This provision assures that patents in this area cannot become obstacles to research; it guarantees freedom of research in the medical research area; and it eases access to research instruments as required by the Action Plan Element 2.2.

The amendment of the Patent Act also legislates on the so-called research exemption, which is recommended in action plan item 2.4 (e). The research exemption allows scientific research on an invention without the permission of the patent holder, under certain circumstances of demonstrated public health interest, thus streamlining research in the areas of biotechnology and pharmaceuticals.

To prevent the misappropriation of genetic resources and traditional knowledge, the amended Patent Act now also obliges patent applicants to list details for the source of genetic resources and traditional knowledge. This measure creates greater transparency. It also simplifies later monitoring of the right to access the resources or, respectively, the knowledge, as well as the distribution of any economic benefits arising from the use of such and thus works towards implementing the recommendation in item 5.2 (e) of the action plan.

The amendment also implements the action plan recommendation to introduce a so-called "Bolar"-type provision (see Element 6.3 (a)). Producers of generic medicines are now allowed to undertake all required actions necessary for the approval of the medicine even during the lifespan of its patent. This

includes experiments to gather data for drug approval as well as allowing the manufacturing, import, and storage of a patent-protected substance, insofar as the actions are for the purpose of acquiring approval of a pharmaceutical product.

Switzerland was one of the first countries⁶ to implement the recommendation under Action Plan Element 5.2 (d), which requires WHO Member States to implement the August 30, 2003 decision of the WTO General Council, through its legislative amendment. This decision of the WTO allows WTO Member States with sufficient pharmaceutical manufacturing capacity to provide a compulsory license for the manufacturing and export of patented pharmaceutical products under clearly defined conditions. This measure should make it possible for developing countries with insufficient or no manufacturing capacity in the sector to have access to patented pharmaceutical products at prices they can afford, if they need them for responding to serious public health problems such as AIDS or malaria.

As already described above for SECO, the Institute also carries out bilateral projects for SECO in developing countries to improve and increase the use of intellectual property rights, such as projects in Vietnam, Azerbaijan, and Serbia and Ghana, Laos, and Egypt.

In the Vietnam project, the Institute helped to establish a database on traditional knowledge in which data on more than 2,000 traditional medicinal plants have been systematically collected and made accessible. Patent examiners regularly access these data to check novelty and inventive steps, particularly in the field of pharmaceutical inventions. This availability significantly facilitates substantive examination of patent applications. The database was one of the first of its kind in the world and was subsequently studied by other countries. The establishment of this database works towards implementing element 5.1 (f) of the action plan.

The Institute also provides free patent searches to less developed countries so that these countries can inform themselves about the status of patents for medicinal products. In addition, the Institute regularly supports the WTO and WIPO in the presentation of seminars and training workshops on implementing the provisions of the WTO/TRIPS Agreement and the flexibility it has in the area of public health by sending experts.

With these different activities, the IPI is contributing to elements 2, 5, and 6 of the action plan.

⁶ The amended patent law came into force on July 1, 2008.

4.1.6 Swissmedic

Swissmedic is the central Swiss supervisory authority for therapeutic products. It is a public service organisation of the federal government and has a service agreement with the Department of Home Affairs. Its principle is to protect the health of humans and animals by ensuring that medicines and medical devices in Switzerland are effective and safe.

Swissmedic has various co-operations with other regulatory and supervisory authorities and with international organisations in the sector of medicinal products and medical devices.

For example, Swissmedic works closely with WHO by participating in expert commissions for the development of new guidelines or support for training projects.

Swissmedic also participates regularly in the International Conference of Drug Regulatory Authorities (ICDRA) where it shares its expertise. Since 1980, the ICDRA has been providing drug regulatory authorities of WHO Member States with a forum to meet and discuss ways to strengthen collaboration. It continues to be an important tool for WHO and drug regulators in their efforts to harmonise regulation and improve the safety, efficacy, and quality of medicines globally. In 2008, this conference was organised, in close collaboration with WHO, in Switzerland [12, 13].

Swissmedic is contributing to elements 3 and 6 of the action plan.

4.1.7 Contributions of the Federal Offices to the different elements of the GSPA-PHI

Summarising the contributions of the different Federal Offices, it can be stated that they are contributing as a whole to all different elements of the GSPA-PHI.

A substantial part of the contribution is related to the allocation of funding. SER, for example, is mainly offering funding. It is mostly the academic sector, which then implements the different activities (see section 4.2. for more details).

The contribution of SDC covers broader aspects and includes support for health projects in the bilateral cooperation with selected countries, support for the policy dialogue with different multilateral stakeholders, and the funding of selected programmes in the academic sector, such as, for example, the NCCR North–South programme.



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SECO is carrying out public health projects in the field of infrastructure through the infrastructure support programme WEIN; in addition, it runs some of its activities in collaboration with the IPI. The contribution of FOPH covers a wide spectrum, including financial support, capacity building, sharing its expertise, and advocacy at the national and international levels.

IPI is the actor involved in this assessment with the most relevant contribution to element 5 of the action plan, related to the application and management of intellectual property to contribute to innovation and promote public health.

From the different sectors contributing to the implementation of this GSPA-PHI that are included in this assessment, the Federal Offices are the only sector contributing to element 8, related to the establishment of a monitoring and reporting system. This distinction can be explained by the fact that the key stakeholders for the activities under element 8 are the governments and WHO.

4.2 The Academic Sector

The scientific cooperation of Switzerland with developing and emerging countries has a long tradition. More than 50 years ago, two research centres, the *Centre Suisse de Recherches Scientifiques* in Côte d'Ivoire and the *Ifakara Health Institute* in Tanzania, were established and subsequently integrated as partnering country institutions. Switzerland maintains ongoing close research and management activities with these centres. Besides these two research centres, research partnerships with institutions all over the world have been built up over the last decades and offer the basis for the implementation of many success stories for collaboration between Switzerland and partner countries.

The following overview is structured into the main programmes that are supporting research in the academic sector in partnership with developing and emerging countries.

4.2.1 The NCCR North–South Programme

This programme is one of the 28 NCCR⁷ established so far by the Swiss National Science Foundation (SNSF). It is funded by the SNSF, the SDC, the home institution (University of Bern) and by self funding from project participants.

The NCCR North–South encompasses a network of over 400 researchers active in more than 40 countries worldwide. Its overall goal is to contribute to mitigating the negative effects of global change and enhancing sustainable development through partnership research, capacity development, and societal empowerment in developing and transition countries, while developing a formal institutional network among these countries and in Switzerland. The research activities are carried out in partnership with Swiss research organisations and partner institutions in Africa, Asia, and Latin America.

The programme includes three thematic nodes, one of which is “Health, Services, Planning”. This node currently comprises four research projects, two of them in the field of health and the other two focused more on sanitation. The two health-related projects are

- sexual and reproductive resilience of adolescents in East and West Africa and
- social services and control of infectious diseases in mobile populations of Africa and Asia.

The management centre is hosted by the Centre for Development and Environment of the Department of Geography at the University of Bern. It coordinates the research, reports, publications, and other programme activities. Coordinating partner institutions are the Swiss TPH in Basel and the Department of Water and Sanitation in Developing Countries in Dübendorf [14].

The NCCR North–South Programme itself contributes to elements 1, 2, and 3 of the GSPA-PHI, and depending on the focus of the supported projects, it might also contribute to elements 4 and 6 of the GSPA-PHI.

4.2.2 Programme “Research partnerships with developing countries” (RPDC)

This programme is supported jointly by the SNSF and the SDC and funds research partnership projects between Swiss universities and research institutions in the South [15]. The programme aims

⁷ National Centres of Competence in Research promote long-term research projects in areas of vital strategic importance for the development of science in Switzerland, for the economy of the country, and for Swiss society. They are mainly financed through federal funds, complemented by funds from the universities themselves and third-party funds.



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at supporting high-quality research projects focusing on problems that are relevant for disadvantaged countries. It further encourages the development of North–South scientific interactions and partnerships. In this way, the programme contributes to capacity building and scientific performance in the South and helps these countries to integrate into the international scientific community.

The programme is open to all disciplines. For the timeframe 2008 to 2012, 13 projects receive funding; five of these projects are in the field of health, all of them having a duration of three years [15].

The health related projects address the following topics:

- TB epidemiology in Papua New Guinea and drug resistance monitoring using molecular markers (University of Basel)
- Improving quality of health care for Tanzanian children: assessing the use of electronic decision support to promote evidence-based medicine and rational use of drugs (University of Basel)
- Improving equity in access through adherence to HIV care and treatment (University of Basel)
- Aetiology, prevention, and control of anemia in sub-Saharan Africa (ETHZ)

- Interactions of lead intoxication and iron deficiency in Morocco (ETHZ)

Like the NCCR North–South Programme, the RPDC itself contributes to elements 1, 2, and 3 of the GSPA-PHI, and depending on the focus of the supported projects, it might also contribute to elements 4 and 6 of the GSPA-PHI.

4.2.3 Research in Development and Cooperation of Swiss Universities for Applied Science

The SDC supports the program of the Rectors' Conference of the Swiss Universities of Applied Sciences for the promotion of research partnerships of Swiss Universities for Applied Science (UAS) and institutes in developing and transition countries. The program aims at realising application-oriented research and development, building research capacities, and transferring knowledge [16].

One example of such a project in the field of health is "Enabling Health Communication - Feasibility Study", which is a research project of the Zurich University of Applied Sciences (ZHUAS) with the Kenya Medical Research Institute. The study aims to identify the most relevant subjects of future research in the area of health journalism and its link to behaviour change [16].



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Contributions mainly concern elements 1, 2, and 3 of the GSPA-PHI.

4.2.4 Programme "Scientific Cooperation between Eastern Europe and Switzerland" (SCOPEs)

This programme is financed by the SNSF and SDC, and it promotes scientific cooperation between research groups and institutions in Switzerland, Eastern Europe, the Western Balkans, and Central Asia. The goal of SCOPEs is the production and exchange of knowledge and the training of qualified scientists. In addition to the funding of research projects, SCOPEs also supports institutional partnerships.

The projects are open to all disciplines, and quite a few projects are related to fundamental research [17]. The following two examples are ongoing projects in the field of health:

- Development of disability status assessment methodology for Georgia; University Hospital of Basel in collaboration with MED-CONSILIUM in Vevey and the Institute of Strategic Research in Tbilisi, Georgia
- Clinical and Educational Telemedicine Network in Armenia: Telemedical cooperation between Armenia and Switzerland; University Hospital of Basel in collaboration with Pediatric Orthopedic Department of Health of Armenia - Arabkir Joint Medical Center and Institute of Child and Adolescent Health in Yerevan, Armenia, and Hardware and Software Development of "Orgservice" Computer Research Centre for PC, Yerevan, Armenia

Contributions mainly concern elements 1, 2, and 3 of the GSPA-PHI.

4.2.5 Capacity development of SDC in the scientific sector

SDC supports capacity development in the scientific sector through the University Exchange Programme, supporting exchanges between Swiss scientific institutions and developing countries for mutual, shared learning and the development of joint projects and through financing PhD and postdoctoral students who are conducting research at a Swiss institution in collaboration with a local partner institution [18, 19].

Contributions mainly concern element 3 of the GSPA-PHI.

4.2.6 Swiss Network for International Studies (SNIS)

The SNIS promotes academic research on phenomena that transcend traditional nation–state boundaries. The SNIS strongly encourages pluridisciplinary research and fosters collaboration among Swiss organisations of higher education, international organisations, and NGOs. Bringing together academics, practitioners, and policy makers, the SNIS bridges the gap between theory and practice in international studies and contributes to sharpening the Swiss profile in this highly relevant field. The current projects do not focus primarily on health, but on health determinants, and include different sectors.

The Governing Committee is composed of SNIS founding members from the University of Geneva and the Graduate Institute of International and Development Studies, Geneva, as well as institutional founding partners in Switzerland: the World Trade Institute, Bern; the Center for Comparative and International Studies, University of Zurich and the ETHZ; the Swiss TPH, Basel; and the Swiss Institute for International Economics and Applied Economic Research, University of St. Gallen.

The SNIS is funded by the SER and the Department of Public Instruction of the Republic and Canton of Geneva [20].

Contributions mainly concern elements 1, 2, and 3 of the GSPA-PHI.

4.2.7 Swiss Commission for Research Partnerships with Developing Countries (KFPE)

The Swiss Academy of Sciences (SCNAT) supports and connects the natural sciences at the regional, national, and international levels. Because of its broad support of science, SCNAT is a representative and important partner in policy-making within Switzerland. It relies on a network of over 35,000 scientists working within and at the interface of many different disciplines. SCNAT is devoted to making the future of scientific culture and research a priority and building a basis for dialogue between science and society.

The SCNAT has established the Swiss Commission for Research Partnerships with Developing Countries (KFPE) [21]. KFPE is dedicated to promoting research partnerships with developing and transition countries. In this way, the commission seeks to contribute to sustainable and effective development and help find solutions to global problems. KFPE is engaged in Swiss scientific



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policies and is committed to promoting the interests of researchers and their affiliated institutions on both national and international levels. It furthers innovative and development-oriented research and designs concepts for research strategies. In this context, KFPE ensures that partnership principles are followed, the quality of research is assured, and the interests of all partners are covered.

Contributions mainly concern elements 1, 2, and 3 of the GSPA-PHI.

4.2.8 Bilateral research partnerships with priority countries

As mentioned in section 4.1.1, SER has, in addition to the above programmes, signed bilateral research partnerships for fostering scientific collaboration with different priority countries, such as India, China, South Africa, Russia, South Korea, Brazil, Chile, and Japan. The agreements include joint research projects and faculty and student exchange programmes. Complementary funding is playing a key role in these research projects. For each agreement, there is a Swiss academic institution defined as being the coordinator and one as being the associated leading house [22]. For example, the collaboration with India is coordinated by the EPFL, with the University of Lausanne as the associated leading house [23], and the collaboration with South Africa is coordinated by the University of Basel, with the Swiss TPH as the associated leading house [24]. Of the 22 joint research projects with India, 12 are in the field of human health sciences. The 16 joint research projects with South Africa cover three main topics: Public Health & Biomedicine, Bio- & Nanotechnologies, and Human & Social Sciences. Of these, projects of the health sector include subjects such as:

- Valorising the potential of South African medicinal plants—discovery of new natural products scaffolds as leads against neglected tropical diseases

- Analyses of geographical patterns of malaria transmission and mortality in Africa using Bayesian spatio-temporal modelling
- South Africa/Swiss Initiative in HIV drug discovery from medicinal plants

Contributions mainly concern elements 1, 2, and 3 of the GSPA-PHI.

4.2.9 Other projects of the academic sector

In addition to projects funded by the abovementioned sources, a range of other projects are ongoing in the academic sector of Switzerland that are contributing to the implementation of the GSPA-PHI. The following overview lists some examples of such projects from universities, affiliated institutes of universities, and university hospitals.

The Swiss TPH offers a long list of projects contributing to the implementation of the WHO action plan, as an academic institution and also as a partner in PPPs and product development partnerships (PDPs). While the PPPs with the Swiss TPH as partner are described in section 4.5., the following activities are examples related to projects where the institute is collaborating with other academic institutions and public partners [25]:

- Being a member of the EANETT (Eastern African Network for Trypanosomiasis)
- Being partner in the TDR business line 3 network for compound screening and evaluation
- Being partner in the EU-funded ARVMAC and AMASA projects, and in the Alliance for Clinical Research & Clinical Epidemiology (ARCEAU–DRC)
- Collaboration with the Egyptian Ministry of Health and Population in the Egypt–Swiss Radiology Project, funded by the Egyptian and Swiss governments

The EPFL, in collaboration with the hospital of Lausanne, is supporting interesting projects in the areas of cancer and cardiovascular diseases as well as infectious diseases and immunology. In addition, the EPFL-SDC fund supports research projects conducted in partnership between a research unit at EPFL and a scientific institution of the South. This programme is open to all disciplines at the EPFL. Its primary objective is to promote scientific cooperation that offers solutions to important problems in developing and emerging countries and contributes to research capacity building in the partner countries [26]. Further contributions to the implementation of the GSPA-PHI are done through the GHI of the EPFL. The GHI comprises 8 groups,

all engaged in different facets of research linked to human health but with strong emphasis on diseases of global importance such as HIV/AIDS, TB, and malaria [27].

The University of Lausanne also has research projects in the field of HIV and malaria, funded by the European Union (FP7 projects) and a project focusing on the development of a polio vaccine, in collaboration with WHO. Furthermore, in January 2010 it has inaugurated a centre for ‘vaccine formulation and adjuvants’ to enhance appropriate adjuvants use in low and middle income countries and address the challenges of the WHO Global Adjuvant Development Initiative.⁸ Since October 2010, the centre created the technology transfer hub aimed at developing a sustainable manufacturing of adjuvant for pandemic influenza [28].

The University of Zurich is currently building up partnerships with Makerere University in Uganda and the National University of Rwanda.

The ZHUAS has a large network with partner universities all over the world, focusing on student exchanges, faculty exchanges, and cooperation in research projects. In the field of health professions, the University has settled a collaboration with the Health Science University Mongolia in Ulaanbaatar.

The University of Geneva, in collaboration with the Foundation for Innovative New Diagnostics (FIND) and the Institute of Primate Research in Kenya, runs a project aimed at developing a simple method to confirm cure after treatment of sleeping sickness patients [29]. In addition, the University guarantees the recognition of diplomas delivered by the Graduate Institute in Geneva, which offers among other curricula a Global Health Programme [30].

Many Swiss university hospitals have established partnerships with developing countries that may contribute, directly or indirectly, to the implementation of the GSPA-PHI. A recent survey, conducted between October 2007 and March 2009 with all the Swiss hospitals and clinics, targeted identification of existing projects of international cooperation based on clear institutional strategies and supported accordingly with identifiable financial resources. Out of the 200 contacted institutions, 30 reported having conducted cooperation interventions for a total of 93 projects.

⁸ 1. Supply portfolio of proven adjuvants accessible to the public sector 2. Provide vaccine formulations services and training courses 3. Facilitate technology transfer of adjuvants to developing countries.

A more detailed analysis will be published soon in the *Bulletin des Médecins Suisses*. A few examples of projects contributing to the implementation of the GSPA-PHI include the University of Bamako training programme in pharmacy for the hospitals (with the involvement of the University Hospital of Geneva (HUG) and the University of Geneva), the RAFT project (Le Réseau en Afrique Francophone pour la Télémédecine), coordinated by the HUG, in partnership with the Solidarity Fund of the Canton Geneva, Eagle Foundation, WHO, Université Numérique Francophone Mondiale, Health-on-the-Net, and UNESCO and the joint project of the HUG with the B.P. Koirala Institute of Health Sciences of Dharan, Nepal, on visceral leishmaniasis, in collaboration with the Institute of Tropical Medicine in Antwerp, the London School of Tropical Medicine and Hygiene, and WHO.

The HUG has established the “Commission of humanitarian affairs for supporting international development”, which enjoys its own financial fund. In January 2008, the Department of Community and First Intervention established the international and humanitarian medical service (SMIH, Service de Médecine Internationale et Humanitaire) aiming at training and innovation. SMIH’s field activities are implemented in close collaboration with the health authorities of the developing countries concerned and their local institutions and NGOs.

The HUG, in partnership with the Faculty of Medicine of the University of Geneva and with the main international organisations in Geneva and around the world, has launched the Geneva Health Forum as a joint initiative. The “Geneva Forum: Towards Global Access to Health” is a biennial international conference organised by the SMIH that brings together on equal footing all the actors involved in the field of access to health. The Geneva Health Forum and the Global Access to Health Platform bring together the major stakeholders in global access to health, from field workers to policy-makers. The Forum and the Platform together form a developing global network for international and inter-sectoral dialogue, aiming to facilitate the strengthening of health systems and basic health services and striving to keep global access to health on the international agenda [31].

These research collaborations and joint research projects are mainly contributing to elements 1 and 2 and also to element 3 of the GSPA-PHI. Some of the projects, such as the Geneva Health Forum, for example, contribute also to element 6 of the GSPA-PHI.



4.2.10 The contribution of the academic sector to the elements of the GSPA-PHI

The academic sector contributes on different levels to the implementation of the GSPA-PHI. The main areas are related to the promotion and conduction of research (elements 1 and 2) and capacity building (element 3), which also belong to the general key missions of the academic sector. Swiss universities employ a number of foreign doctorate candidates and post-docs, some of them coming also from low-resource settings. This can be seen as an indirect but important contribution to capacity building in these countries.

Specific institutes and programmes in the academic sector have been established for engaging in partnerships with developing countries and projects of international cooperation, such as the Global Health Programme at the Graduate Institute in Geneva, which is linked to the University of Geneva; the GHI, linked to the EPFL; and the Swiss TPH, as an affiliated institute of the University of Basel. These institutes and programmes clearly address the question of improving innovation and access.

Different research partnerships are supported by federal offices and institutions. Together with the SDC, the SNSF promotes research partnerships with developing and transition countries through the RPDC and the SCOPES programme; in both programmes, health and biomedical research are thematically represented among many other topics. The partnerships are aimed at improving individual and institutional research capacities. Health issues are one of the main themes in the NCCR North–South, co-financed by the SNSF and SDC. The SNIS, supported by the SER, promotes pluri-disciplinary academic research on phenomena that transcend traditional nation–state boundaries. Research topics are related to health determinants.

An important contribution of the academic sector is directed to element 2.4.a, related to the development of the Berlin Declaration. The declaration targets establishing open access to knowledge by using the Internet for distribution and

promoting greater access to the knowledge and technology relevant to meeting the public health needs of developing countries. This declaration has been signed by a number of Swiss academic institutions, such as the Swiss Foundation for Research in Social Sciences (FORS), the Universities of Fribourg, Bern, Basel, St. Gallen, and Zurich, the Paul Scherrer Institute, the Swiss Federal Institute of Zurich, the Rectors' conference of the Swiss Universities of Applied Sciences, the Swiss National Science Foundation, the Swiss Academy of Medical Sciences, and the European Organization for Nuclear Research (CERN) [32]. With signing this declaration, the institutions declare their intent to offer open access to their original scientific research results, raw data and metadata, source materials, digital representations of pictorial and graphical materials, and scholarly multimedia material.

The Swiss academic sector also contributes to the activities of element 4 of the GSPA-PHI, related to the transfer of knowledge and technology such as, for example, the Swiss–Egypt radiology project of the Swiss TPH and the technology transfer hub of the centre for 'vaccine formulation and adjuvants' of the University of Lausanne. Contributions to element 5 are made via many research and joint research projects following the Global Access Strategy, which is driven by the public health interest, ensuring the application of the most appropriate patent filing and licensing strategy in each case.

The Geneva Health Forum provides an important contribution to element 6 of the GSPA-PHI, improving delivery and access, even while it is not the main focus of the academic sector. The Swiss TPH is involved in different access programmes, but they are mostly done in the context of PPPs and are therefore described in section 4.5. Finally, it can be argued that many of the small individual projects undertaken by Swiss hospitals and clinics, often as bilateral partnerships, in developing countries are geared towards improving health and health care systems, thus improving delivery and access.

The SNSF in general and the universities and institutes being partner in different PDPs and PPPs contribute to the implementation of element 7 of the GSPA-PHI.

4.3 Non-Governmental Organisations

The assessment of Swiss NGO contributions to the implementation of the WHO GSPA-PHI was mainly based on the activities of the 43 NGOs represented in the Network Medicus Mundi Switzerland (MMS) working in the field of international health

cooperation [33] as well as other developmental and humanitarian NGOs not formally part of the network. MMS coordinates the Swiss platform HIV/AIDS and international cooperation (aidsfocus.ch), bundling Swiss organisations engaged in the response to HIV and AIDS, which also were included. All NGOs working in international health cooperation and humanitarian aid contribute to capacity building and improving delivery and access to medicines and therapies oriented to the needs of the poor by supporting health programmes in cooperation with local hospitals, clinics, and community-based organisations. The current overview of activities contributing to the implementation of the GSPA-PHI focuses on research and development of neglected diseases, promotion of innovation capacity in traditional medicine, information sharing, capacity building, and challenges of intellectual property. It is only as comprehensive as possible and does not pretend to be complete.

In general, Swiss NGOs are not well aware of the GSPA-PHI, even though they are confronted with the effect of lacking and overpriced medicines for neglected diseases and those diseases which disproportionately affect people in developing countries. Scattered activities and sensitisation efforts do exist to raise awareness about this topic area. MMS, for example, regularly publishes information updates about the WHO action plan on its website, in electronic news sources, and in the MMS-Bulletin. Directly or through the MMS platform, the Swiss NGOs are also well connected with international organisations that are specialised in this topic area such as Health Action International (HAI), MSF Access Campaign, Knowledge Ecology International (KEI), and the BUKO pharma campaign. A specific effort to highlight the effect of pharmaceutical research for countries of the South was taken up and discussed in the 2008 Berne Declaration (BD) pamphlet, "Pharmaceutical research and diseases of the South, a shameful negligence".

An overview of key projects/programmes of NGOs actively targeting the implementation of the WHO GSPA-PHI is presented in the following paragraphs.

4.3.1 Médecins Sans Frontières (MSF) Switzerland

MSF Switzerland is an international humanitarian organisation with headquarters based in Geneva. MSF is the most important and most active NGO in the field of R&D promotion and research policy, especially with regards to neglected diseases combining direct medical aid with the fight against the obstacles that prevent effective aid.



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At the political level, MSF is frequently involved in dialogue with major decision-making actors at the governmental and international levels but at the same time very active at the grass-roots level by participating and organising petitions and demonstrations. MSF international is a founder member of DNDi, a PPP focusing on the promotion of R&D of affordable drugs for neglected and tropical diseases (see sector 4.5.). Founded in 1981, MSF Switzerland represents one of five operational centres with projects focusing on TB in Kyrgyzstan and TB/AIDS co-infection in Swaziland [34]. MSF Switzerland defines its goal as saving lives and reducing suffering by providing medical care for individuals in crisis situations.

Three GSPA-PHI areas of action where MSF Switzerland is currently involved are described below.

Promoting research for neglected diseases

MSF conducts critical assessments of drugs and diagnosis methods, which are currently under development for the neglected diseases visceral leishmaniasis, sleeping sickness, and Chagas disease. The aim is to encourage the research community from the North and the South to conduct and include field research in their studies and to define needs-oriented research and development priorities. At present, MSF Switzerland is managing a program targeting sleeping sickness (African trypanosomiasis) together with DNDi. It is testing a new therapy that is easier to use than conventional treatment and is already available in some countries.

Access Campaign

In 1999, MSF initiated the “Access Campaign”, which targets the dual problem associated with modern drug development: high-priced drugs on the one hand and a lack of research and development investments in diseases of developing countries on the other hand. The MSF approach consists of promoting medical innovation to develop and research for new drugs and vaccines, etc., and of increasing access to much-needed drugs at an

affordable price. TB and HIV/AIDS are among the main diseases currently targeted.

Patent pool campaign

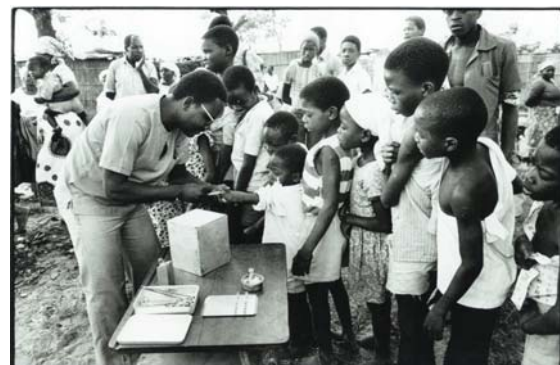
The implementation of the GSPA-PHI is heavily dependent on suitable and sustainable financing mechanisms. The WHO has established an expert group to identify potential innovative financing mechanisms to support R&D activities. Possible financing tools could be indirect taxes (taxes for specific products or transactions), voluntary contributions by the economic sector or consumers, or the establishment of new funds for health R&D. One specific idea that is supported by MSF is the establishment of a patent pool for effective drugs that are especially accessible for poor countries. The initiative of creating a voluntary patent pool for medicines was taken up in 2008 by UNITAID. MSF has launched a campaign in which it requests large pharmaceutical companies such as Abbot, Boehringer Ingelheim, Bristol-Myers, Squib, GlaxoSmithKline, Merck, and Pfizer to make their HIV drugs available in the patent pool. The patent pool focuses on increasing access to newer antiretroviral medicines through stimulating the production of generics and encouraging the development of adapted formulations such as fixed-dose combinations of newer products and special formulations for children.

The pool aims at voluntary collaboration of patent owners to share their patents and make their intellectual property available for generic production of antiretroviral drugs for marketing in low-resource settings [35].

MSF mainly contributes to the GSPA-PHI elements 1, 2, 5, 6, and 7, but also to element 3 through its daily work in countries, collaborating with local staff.

4.3.2 Swiss Red Cross (SRC)

The Swiss Red Cross (SRC) is a private humanitarian non-profit organisation. As a member of the worldwide network of the Red Cross, it carries out its work according to the principles of the International Red Cross and Red Crescent movement. In Switzerland, SRC is active in the



social, health, migration, and education sectors and encourages voluntary work at the community level. Its international activities embrace emergency relief, reconstruction, and rehabilitation as well as development cooperation. While health is an important element in emergency relief and reconstruction (e.g., rehabilitation of health infrastructure after natural disasters), it is the main focus of intervention in the long-term development programmes.

SRC is supporting health programmes in 26 countries in Africa, Latin America, Asia, and Eastern Europe by strengthening community-based health systems through innovative approaches and methods (health promotion, disease prevention, creating access for the poor and marginalised population, strengthen public health structures, health financing, and capacity building and development of educational material) and community-based home care services. Community action for health and empowerment are key elements of the SRC approach. Through policy dialogue, technical assistance, technology transfer, and capacity building, SRC contributes to improving specific areas of health services (e.g., national blood transfusion or eye care services).

Some examples of SRC activities are as follows:

- Laos, Cambodia: Improving access to public health care through health equity funds for the poor, health insurance, quality improvement of services, and mobilisation of village communities for health promotion, water, and sanitation.
- Ghana: Strengthening human resources, improving infrastructure and technology for eye care delivery, and introduction of monitoring systems for the quality of care.
- Swaziland: Comprehensive HIV/AIDS programme (prevention, testing, counselling, treatment, home care) with a systemic and community approach.
- Ecuador, Bolivia: Development of a culturally adapted model of a health system at the district level (in regions with mainly indigenous population) with strong involvement of civil society organisations.
- Kyrgyzstan (SDC mandate): Support for the health reform process by improving the health infrastructure at the district and community levels; building up and strengthening of the health promotion system with community involvement (Community Action for Health).
- Romania, Moldova, Belarus: Health promotion and strengthening the home-based care and Visiting Nurse services (capacity building,

training of professionals, community participation).

- Egypt (SECO mandate), Eritrea, Zimbabwe: Strengthening national blood transfusion services, improving quality management by technical assistance and technology transfer, enhancing certification of the blood transfusion services.

SRC is mainly contributing to elements 3, 4, and 6 of the GSPA-PHI.

4.3.3 Novartis Foundation for Sustainable Development (NFSD)

NFSD is a private non-profit-based organisation and represents one arm of the corporate responsibility portfolio of Novartis. Currently, NFSD is engaged in eight main projects and programs in sub-Saharan Africa and on the Indian subcontinent, all of them directly or indirectly related to health [36]. The following projects contribute to the realisation of the GSPA-PHI.

Access programs

NFSD currently runs different access programs. In Tanzania, one project focuses on improving access to malaria treatment, and the other project focuses on patient-centred TB care. In Mali, there is a program that targets improving access to primary health care services for rural populations, and in India, the project provides comprehensive leprosy care. Some of these access programs are set up as a PPP.

Capacity-building projects

NFSD runs three projects in the field of capacity building: one project is the ICATT project, offering a computer-based learning program for health professionals on the topic of Integrated Management of Childhood Illness (IMCI) in developing countries; the second project offers support to the Tanzanian Training Centre for International Health (TTCIH) in Ifakara, which is supported by the Tanzanian Ministry of Health and Social Welfare, the Swiss TPH and SDC. The third project is a telemedicine project in Ghana aimed at providing quality primary health services that are affordable and sustainable and that meet the needs of patients through appropriate mobile and information technologies.

Novartis Foundation mainly contributes to GSPA-PHI elements 3 and 6.

4.3.4 Afro-European Medical and Research Network (AEMRN)

The Bern- and Liberia-based NGO, founded in 2006, realises projects in various resource-poor countries, especially in sub-Saharan Africa. With a focus on health and educational projects, it has defined knowledge transfer as its key mission [37].

AEMRN acts as a platform where, among others, health specialists and nurses as well as those specialised in providing trainings can organise meetings, seminars, workshops, and conferences themselves. An example is the 2008 symposium on knowledge management, resource mobilisation, and HIV/AIDS research in low-income countries. Contributions mainly concern element 3 of the GSPA-PHI.

4.3.5 Antenna Technologies (AT)

Founded in 1989, AT is an NGO based in Geneva. Its members are primarily scientists, researchers, and engineers. Funding comes from foundations, private donations, and institutional funds. A major goal of the NGO is to improve the image of traditional medicine [38].

AT is currently involved in traditional medicine-related projects in Mauritania and Mali. The aim is to contribute to improved effectiveness, reduce risks, and strengthen the links between traditional and conventional knowledge. A concrete project example is the effort of Antenna researchers to identify herbal formulas for malaria treatment in an urban region in Mali. So far, six plant species have been identified that are being researched by the Swiss TPH in Basel in close cooperation with the Mali MoH. The project is supported by SDC.

Contributions mainly concern element 1 of the GSPA-PHI.

4.3.6 Esperanza Medicines Foundation

The Swiss-based NGO Esperanza Medicines Foundation was founded in Basel in 2004 with the aim of making valuable contributions in non-profit



research and development of safe, effective, and affordable HIV and AIDS drug therapies. These will be specifically designed to meet the unique needs and capabilities of developing countries [39].

The current antiviral project aims at the discovery of potent and efficacious natural compounds with demonstrated anti-HIV-1 activity and is based on the screening of a well-characterised collection of natural products. Additionally, two projects deal with natural products that can potentially be used as topical microbicides for preventive use against HIV-1 transmission through intercourse, such as Cyanovirin-N, a protein with clearly demonstrated activity as an inhibitor of viral transmission, and RANTES analogues that have been identified recently as effective inhibitors of vaginal HIV transmission in rhesus monkeys.

Contributions mainly concern element 1 of the GSPA-PHI.

4.3.7 mediCuba-Suisse

Founded in 1992, the NGO supports a range of public health projects in Cuba. Regular information bulletins and annual reports as well as the homepage provide information about the various public health projects covering a range of topic areas such as promotion of R&D related to traditional medicine, HIV and AIDS prevention, cancer care, and continuous education measures for Cuban medical doctors in Switzerland [40].

Traditional medicine

In Cuba, mediCuba-Suisse is supporting the implementation of a regional centre for green and traditional medicine. The aim is to promote the innovation and application of basic R&D of traditional medicine. The program supports the collaboration of homeopathic reference pharmacies in five provinces with the goal of improving basic and continuous educational training programs, teaching, and research approaches and increasing the availability of homeopathic drugs and therapies.

Financing raw materials for antibiotic production

mediCuba-Suisse finances the purchase of raw materials for antibiotic production on an annual basis. The project allows Cuba to produce its own antibiotics, saving drug imports in the range of 10 million Swiss Francs and covering 60% of Cuba's annual antibiotic needs.

Support of the national cancer clinic in Cuba

The national cancer clinic based in Havana hosts the national cancer register. In 2006, the national department against cancer was founded for streamlining cancer prevention, diagnostics, and treatment at the central and local levels. All cancer-

relevant data are managed by the cancer observatory and facilitate the identification of new control strategies. As a complement, a virtual network connects health centres and entities at the national, regional, and local levels with the national cancer institute and the statistical office. A new project focuses on cancer in children and on breast cancer.

mediCuba-Suisse mainly contributes to GSPA-PHI elements 1, 3, 4, and 7.

4.3.8 mission 21

mission 21, the Protestant mission in Basel, is a community of churches and Christian organisations bringing together people of dissimilar countries and cultures, fostering contact with other ways of life, and providing tangible help wherever peace, justice, and the creation itself are under threat. mission 21 works in 17 countries with 57 partner churches and organisations and assists in 100 projects, fighting against poverty, promoting health, resolving conflicts peacefully, and educating people in theology and the church [41]. By supporting and strengthening community-based health systems and clinics and the production and distribution of cost-effective drugs from local plants and substances, access to health care services is promoted.

mission 21 supports a project in Chile to increase access to affordable drugs based on herbal remedies. Training courses and workshops are offered on basic knowledge about health and diseases and how to produce simple remedies based on herbal essences. Close cooperation exists with the local Mapuche community and ensures the preservation of their traditional knowledge about herbal plants.

mission 21 mainly contributes to GSPA-PHI elements 1 and 6.

4.3.9 medico international schweiz

medico international schweiz was founded in 1937 as Centrale Sanitaire Suisse. It has a vision of assuring basic health care services for all. The NGO manages several health care-related projects in eight countries, with a focus on Central America, covering topic areas such as midwife training, HIV prevention, psychological support, and many more [42].

SADEC, the local partner of medico international Switzerland in Chiapas, Mexico, works for community health and development and is active in the training of health promoters and midwives. A new focus of SADEC is herbal medicine. They started to work in this field with the aim of

strengthening indigenous knowledge and autonomy. However, herbal medicine is not seen as a replacement but as an addition to conventional medicine.

Another partner of medico international Switzerland is GPSIDA. This NGO works in Cuba in the field of HIV prevention.

medico international schweiz mainly focuses on GSPA-PHI elements 3, 4, and 6.

4.3.10 Berne Declaration (BD)

BD is a Swiss NGO with more than 20,000 members, founded in 1968, with the mission to promote equitable, sustainable, and democratic North–South relations. The most common activities comprise conducting research, organising public awareness campaigns, and carrying out advocacy work, e.g., on the following key topic areas: (1) international trade, (2) international financial relations, (3) corporate social accountability (Public Eye Awards), (4) agriculture, and (5) health [43].

The BD campaigns for concrete improvements that benefit developing countries in their economic and political relations to Switzerland.

The following BD initiatives are relevant for the GSPA-PHI:

Misappropriation of traditional knowledge and rights of indigenous peoples

The BD is uncovering and raising awareness of specific cases of biopiracy, some of which are related to health. Together with and in support of indigenous communities, the BD is filing appeals against abusive patenting by private companies of genetic resources resting on traditional knowledge, such as the pelargonium case from South Africa involving a German pharmaceutical company. Simultaneously, the BD is also actively involved in negotiations related to the patent law and to the Access and Benefit Sharing instruments of the Convention on Biological Diversity.

Innovation and access to medicines

As a member of HAI, the BD actively follows all the deliberations and developments related to these subjects at the WHO and in other international fora. The organisation has portrayed the situation in the field of pharmaceutical research in relation to developing countries in a 2008 publication entitled, “Pharmaceutical research and diseases of the South, a shameful negligence”, which was widely disseminated in Switzerland. Building on this accumulated expertise, the BD is advocating in Switzerland for the necessity of de-linking the cost of R&D from the prices of medicines and to define

needs-driven health research to improve innovation and access.

Intellectual property and public health

In the view of BD, a major and fundamental discrepancy exists between the desire of the general public to have access to affordable drugs and the goals of industry to generate profit through patenting. The GSPA-PHI suggests a compromise: countries of the South are supported in their efforts to build up suitable management systems for intellectual property that preserve their public health interests. In this regard, Swiss organisations are mainly active at the level of advocacy, especially BD and MSF. They closely monitor international negotiations and treaties and the practices of international private companies that might have a negative effect on access to drugs in developing countries. Some concrete examples for advocacy efforts by the BD are the campaigns against TRIPS-plus bilateral free trade agreements with developing countries, the international mobilisation around the Novartis court cases in India, the critical analysis of IP-maximalist agendas to address the issues of compromised medicines or Pandemic Influenza Preparedness, and the open letter to the Swiss government regarding the issuance of compulsory licenses in Thailand (TRIPS flexibilities).

Clinical trials in developing countries

The number of clinical trials carried out in countries of the South by the pharmaceutical industry – either directly or through Contract Research Organisations (CRO) – has been increasing substantially over the last decade, raising much concern about ethical violations. The BD campaigned against the conduct of unethical studies. Subsequently, the BD is also actively involved in reflections at the European level related to the promotion of ethical principles for clinical trials and to more transparency.

The GSPA-PHI contributions of BD mainly focus on elements 1, 2, 5, and 6.

4.3.11 Swiss Aids Care International

Established in 2003, the aim of the foundation is to help people with HIV and AIDS in the poorest countries in the world. It has set up ambulatory clinics that offer comprehensive medical treatment and care that take into account the local conditions and customs. The foundation is mainly funded through donations and SDC [44].

Swiss Aids Care International finances the Newlands Clinic in Zimbabwe. Every year, 3,000 HIV and AIDS patients receive treatment, and 100 local doctors and nurses benefit from training

opportunities in the field of clinical and comprehensive HIV care.

The Swiss Aids Care International mainly contributes to GSPA-PHI elements 3, 4, and 6.

4.3.12 SolidarMed

SolidarMed, a Swiss NGO focusing on health in Africa, was founded in 1926. SolidarMed particularly focuses on primary health care in the most disadvantaged areas of Tanzania, Mozambique, Lesotho, Zambia, and Zimbabwe. It initiates health programmes to support the management of HIV and AIDS, cholera and malaria, hospital development, management support at district level, promotion of training opportunities for specialised staff, construction of health facilities, and support of health promotion and prevention initiatives [45].

A GSPA-PHI-relevant example is the program SMART (“SolidarMed Antiretroviral Treatment”) in Southern and Eastern Africa through which SolidarMed contributes to the strengthening of health systems to promote access to voluntary counselling and testing (VCT), treatment of sexually transmitted diseases, antiretroviral treatment for adults and children, and prevention of vertical HIV transmission for people in need.

Another example is a project in Tanzania, where more than 10,000 nurses are needed to provide care for AIDS patients. SolidarMed has decided to invest in the provision of basic and continuous education opportunities and infrastructure support.

The GSPA-PHI contributions mainly focus on elements 3, 4, and 6.

4.3.13 NGO contribution to the elements of the GSPA-PHI

Despite their differing knowledge about the details of the GSPA-PHI, Swiss NGO strategies contributing to the WHO Action Plan are manifold, which makes it difficult to classify them into universally valid categories. The most active players from the Swiss NGO sector are the BD, MSF, mediCuba-Suisse, the SRC, and the NFSD.

As a whole, the NGOs are contributing to all elements except for element 8 of the GSPA-PHI, because element 8 involves only WHO and the government

Although the promotion of research is not a central focus for many NGOs, it has to be highlighted that several Swiss NGOs attempt especially to combine conventional R&D with traditional medicine and try to support the use and distribution of traditional

medicine in coherence with international biodiversity conventions, with a view to assuring access to payable and needs-based medicines and compensation of the local population.

Swiss NGOs appear in general to be strong in interlinking on-site programmes with political advocacy. Advocacy at the political level is commonly combined with activities to sensitise the general public. Some NGOs, such as MSF Switzerland and the BD, closely follow the international discussions and negotiations within the framework of the WHO, WTO, and private companies as well as the development of international treaties that influence on one side the prioritisation of research and on the other side access to medicines in developing countries.

Swiss NGOs strongly emphasise capacity building (North–South, South–South) of local expertise through basic and continuous education. The large majority of Swiss NGOs support capacity-building measures in some way. Many of the NGOs offer services at the country level, involving local staff and therefore contributing to capacity building and skill transfer. Through their in-country projects, NGOs often also strengthen health surveillance and information systems. Nevertheless, they remain limited in terms of continuous analyses of their own concepts and use of recent research findings in their projects/programmes.

Swiss NGOs participate in programmes of applied research together with local and international partners. Compared to other players presented in other sections of this report, these programmes often target improved access to and distribution of medicines at an affordable price as well as the availability of affordable diagnoses and therapies for the poor.

A key demand of several NGOs, such as MSF, but also KEI and HAI, is the development of new financing systems for R&D that are independent from market prices and production monopolies. The development of a patent pool, as initiated by UNITAID and strongly supported by MSF, is valued as a promising model by the NGO sector.

4.4 The Private For-profit Sector

The contribution of Switzerland to the implementation of the GSPA-PHI from the private for-profit sector focuses in the current assessment on the two big pharmaceutical companies Novartis and Roche, which have their roots in Switzerland and are therefore counted as Swiss companies, although they are big international companies. However, there are additional activities from smaller

Swiss pharmaceutical and biotech companies contributing to the implementation of the action plan that are not taken into account in this assessment.

4.4.1 Novartis

Novartis' mission is to discover, develop, and successfully market innovative products to prevent and cure diseases, to ease suffering, and to enhance quality of life. In addition, Novartis wants to provide a shareholder return that reflects outstanding performance and to adequately reward those who invest ideas and work in the company [46].

Although Novartis has a strong focus on the markets in the industrialised countries, there are also some activities that contribute to the implementation of the GSPA-PHI.

Activities in the field of drug research

Regarding the contribution to drugs and vaccines for neglected diseases through drug discovery and vaccine research, Novartis has built up two corporate research institutions: the Novartis Institute for Tropical Diseases (NITD) in Singapore and the Novartis Vaccines Institute for Global Health (NVGH) in Siena. While NITD was set up as a PPP between Novartis and the Singapore Economic Development Board, NVGH is a not-for-profit research institute [47]. Activities of NITD contributing to the implementation of the GSPA-PHI in the context of this assessment report are described in the section 4.5.



NVGH was established by Novartis in 2007 and inaugurated in February 2008. It is dedicated to the translational research and development of vaccines. NVGH focuses on neglected diseases, especially diseases that are particularly devastating to developing countries. The fact that vaccines have saved billions of lives in the past century and are still the most cost-effective way of controlling the spread of infectious diseases is the reason why the target is vaccine research. The institute aims to bridge the translational gap between basic research and the subsequent technical product development and manufacturing. The gap is usually caused by the perceived risk of poor commercial return to be expected as the disease afflicts mainly developing countries. This perception limits investments in production and manufacturing. NVGH provides the means and expertise for pilot-scale vaccine production and human proof-of-concept studies.

The institute works in partnership with universities, research institutes, and other public and private organisations to develop the scientific basis for vaccine development. It has a strong capacity-building component. In addition, NVGH collaborates with organisations such as GAVI, WHO, UNICEF, and other nongovernmental and non-profit organisations to bring international attention to this important issue.

Currently, NVGH is focusing its research on conjugate vaccines for diarrhoeal and enteric diseases, such as infections with *Salmonella* bacteria, which are important causes of infections and diseases in children [48].

Novartis is an active partner of WHO and other stakeholders on R&D financing for neglected diseases and has developed a proposal for a Fund for Research and Development in Neglected Diseases (FRIND).

Activities to increase access to medicines

Novartis is one of the world's largest generic producers and is also running several "access to medicines" projects in low-resource settings. The approach to access is patient-centric and meant to enable superior patient outcomes. The access programmes are tailored to patient needs: from prevention to treatment and from donations to shared contribution or co-pay models [49]. In this respect, according to the company, 387,000 patients with fascioliasis received free Egaten® treatment in 2009; 5 million of the 14 million people that have been cured of leprosy since 1985 were treated with drugs provided free of charge by Novartis since 2000. Vaccines and medicines



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developed through the NITD and NVGH research programs will be made available at not-for-profit prices.

In partnership with the WHO, UNICEF, and the Presidents Malaria Initiative (PMI), Novartis provides the antimalarial medicine Coartem® on a non-profit basis for public-sector use in developing countries in Africa, Asia, and Latin America. During 2009, 75 million patients received treatment courses of Coartem® [49]. Also in 2009, Novartis launched Coartem® Dispersible, the first pediatric formulation of an Artemisinin Combination Therapy (ACT) for children. The same drug combination (artemether-

lumefantrine) is sold as Riamet® in industrialised countries. This differential pricing strategy ensures the return of investment.

Since 2005, Novartis has been delivering fixed-dose-combinations of anti-tuberculosis treatment in Tanzania with directly observed short-course therapy through the WHO. In 2009, Novartis announced plans to further extend this TB drug donation program [46].

The Glivec® International Patient Assistance Program (GIPAP) provides access to Glivec®, a drug against chronic myeloid leukaemia for patients in need of it. The patient access programs range from full donation to a shared contribution model and co-pay model. It was initiated in 2002 and

operates in about 80 developing countries in Africa, Asia, Eastern Europe, South America, and the Caribbean that have no comprehensive reimbursement system or available generics [46].

The Novartis Arogya Parivar program is operating in 20% of India's districts and offers improved access to health education and affordable medicines for 40 million people. Its approach is based on the four As: awareness, acceptability, affordability, and availability, adapted to low-income markets. The project focuses on the delivery of 75 medicines, vaccines, and micronutrient medicines that address 12 therapeutic areas including TB, diabetes, mother and childhood malnutrition, and respiratory and gastrointestinal problems. A similar program is being launched in Kenya in 2011. The products are tailored to the villagers, simple to use, and available in small packages with instructions in local languages. The programme further supports the supply chain to ensure continuous supply, and it provides community health education to address low levels of disease awareness [49].

Practical project and program work

The activities in the field of practical project and program work, networking, and information work are covered by the NFSD, which is a privately registered NGO in Switzerland, funded by Novartis [36]. More details are offered in section 4.3.

In addition to the abovementioned contributions to the implementation of the GSPA-PHI, Novartis is supporting different organisations and is a partner in different PPPs and alliances, such as, for example, in the PPP ACT in Zambia, ALIVE in Tanzania, and SMS for Life in Tanzania, as described in section 4.5. It is also one of the many other partners in the Global Alliance for TB Drug Development (TB Alliance). The mission of the TB Alliance is to accelerate the discovery and development of cost-effective new anti-TB medicines, which should shorten or simplify treatment, provide a more effective treatment of multi-drug resistant TB, and improve treatment of latent TB.

Novartis does not file patents in the least developed countries (LDCs). This is in line with the transition period for LDCs to implement TRIPS regulations until January 1, 2016, for pharmaceutical patents.

Contributions concern mainly elements 1, 2, 3, 4, 6, and 7 of the GSPA-PHI.

4.4.2 Roche

Roche's corporate responsibility is reflected by a tradition of commitment, as stated on their webpage. Roche is committed to sustainability and

thus to running the business in a way that is ethical and responsible and creates long-term value [50].

Roche's approach in the world's LDCs (as defined by the United Nations) is driven by the need to create sustainable solutions to help facilitate better access not only to medicines and diagnostics but to health care as a whole. The company has the following long-term strategies [51]:

- have a clear patent and pricing policy for the medicines rather than donating products
- build partnerships with governments, NGOs, and other committed parties
- continue research and development into new and existing medicines in areas of unmet medical need
- promote education, training, and knowledge sharing
- donate technical expertise to local service providers and manufacturers

Support for drug research

In 2009, Roche started collaboration with the Institute of OneWorld Health, which allows OneWorld Health to screen compounds from the Roche library with the view of identifying new drugs for treating childhood diarrhoea. In a first round, OneWorld Health identified 40 compounds to investigate as possible new treatments [51].

In 2009, Roche partnered with Google.org, the philanthropic arm of Google.com, by donating its medical research and sequencing expertise to support a multidisciplinary surveillance, research, and response system for emerging infectious diseases in East Africa. The project focuses primarily on arboviruses, which frequently cause emergent diseases such as viral encephalitis or hemorrhagic fever [52].

Access programs

Roche Diagnostics' HIV viral load test has become the gold standard for monitoring the efficacy of HIV treatment. Since 2002, the AmpliCare initiative has made these tests available at the lowest possible price in sub-Saharan Africa, South America, and the LDCs most affected by HIV and AIDS, along with education programmes to support the use of tests and treatments. Roche Diagnostics works in partnership with international agencies, local communities, hospitals, and the Clinton Foundation.

Recently, Roche Diagnostics started a partnership with the Clinton Foundation to improve access to HIV testing for infants in 35 countries in sub-Saharan Africa by providing molecular-based HIV infant diagnostic tests in combination with dry blood



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spot methodology, which are used to diagnose HIV in children younger than 18 months [51].

Other initiatives to increase access to laboratory services include, for example, the development of screening techniques for TB and resistant strains [51].

The Phelophepa Health Care Train is a mobile clinic with 16 coaches to supply general, dental, eye, and psychiatric care to rural South Africa. The train provides primary health care to about 40,000 patients a year and is staffed by 14 health professionals and 40 student volunteers. The project started in 1994, and Roche is the main sponsor. Recently, cancer education and the screening process were enhanced as a service [51].

Two HIV medicines are supplied at a non-profit price to the LDCs and sub-Saharan Africa. Since 2007, Roche has offered Valcyte® (valganciclovir) at a substantially reduced price to the international NGOs treating AIDS-related cytomegalovirus infection in all low- and lower-middle income countries [51].

In collaboration with Novo Nordisk, the World Diabetes Foundation, and governments, Roche is running a project aimed at improving the lives of children with diabetes in developing countries. In addition to access to treatment, the project focuses on sustainable diabetes care including awareness building, screening, education, and training for health care workers, patients, and their families [51].

In 2009, Roche launched the Tamiflu® Reserves Programme for developing countries. Roche will produce and store Tamiflu® pandemic stockpiles for specified⁹ developing countries at a significantly reduced price with the cost spread over a number of years. Furthermore, Roche renewed sub-license contracts for the production of Tamiflu® in China, India, and specified developing countries. In

⁹ Countries that are members of the Global Alliance for Vaccines and Immunization (GAVI)

addition to its donations of Tamiflu® to the WHO from 2004–2005, Roche announced in 2009 another donation of Tamiflu® to WHO to replenish their pandemic stockpiles [51]. Overall, Roche has donated over 5 million packages of Tamiflu® to WHO.

Skills transfer/education

Roche is supporting many different training and skill transfer programmes, many of which not only provide skill transfer but also support local health care infrastructure in a broader sense.

For three years, Roche has supported physicians from the Albert Einstein College of Medicine to train over 200 Ethiopian doctors, nurses, clinical officers, and final-year medical students by addressing the greatest educational needs of local health workers such as complications in pregnancy and childbirth or treatment of infectious diseases.

EDUCARE (EDUcation for Cancer in African REgions) is a PPP between Roche and the International Atomic Energy Agency (IAEA) to improve training in cancer care for health care workers in sub-Saharan Africa [53]. EDUCARE aims to reach over 200 health care workers in the first year of the programme. The programme will initially focus on four pilot countries: Ghana, Tanzania, Uganda, and Zambia. Roche has committed to a five-year plan.

Since 2007, Roche has been sponsoring pharmacists and doctors from LDCs to spend between three and six months at a Roche clinical pharmacology unit with the aim that the trainees will be able to manage clinical trials in their own countries afterwards.

In South Africa, Roche has formed a partnership with the National Institute for Communicable Diseases to establish the 'PCR Academy' with the aim of addressing the skills shortage in molecular biology laboratories by providing accredited training programmes and improving quality control.

Roche supports the WHO's Division for Tropical Diseases to train researchers, clinical monitors, and ethics committees in compliance, good clinical practice, and quality assurance. For instance, it has carried out a series of workshops for researchers managing and monitoring WHO-sponsored trials on tropical diseases.

Since 2006, Roche has a Secondment Policy to enable its employees to contribute their skills and expertise to help developing countries for a duration of 3 to 18 months [51].

In 2006, Roche commenced the 'AIDS Technology Transfer Initiative', designed to help local manufacturers in countries with limited resources to manufacture generic versions of HIV medicines. It aims, through sharing of know-how, to increase local capacity to be able to provide treatment and to decrease reliance on wealthier nations. Knowledge and skills transfer is done at local manufacturers' production sites with on-site training provided by experienced Roche teams [51]. In addition, Roche has also granted knowledge transfer to a South African manufacturer for the provision of generic Tamiflu® for pandemic use on the African sub-continent.

Roche has developed an electronic interactive education tool on the basics of genetics for physicians, scientists, students, and educators, which is available on-line or as CD-ROM in 11 languages and is distributed free of charge for educational purposes.

In addition to the abovementioned contributions to the implementation of the GSPA-PHI, Roche is a partner in different PPPs such as the Accelerating Access and the Cambodian Treatment Access Programme. More details are given in sections 4.5.1 and 4.5.2. of this report.

Roche's clinical trials policy

Roche's clinical trials policy¹⁰ for low- and middle-income developing countries was adopted in 2005. It states that Roche will not conduct clinical studies in such countries solely for the purposes of registering the drug in another country, meaning not performing clinical trials in countries where the company will not seek marketing approval.

Patent and pricing policies

Since 2001, Roche has applied the following patent policy: Roche does not file for new patents on any Roche medicines, for any disease, in LDCs defined by the United Nations (UN)¹¹. Nor does Roche enforce existing patents in these countries. This means generic versions of any Roche medicine can be produced and distributed in the LDCs without applying for a license.

Not all countries in sub-Saharan Africa, the region hardest hit by HIV/AIDS, are defined as LDCs. Roche's policy is not to file patents on any new antiretroviral treatments for HIV/AIDS¹² in the hardest-hit region, sub-Saharan Africa, nor to enforce existing patents, thus including countries that are not defined as LDCs. In 2010, Roche expanded this policy to include the low-income

countries defined by the World Bank, thus covering another six countries.

In 2008, Roche adopted a position on pricing¹³ including six guiding principles. Principle No. 6 states that to respond to the social responsibility of providing and improving access to products and services, especially in less affluent economies, Roche is assessing the structure and feasibility of special pricing schemes. Roche considers preferential pricing schemes in low and lower-middle income countries (as defined by the World Bank) for diseases that are deemed key priorities by appropriate supra-national institutions. The differential pricing policy already applied in the Roche AmpliCare programme (see above) is being extended to include other neglected diseases for which Roche may have applicable diagnostic solutions.

Contributions concern mainly elements 1, 2, 3, 4, 6, and 7 of the GSPA-PHI.

4.4.3 The contribution of the private for-profit sector to the elements of the GSPA-PHI

Although the main focus of the private for-profit sector is not on health issues in low-resource settings, both Novartis and Roche have programmes and activities supporting the implementation of the GSPA-PHI across most of its elements. These programmes and activities are part of the corporate responsibility of the private industry.

Novartis implements these programmes and activities in a blended approach that combines direct and indirect involvement. Programmes with direct involvement are, for example, the Malaria Initiative program and Arogya Parivar; more indirect involvement is reflected through the programmes of NVGH or NFSD, both institutions set up and funded by Novartis. Roche seems mostly to be directly involved in specific projects. Both Novartis and Roche are also partners in various PPPs.

The private industry does not prioritise and promote research and development needs of low-income countries in a direct way; rather, they do it through other channels, such as through the NVGH, which was set up by Novartis, or through facilitating access to compound libraries such as the collaboration between Roche and OneWorld Health. These activities contribute to elements 1 and 2 of the GSPA-PHI.

Roche's contribution to elements 3 and 4 is manifested through the technology transfer initiative

¹⁰ Roche clinical trials policy for low- and middle-income countries available at http://www.roche.com/clinical_trials.htm

¹¹ Roche's statement available at

http://www.roche.com/medical_value_patents_and_pricing.htm

¹² Roche's research into new HIV/AIDS medicines was discontinued in 2008.

¹³ Roche Position on Pricing available at

http://www.roche.com/medical_value_patents_and_pricing.htm

and several specific capacity-building and skill transfer programmes. Novartis contributes to these elements mostly through its non-profit institutes with NITD having a strong capacity-building component.

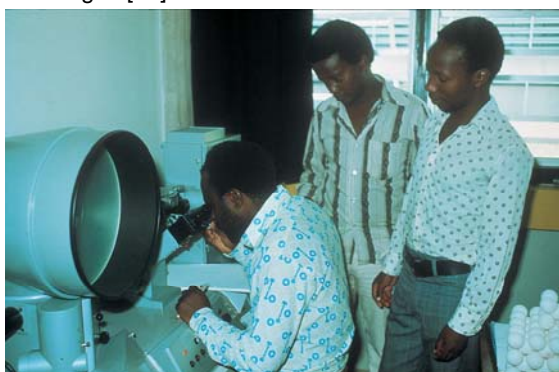
Roche and Novartis consider themselves as contributing to element 5 because they are not filing any patents for pharmaceutical products in LDCs. This is in line with the transition period for the implementation of the TRIPS regulation for LDCs until January 1, 2016.

Both companies have a range of activities supporting access to treatment and therefore the implementation of some activities of element 6. Activities include, for example, the application of differential pricing policies such as for the antimalarial medicine Coartem® by Novartis, for the two HIV medicines by Roche, and by Roche's AmpliCare Initiative.

Through channelling of funds to health-oriented research institutions and through the support of PPPs and PDPs, the for-profit private sector is also contributing to element 7 of the GSPA-PHI.

4.5 The Private–Public Partnerships

Over the last few years, partnerships between public and private sector organisations have become an increasingly common mechanism to address some of the diseases of the poor in developing countries [54]. Current evidence shows that PPPs have a beneficial effect by increasing the number of products in development, greater funding, the potential for lower costs, a reduced time to market, and improved availability of and access to products, as well as for an improved health impact and higher innovation levels [55]. PPPs bring together skills, knowledge, and resources from a variety of sectors including academia, nongovernmental organisations, philanthropists, government, and intergovernmental agencies, as well as members of the for-profit private sector such as pharmaceutical and biotech companies to create a unique approach to solving global health challenges [54].



Each partnership has its own characteristics, and the variety of the PPPs makes a common definition difficult; therefore, no generally recognised definition exists. The working definition used in the context of this assessment is as follows: a PPP is a cooperative venture between the public and private sector, built on the expertise of each partner that best meets clearly defined public needs through the appropriate allocation of resources, risks, and rewards [56].

In the context of this assignment, where the contribution of Switzerland to the implementation of GSPA-PHI will be described, the PPPs must have a Swiss component. Therefore, at least one of the partners contributing to the PPP should be a Swiss company or institution. The Swiss contribution can be either financial, or operational, or intellectual, where, for example, Swiss experts are on the board of a global PPP, or can be a combination of these categories.

This assessment has identified a total of 18 PPPs corresponding to the above definition. Basically, the PPPs can be classified into two categories, namely into global/international PPPs and local/national PPPs. While the global PPPs listed in the frame of this mandate have a broad aim and focus on low-resource settings in general (or diseases endemic areas), the local PPPs have a mission with a more narrow focus on activities for a specific country.

In the following paragraphs, an overview of the 18 identified global and local PPPs is presented. The contributions of the larger programs such as MMV, DNDi, and the NITD, for example, are presented as a summary of the initiative rather than describing each individual project.

4.5.1 Global/International PPPs

Accelerating access initiative (AAI)

AAI is a partnership between UNAIDS, WHO, UNICEF, UNFPA, the World Bank, and five research-based pharmaceutical companies founded in 2000. One of the pharmaceutical companies involved since the beginning is Roche. Four other pharmaceutical companies joined the initiative later. The partnership is committed to working with governments, international organisations, and other stakeholders to find ways to broaden access while ensuring rational, safe, and effective use of medicines for HIV and AIDS. The commitment is to provide antiretroviral drugs at about 10% of the commercial price to the public and nongovernmental sector [57, 58]. Contributions mainly concern GSPA-PHI element 6.

Buruli Vaccine Research Project (BuruliVac)

The BuruliVac consortium started to operate in March 2010 with the aim of identifying and developing novel vaccine candidates against Buruli Ulcer disease suitable for translation into clinical application. A multidisciplinary approach is used, focusing on basic and applied research in immunology, bioinformatics, molecular genetics, tropical medicine, microbiology, and clinical bacteriology. The project also involves extensive technology transfer, training activities, and human capacity building. The research project is funded by the European Union; the Swiss TPH, as one of the fifteen partners, provides scientific input [59]. Contributions mainly concern GSPA-PHI elements 1, 2, 3, and 4.

Consortium for parasitic drug development (CPDD)

The non-profit consortium was set up in 2000 to fill a gap in the discovery and development of new drugs for the treatment of specific neglected diseases with a focus on sleeping sickness and visceral leishmaniasis. All members are scientists and clinicians from academic and not-for-profit organisations. The work areas include a whole range of activities from early lead optimisation up to clinical trials and registration; during the later phases of the drug development process, partnerships with industry and global institutions are sought. The CPDD also offers a grant program providing funds to individual investigators for promising new research approaches. Resources are shared between CPDD members and investigators. The Swiss TPH acts as one of fifteen consortium members providing scientific input [60]. Contributions mainly concern GSPA-PHI elements 1, 2, 3, and 4.

Drugs for Neglected Diseases initiative (DNDi)

DNDi was founded in 2003 as an independent, not-for-profit PDP working to research and develop new and improved treatments for neglected diseases such as leishmaniasis, sleeping sickness, Chagas disease, and malaria. DNDi mainly consists of public partners but also closely collaborates with the international research community, the pharmaceutical industry, and other organisations to bridge the existing R&D gaps to find essential drugs for these diseases. DNDi also has a strong focus on supporting existing capacity in countries where the diseases are endemic.

DNDi contributes on different levels to the implementation of the GSPA-PHI through the following:

- Implementation of research projects. Since its start in 2003, more than 350 research,

technical, or funding agreements have been signed. The current portfolio includes 18 projects in the field of drug discovery, preclinical, and clinical studies and medicines available to patients.

- Technology transfer in low-resource settings.
- Advocacy efforts for improved access to medicines.
- Decisions on patent ownership/licensing terms on a case-by-case basis through its own intellectual property policy guide for R&D activities ensuring affordable treatments, equitable access to treatment, and drugs as public goods.
- Adapting drug regulations, including drug registration processes, to the particular needs of developing countries.

DNDi's Swiss component includes an intellectual contribution with two Swiss experts serving on the board of directors, and financial contributions from SDC and the Canton of Geneva [61, 62]. Contributions mainly concern GSPA-PHI elements 1, 2, 3, 4, 5, 6, and 7.

European Malaria Vaccine Development Association (EMVDA)

EMVDA, set up as a five-year project starting in 2008, aims at systematically developing and testing vaccines against malaria by comparative and continuous evaluation of candidates. The Swiss TPH is a member of the consortium. EMVDA closely collaborates with public and private partners. The EMVDA has established a Research Reagent Repository with the aim of sharing useful reagents for the development of malaria vaccines among members of the EMVDA Consortium members. Key activities comprise vaccine research and development and production, training and partnership activities for African partners, and product management [63].

Contributions mainly concern GSPA-PHI elements 1, 2, 3, and 4.

Medicines for Malaria Venture (MMV)

MMV is a not-for-profit PPP founded in 1999. Its main mission is to reduce the burden of malaria in disease-endemic countries by discovering, developing, and facilitating delivery of new, effective, and affordable antimalarial drugs through PPPs. Today, MMV works in partnership with more than 80 research institutions and companies around the world, mainly in the United States, Australia, and Europe and with universities in South Africa and Contract Research Organisations in India [64].

Key characteristics/activities of MMV are as follows:

- Implementation of research projects: At the end of 2009, the MMV portfolio included a range of 32 projects in the fields of lead generation, lead optimisation, preclinical studies, Phase I, Phase IIa/IIb, and Phase III studies, drug registration, and Phase IV. Two of the current projects are in the registration process (Dihydroartemisinin-Piperaquine (Eurartesim™/sigma-tau) and Pyronaridine-Artesunate (Pyramax®/Shin Poong Pharmaceuticals), and two medicines have already reached the market—Coarsucam®/sanofi aventis developed together with DNDi and Coartem® dispersible/Novartis—both of them WHO pre-qualified and approved in several countries.
- Implementation of clinical trials in the disease-endemic countries in collaboration with local universities sharing expertise and technologies.
- Development of strategies to improve access to and uptake of medicines through support of product adoption, expansion, and product development.
- Implementation of the MMV intellectual property policy. Final decisions about patenting and licensing are made on a case-by-case basis, following the principle of ensuring wide access to the newly developed medicine according to their public health mission.
- MMV recently joined the pool for open innovations against neglected tropical diseases, which was started by GlaxoSmithKline in February 2009. This pool was established by GlaxoSmithKline in February 2009 with the aim of motivating innovative and efficient drug discovery and development by opening access to intellectual property or know-how in the field of product development for the treatment of neglected tropical diseases. The pool is outlined by two core principles that (1) include therapeutics to treat the 16 neglected tropical diseases as defined by the FDA (TB, malaria, blinding trachoma, buruli ulcer, cholera, dengue/dengue haemorrhagic fever, dracunculiasis, fascioliasis, human African trypanosomiasis, leishmaniasis, leprosy, lymphatic filariasis, onchocerciasis, schistosomiasis, soil transmitted helminthiasis, and yaws) and (2) will be royalty free for sales in the world's least developed countries as defined by the United Nations [65].

MMV receives funding from SDC; furthermore, one of the founding members is the current director of the Swiss TPH, Marcel Tanner [64]. Contributions mainly concern GSPA-PHI elements 1, 2, 3, 4, 5, 6, and 7.

NGBS program in malaria drug discovery

This program, set up in 2006, aims at developing medicines for malaria treatment. Among the members of the consortium are the Swiss TPH and the NITD. The program has its own pipeline with projects ranging from target identification through lead optimisation to preclinical studies. Contributions mainly concern GSPA-PHI elements 1 and 2.

Novartis Institute for Tropical Diseases (NITD)

NITD was set up as a PPP between Novartis and the Singapore Economic Development Board in 2002. The institute aims to discover novel treatments and prevention methods for major tropical diseases with a focus on dengue, TB, and malaria. In developing countries where these diseases are endemic, Novartis makes treatments readily available for poor patients without profit. Activities include the fields of target discovery, screen development, compound optimisation, preclinical development, and proof-of-concept clinical trials; their implementation is based on global partnerships. In 2009, the portfolio included an estimate of 20 different projects for the three target diseases [66].

The Swiss component comprises Novartis as an international company with Swiss roots as one of the partners and also intellectual contributions that are offered by a leading Swiss expert who is part of the scientific board of the institute.

Contributions mainly concern GSPA-PHI elements 1, 2, 3, 4, 5, and 7.

PF1022A Consortium

The three-year partnership between the Swiss TPH and Bayer AG is based on a Memorandum of Understanding and targets the further development of PF1022A, a substance with anthelmintic activity that is currently used in cats, to make it available for the use in humans.

Contributions mainly concern GSPA-PHI elements 1 and 2.

Tribendimidine Consortium

The aim of this consortium that started in 2007 is to further develop the anthelmintic drug tribendimidine to reach worldwide availability and distribution. Currently, tribendimidine is only available in China. In this consortium, the Swiss TPH is partnering with OneWorldHealth and a Chinese pharmaceutical company.

Contributions mainly concern GSPA-PHI elements 1 and 2.

4.5.2 Local PPPs

In addition to the global PPPs, there are also several more locally acting PPPs with activities that

are mostly limited to one country. A short overview is presented in the following list:

- ACCESS in Tanzania, focusing on improved malaria treatment; Swiss partners are the NFSD and the Swiss TPH.
- ACT treatment for malaria in pregnant women in Zambia; the Swiss partner is Novartis.
- ALIVE for malaria treatment in Tanzania; Swiss partners are the Swiss TPH, NFSD, and Novartis.
- Cambodian Treatment Access Programme (in the field of HIV); the Swiss partner is Roche.
- Accès initiative in Mali to strengthen the national health system at the primary level; the Swiss partner is the NFSD.
- NATNETS in Tanzania to promote the national use of insecticide-treated nets by making nets affordable, accessible, and acceptable; Swiss partners are the Swiss TPH and SDC.
- SMS for Life in Tanzania is a partnership that deploys SMS technology to significantly reduce health facility stock-outs, thereby leading to improved access to essential medicines; Swiss partners are Novartis and SDC.
- The Tanzanian Training Centre for International Health (TTCIH), aiming to be among the leading public health training centres; Swiss partners are the NFSD and the Swiss TPH.

4.5.3 Contributions of the PPPs to the different elements of the GSPA-PHI

Overall, it can be stated that PPPs with a Swiss involvement are contributing to all GSPA-PHI elements except element 8, which is addressed only by WHO and the government. This level of contribution is achieved through a diversified range of individual activities as indicated by involvement in the abovementioned initiatives, consortia, programs, and projects.

PPPs have become a popular mechanism to address research and development needs focusing on neglected diseases. Because the abovementioned PPPs were set up with a focus on research and development needs of developing countries, they are all contributing to many activities given in elements 1 and 2 of the action plan, which are focused on prioritising and promoting research. It has to be highlighted that the PPPs that are listed here in the context of this assignment follow the “Global Access Strategy”, especially DNDi, MMV, and NITD, and therefore contribute substantially to element 2.4.d of the action plan, which recommends further development and dissemination of publicly or donor-funded medical interventions and know-how through appropriate licensing policies. The “Global

Access Strategy” is driven by the public health interest, ensuring the application of the most appropriate patent filing and licensing strategy in each case. This can include the decision not to file any patent or to file a patent and then clearly define license agreements that ensure optimal access to the medicine for use in the public health sector in low-resource settings.

Many PPPs participate in programs of applied research in collaboration with local partners, such as MMV, DNDi, NITD, BuruliVac, and many others. These collaborations support not only the exchange of knowledge and therefore the contribution to element 3, the building and improving of innovative capacity, but also the transfer of technology, which is reflected in element 4.

A contribution to element 5 is limited; however, it includes encouraging and supporting the application and management of intellectual property in a manner that maximises health-related innovation and also includes capacity building of national and regional institutions in this area. As already mentioned above, the PPPs listed here follow the “Global Access Strategy”.

Many of the local PPPs have a stronger focus on the implementation of research results and policy development than on research activities themselves, such as, for example, NATNETS and the different access programs, and therefore have their main contribution to the implementation of the GSPA-PHI in the activities of element 6, related to improved delivery and access.

DNDi, MMV, and NITD are not only set up as PPPs but also are partners in many different PPPs and PDPs and therefore contribute to sub-element 7.2.c of the GSPA-PHI, which is described as supporting public–private and product development partnerships and other appropriate research and development initiatives in developing countries.



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Table 1: Overview of the contribution of different sectors to the implementation of the GSPA-PHI

GSPA-PHI: Framework for needs-driven research focusing on target diseases; plan of action according to 8 different elements and over 100 specific activities

Federal Offices	Academic Sector	NGOs	Private For-Profit Sector		PPPs	
<p>SER: Contributing to elements 1,2,3,4 and 6; mostly through funding support</p> <p>SDC: Contributing to elements 1,2,3,4 and 6; support to health projects in bilateral cooperation, support to the policy dialogue, and funding support</p> <p>SECO: Contributing to elements 3 and 4; support in the field of infrastructure, collaboration with IPI</p> <p>FOPH: Contributing to elements 1,3,5,6, and 8; financial support, capacity building, advocacy at national and international level</p> <p>IPI: Contributing to elements 2 and 6, and most relevant contribution to element 5</p> <p>Swissmedic: Contributing to elements 3 and 6</p>	<p>Contributing to element 1, 2 and 3 through different research partnerships and networks, such as NCCR North-South, RPDC, SCOPES, SNIS, supported by SNSF, SDC, and SER</p> <p>Specific programmes or institutes, such as SMIH, GHI, and Swiss TPH with main focus on improving innovation and access in low resource settings, contributing to element 4 and 5</p> <p>Open access to knowledge and technology (activity 2.4.a)</p>	<p>Main actors are BD, MSF Switzerland, mediCuba-Suisse, SRC, NFSD; as a whole, NGOs are contributing to all elements except for element 8</p> <p>Contribution to R&D in the field of traditional medicine</p> <p>Strong emphasis on capacity building, strengthening health surveillance and information system through local presence; interlinking of on-site programmes with political advocacy</p> <p>Contribution to element 6 through participation in programmes of applied research</p>	<p>Novartis Direct involvement in specific projects (e.g. technology transfer/educational programs), indirect contribution through the set up and funding of non-profit institutions such as NVGH, NITD, NFSD</p> <p>Differential pricing and full donation access programmes for medicines for malaria, several cancers, leprosy, fascioliasis and TB</p> <p>Partner in various PPPs</p>	<p>Roche Direct involvement in specific projects, especially in the field of capacity building and technology transfer</p> <p>Differential pricing access programme for two HIV medicines and HIV monitoring tests</p> <p>Partner in various PPPs</p>	<p>Global PPPs Main contribution to element 1 and 2; research and development focusing on diseases in endemic areas</p> <p>Global Access Strategy contributing to activity 2.4d</p> <p>Applied re-search in collaboration with local partners, contributing to element 3 and 4</p>	<p>Local PPPs Focusing on activities for a specific country, implementation of research results, contribution to element 6</p>

Elements: 1- Prioritizing research and development needs 2- Promoting research and development 3- Building and improving innovative capacity 4- Transfer of technology 5- Application and management of intellectual property to contribute to innovation and promote public health 6- Improving delivery and access 7- Promoting sustainable financing mechanism 8- Establishing monitoring and reporting systems.

Activity 2.4a: Promote the creation and development of accessible public health libraries in order to enhance availability and use of publications by universities institutions and technical centres, especially in developing countries.

Activity 2.4d: Encourage the further development and dissemination of publicly or donor-funded medical inventions and know-how through appropriate licensing policies, including but not limited to open licensing, that enhance access to innovations for development of products of relevance to the public health needs of developing countries on reasonable, affordable and non-discriminatory terms.

5 Discussion

The assessment of activities of five major sectors, namely the federal offices, the academic sector, the NGOs, the private for-profit sector, and the PPPs, reflects that Switzerland is contributing to every one of the key elements of the GSPA-PHI. Key activities and contributions of the different sectors are summarised in Table 1.

This general statement, however, needs to be qualified with several important remarks.

5.1 Limitation of the current assessment

It is important to highlight that inevitably, by the nature of the approach and the available resources, this review and assessment of Swiss activities related to the GSPA-PHI has some limitations in relation to the following:

- There is a lack of knowledge of the GSPA-PHI strategy by some key informants, influencing the level of detail and completeness of the provided information; therefore, the list of described activities cannot be claimed to be exhaustive and complete.
- The heterogeneous level of information and the engagement of Swiss actors with respect to the IGWG with concomitant lack of resources made it difficult to collect all necessary information.
- There are possible overlaps in reported activities because of joined efforts between the different actors.
- There is a lack of clear definitions regarding Swiss PPPs and the contribution and involvement of Switzerland in this sector towards the implementation of the GSPA-PHI.
- A quantification of the state of the implementation was not feasible based on the collected information.

The assessment showed that the complexity of the domain covered by the GSPA-PHI limited a comprehensive country-level analysis. There are numerous areas of overlap between the elements and their activities. In addition, the activities reported by the different projects and initiatives are often multipurpose and multidisciplinary and cover a wide range of issues pertaining to different elements. As a result, the appropriate attribution of the information to clearly defined activities of the action plan became partly arbitrary. As mentioned above, the understanding of the interventions relevant to each particular element varied within stakeholders. As a result, many projects and

initiatives were being attributed to a range of different activities.

Therefore, Appendix 1 reflects stakeholders' contributions and embeds the abovementioned limitation.

5.2 Conscious effort and systematic approach needed

The fact that Switzerland contributes essentially to each of the key elements of the GSPA-PHI is not always the result of a conscious effort and a systematic approach, but simply a reflection that many Swiss actors are active in this field and take the challenges serious. Several actors have very interesting initiatives and projects, but there is little evidence of information or lessons learnt being exchanged proactively. For instance, the Swiss delegation participating in the negotiation process of the GSPA-PHI could not be aware of the different activities of Swiss actors because no systematic survey had been conducted before. This lack of exchange of information may lead to scarce complementarities and even unnecessary duplication of activities, which this report could help to overcome.

Current evidence shows that PPPs have a beneficial effect by increasing the number of products in development, attracting funding, and synergising expertise. Their potential, however, for leading to lower costs, reduced time from development to market, improved availability and access, and improved health impact and higher innovation levels has yet to be demonstrated. The latter should be the subject of further research to support the Swiss decision-makers or researchers in the priority setting and distribution of financial and other support to PPPs with scientific evidence.

There would be a clear benefit to be expected from a greater coherence of the Swiss activities concurring in the implementation of the GSPA-PHI through a well-conducted, multi-disciplinary, multi-sector, and multi-partner approach.

5.3 Trends in the contribution and identified gaps

Despite the abovementioned weaknesses in the present assessment, some trends in the current contributions to the implementation of the GSPA-PHI can be identified.

Swiss contributions can be found across all eight elements of the GSPA-PHI with many actors concentrating on two or three elements, some on only one, and some on several; only the government addresses all eight elements because element 8 is addressed only by WHO and the government.

Some elements receive little, if no attention. In particular, PPPs and the private for-profit sector, according to the information provided in this assessment, are not active in the field of traditional medicine in relation to the implementation of the GSPA-PHI, and the academic sector has only a limited involvement. On the other hand, other Swiss stakeholders, namely the NGOs, appear to act as pathfinders in supporting the sustainable development and use of traditional medicine, taking into account the indigenous knowledge and social determinants of the local populations' health-care-seeking paths. The Swiss examples are particularly relevant because, while the GSPA-PHI clearly recognises the importance of traditional medicine, there is still a need to identify actors to move its new agenda forward. The Swiss experience could provide interesting lessons for better including traditional medicine in striving for better access to health.

Swiss academia collaborates with some of these projects by contributing technical know-how and expertise. For instance, Swiss TPH analyses the chemical components of active ingredients of the traditional medical products. Swiss academia also demonstrates creativity and concern for the health of poor populations not only through this involvement in supporting traditional medicine but also in numerous individual projects aimed at developing new technologies, new approaches to training of health professionals, or delivering more accessible and efficient health care services. These activities remain often scattered and unknown, as the health, development, and innovation decision-makers tend to address well-known, readily accessible partners rather than getting into the time-consuming effort of identifying and bringing together the many bilateral projects of individual researchers and small academic institutions or hospitals.

With many Swiss universities having signed the Berlin declaration, the academic sector makes an important contribution to the promotion of open access to the scientific work done at the universities.

The current assessment clearly shows the contribution of the private for-profit sector to many different activities supporting the implementation of the GSPA-PHI. As for the other sectors, it is not possible to quantify the contribution. Recently, several initiatives started, supporting increased

access to knowledge, research results, and intellectual property such as the "Pool for open innovations against neglected tropical diseases" and the "Medicine patent pool", established with the support of UNITAID. Concerning the "Medicine patent pool", the member-companies of Interpharma are discussing possible collaboration. Roche is preparing the negotiation process [35].

Overall, Switzerland enjoys a wealth of expertise and creativity, and any effort to build up a truly national response to the challenges of the GSPA-PHI would certainly benefit from an increased exchange of information and improved coordination of the multiple Swiss initiatives, whether it is from academia, NGOs, or other stakeholders. There is a clear political will to do landscaping and the associated analysis of the Swiss activities related to the GSPA-PHI, with the commitment and interest of some of the major Swiss stakeholders. Innovation and its current landscape in Switzerland are complex issues that require time and the involvement of key informants and actors as well as mid/long-term political and financial support.

5.4 The current policy environment in Switzerland related to the implementation of the GSPA-PHI

Inspiring and leading a process as complex as that of planning and monitoring the GSPA-PHI and involving in the country multiple national and international actors needs a great deal of political "courage".

The engagement of the FOPH and other governmental actors in the CIPIH and IGWG processes demonstrates the growing awareness of Swiss policy makers of the policy challenges they have to address for building up a national policy environment supportive of internationally agreed principles of universal access to essential medical products. These efforts should be in line with a rational, effective, and sustainable implementation of the GSPA-PHI.

Switzerland is both an important drug producer and a well-respected Official Development Assistance (ODA) provider. The current assessment of activities contributing to the implementation of the GSPA-PHI reflects overall relevant contributions of all key actors. It would be of great interest to expand such an assessment to also address underlying factors such as the Swiss policy environment and research culture, incentives, and disincentives driving these factors. This would increase the relevance of such an assessment and provide an even more powerful example and model for the WHO Member States, the WHO Secretariat, and the other stakeholders concerned.

5.5 The issue of sustainable financing

Various priorities and timelines are important factors to take into consideration when looking at sustainability. The current timeline defined by WHO Member States for the GSPA-PHI implementation is 2015. The WHO has to report on progress to the World Health Assembly every two years, and the next progress report is expected in 2012. However, while the GSPA-PHI was adopted in 2008 and activities of the “quick start programme” are currently being implemented, the core of the implementation activities is starting at a much slower pace.

Sustainable financing is absolutely key to the success of the GSPA-PHI. As identified through the current assessment, the usual project timeline of many bilateral development agencies, many North–South research projects, and many PPPs is only three to five years. However, sufficient long-term commitment with a longer duration than only three to five years is needed from the Swiss government and other Swiss actors to implement the GSPA-PHI on a sustainable basis. In general, it can be assumed that the sustainability question is likely to be shifting the existing paradigms regarding R&D and innovation.

6 Conclusions

The current assessment of the Swiss contribution to the implementation of the GSPA-PHI, which was endorsed by the World Health Assembly in May 2008, shows that overall, the Swiss sectors assessed in this report have proactively implemented all eight elements of the GSPA-PHI. This does not mean that all actors are addressing most or all of the eight elements, but many are addressing two to three elements with some actors addressing most of the different elements. This assessment identified a gap in the field of traditional medicine, an important domain in the GSPA-PHI, especially from the PPPs and from the private for-profit sector, with only limited or dispersed identified interventions in this domain.

Moreover, while the list of Swiss activities seems to be quite comprehensive, it was beyond the scope of the assessment to determine the weight of these, their resulting impact, and which one should be favoured or simply sustained in the future. It was indeed not possible to quantify the contributions or to conclude that Switzerland is contributing enough or if it should do more in certain areas.

Further, the assessment was subject to a number of limitations, among others, the lack of a common methodology, shortcomings of the reporting tool, and to a certain extent, incompleteness in the reports submitted by different sectors. Therefore, the current list of activities reflected in this report is not claimed to be complete, which is understandable in view of the complexity of the subject. In addition, these limitations made the classification of activities and data analysis cumbersome if not possibly biased.

Even taking the limitations into account, however, a voluntary coordination in terms of exchange of information and communication among different actors could enhance the synergies in respect to the implementation of the GSPA-PHI.

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Epilog Swiss TPH, the mandated authors of the study

This initial review and analysis of Swiss activities related to the GSPA-PHI was not an easy task. While the different Swiss stakeholders concerned were interested in the exercise, not all of them were sufficiently conversant with the GSPA-PHI. The heterogeneous levels of information and engagement of the different Swiss actors, with regards to the IGWG process and its resulting strategy, did not make it easy for the various organisations mandated to contribute the requested data. Also, given the short time line for the data collection, it was difficult to obtain sufficient and appropriate information. Therefore, the information provided in the different reports is certainly incomplete. Serious efforts, however, were undertaken to complete the information in the consolidated report. For instance, it was rather difficult to explore the various interventions of the Swiss academic sector. There is no central body, where relevant information is collected, and information tends to be with individuals, or within a given part of an institution, city, or canton, with information on their efforts and results not easily accessible. Reliable information from the private for-profit sector is also difficult to obtain. Industries have, for good reason, strong corporate identities and related communication strategies. This leads to reluctance in sharing some information for reasons of image, potential competition, and different interpretations of transparency and sharing of lessons learned. Difficulties with obtaining information from Public Private Partnerships were also faced in terms of finding a widely agreed upon definition, especially regarding the relevant level of Swiss involvement to be considered a Swiss contribution towards implementing the GSPA-PHI.

The tool used to support data collection in the current assessment is based on the listing of all activities of the GSPA-PHI. This tool is not very user friendly for assessing country level activities. In the Swiss context it has proven to be rather difficult to use because there is a lack of common understanding of some of the defined activities. Furthermore, there is an apparent overlap and duplication of activities, making it difficult to classify projects and initiatives. The complexity of the tool increased the risk of resistance to use it, hence, the likelihood of gaps in data collection increased. This could be one reason why the assessment reports of the different sectors were partially incomplete.

To clearly classify the different projects and activities in relation to the activities identified by the GSPA-PHI requires a minimum level of information on the projects and initiatives. This information was not always available, least of all for the projects and initiatives of the different sectors which were added in the consolidated report. Therefore, the completion of appendix 1 was done to the best knowledge of the authors but cannot be claimed as fully complete.

It is also necessary to note that the views and ideas expressed herein do not necessarily imply or reflect the opinion of the authors. This report is a consolidation of activities described by different stakeholders, with each stakeholder having contributed to the description of activities of his/her own sector. This information could not be systematically verified by the authors.

In conclusion, through its history of involvement with the CIPIH and the IGWG processes leading to the adoption of the GSPA-PHI, it can be said that Switzerland has demonstrated its ability to take a leadership role in the area of innovation for health. Generally, Switzerland enjoys a wealth of expertise and creativity, and any effort to develop a comprehensive national response to the challenges of the GSPA-PHI would certainly benefit from an increased exchange of information and improved coordination of the multiple Swiss initiatives - be they from the academia, the NGOs or other stakeholders. Innovation and its current landscape in Switzerland is a complex issue that requires time and the involvement of essential informants and actors, as well as mid/long term political and financial support.

Appendix

Table 2: WHO Global plan of action on public health, innovation and intellectual property - Swiss federal offices interested

Number	Elements and sub-elements	Specific actions	Stakeholder(s)*	Contribution of Switzerland					Activities (key word + n° - see separate list by office)
				1. Swiss Federal Offices	2. Academic sector	3. NGOs	4. Private sector	5. PPPs	
1	Element 1. Prioritizing research and development needs								
1.1 a	(1.1) mapping global research and development with a view to identifying gaps in research and development on diseases that disproportionately affect developing countries	(a) develop methodologies and mechanisms to identify gaps in research on Type II and Type III diseases and on developing countries' specific R&D needs in relation to Type I diseases	WHO; Governments; other relevant stakeholders	X	X			X	1. SER: support to the Swiss Vaccine Research Institute; SDC: support to TDR, COHRED and GFHR 2. Swiss TPH, GHI, and other academic institutions, are, from an academic point of view, interested to identify gaps. 5. MMV, DNDI, NITD: through their collaborations with scientific institutions
1.1 b		(b) disseminate information on identified gaps, and evaluate their consequences on public health	WHO; Governments; other relevant stakeholders	X	X	X		X	1. SDC: support to TDR, COHRED and GFHR; SER 2. Done through scientific publications 3. MSF Switzerland 5. Done through scientific publications
1.1 c		(c) provide an assessment of identified gaps at different levels – national, regional and international – to guide research aimed at developing affordable and therapeutically sound products to meet public health needs	WHO; Governments; other relevant stakeholders	X	X	X		X	1. SDC: support to TDR, COHRED and GFHR; SER 2. Swiss TPH, as an academic institution, is, from an academic point of view, interested to identify gaps; Global Health Programme of the Graduate Institute in Geneva 3. MSF Switzerland 5. MMV, DNDI, NITD: through their collaborations with scientific institutions
1.2 a	(1.2) formulating explicit prioritized strategies for research and development at country and regional and inter-regional levels	(a) set research priorities so as to address public health needs and implement public health policy based on appropriate and regular needs assessments	Governments; regional organizations	X	X		X	X	1. SER: support to the Swiss Vaccine Research Institute; SDC: support to TDR, FOPH: proposal for national research programme to strengthen the research and development of new drugs and vaccines against neglected diseases. 2. Swiss TPH: through ist collaboration with governments and regional organizations 4. Novartis through NVGH 5. DNDI, NITD: through their collaborations with governments and regional organizations
1.2 b		(b) conduct research appropriate for resource-poor settings and research on technologically appropriate products for addressing public health needs to combat diseases in developing countries	Governments; WHO; other relevant stakeholders (including academia, relevant health-related industries, national research institutions and public-private partnerships)	X	X		X	X	1. SER: support to the Swiss Vaccine Research Institute, Swiss TPH and participation in the EU Framework Programme on Research and Development; SDC: support to TDR and ANDI, FOPH: proposal for national research programme to strengthen the research and development of new drugs and vaccines against neglected diseases. 2. Key activity of the Swiss TPH and EPFL-GHI, University of Lausanne through EU- and WHO- funded projects in the field of malaria, HIV and polio-vaccine, HUG-Koirala Institute project, SNSF through NCCR North-South, SCOPES, and RPDC 4. Novartis through NVGH 5. Key activities of DNDI, MMV, NITD and other global PPPs
1.2 c		(c) include research and development needs on health systems in a prioritized strategy	Governments; WHO; other relevant stakeholders (including academia, national research institutions, and public-private partnerships)	X	X			X	1. SER: support to Swiss TPH; SDC: SWAPs and contribution to national health policies 2. Swiss TPH involved in many health system strengthening programmes; Geneva Health Forum; Global Health Programme of the Graduate Institute in Geneva 5. MMV: access program, DNDI: policy for access
1.2 d		(d) urge the leadership and commitment of governments, regional and international organizations and the private sector in determining priorities for R&D to address public health needs	WHO; Governments; other international intergovernmental organizations; other relevant stakeholders (including private sector)	X	X	X		X	1. SER: support to the Swiss TPH and participation in the EU Framework Programme on Research and Development; SDC: support to TDR and COHRED, FOPH: proposal for national research programme to strengthen the research and development of new drugs and vaccines against neglected diseases. 2. Swiss TPH: through its collaboration with governments, regional and international organizations; Geneva Health Forum 3. BD 5. MMV, DNDI, NITD: through their collaborations with governments, regional and international organizations
1.2 e		(e) increase overall R&D efforts on diseases that disproportionately affect developing countries, leading to the development of quality products to address public health needs, user friendly (in terms of use, prescription and management) and accessible (in terms of availability and affordability)	Governments; WHO; other relevant stakeholders (including academia, relevant health related industries, national research institutions, and public-private partnerships)	X	X		X	X	1. SER: support to the Swiss Vaccine Research Institute, Swiss TPH and participation in the EU Framework Programme on Research and Development; SDC: support to TDR and COHRED, FOPH: proposal for national research programme to strengthen the research and development of new drugs and vaccines against neglected diseases. 2. Key activity of the Swiss TPH and EPFL-GHI; University of Lausanne through EU- and WHO- funded projects in the field of malaria, HIV and polio-vaccine, research projects at the University of Basel and the University of Geneva 4. Novartis through NVGH 5. Key activities of DNDI, MMV, NITD and other global PPPs
1.3 a	(1.3) encouraging research and development in traditional medicine in accordance with national priorities and legislation, and taking into account the relevant international instruments, including, as appropriate, those concerning traditional knowledge and the rights of indigenous peoples	(a) set research priorities in traditional medicine	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia; national research institutions; public-private partnerships; and concerned communities)	X					1. SDC: Support to national research programmes in Tanzania and Mali; SER
1.3 b		(b) support developing countries to build their capacity in research and development in traditional medicine	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia, relevant health-related industries, national research institutions, public-private partnerships)	X		X			1. SER: Support to research centres in Ivory Coast and Tanzania; SDC: Support to national research programmes in Tanzania and Mali 3. Support of the regional centre "Medicina Natural y Tradicional MNT" in Cuba through mediCuba-Suisse, mission 21, SRC
1.3 c		(c) promote international cooperation and the ethical conduct of research	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders	X					1. SER: Participation in COST research programmes; SDC: Support to TDR, COHRED and GFHR

Number	Elements and sub-elements	Specific actions	Stakeholder(s)*	Contribution of Switzerland					Activities (key word + n° - see separate list by office)
				1. Swiss Federal Offices	2. Academic sector	3. NGOs	4. Private sector	5. PPPs	
1.3 d		(d) support South-South cooperation in information exchange and research activities	Governments; WHO; other international intergovernmental organizations; regional organizations; other relevant stakeholders	X		X			1. SDC: Support to TDR, ANDI, COHRED and new regional initiatives in Africa 3. Esperanza Medicines Foundation, Antenna Technologies, mediCuba-Suisse
1.3 e		(e) support early-stage drug research and development in traditional medicine systems in developing countries	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders	X	X	X		X	1. SDC 2. Swiss TPH: involvement in research on natural substances (characterized molecules, not on herbal extracts themselves); Uni Basel has a research project in South Africa, screening medical plants for active molecules 3. mediCuba-Suisse 5. DNDI, MMV, NITD: involvement in research on natural substances such as herbal medicines; however mostly focussing on the characterized molecules and not on herbal extracts themselves
2	Element 2. Promoting research and development								
2.1 a	(2.1) supporting governments to develop or improve national health research programmes and establish, where appropriate, strategic research networks to facilitate better coordination of stakeholders in this area	a) promote cooperation between private and public sectors on research and development	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders	X	X		X	X	1. SDC: Support to TDR, COHRED and GFHR; SER; SECO 2. Swiss TPH: most of the activities are done in cooperation; SNSF: SCOPES programme; KFPE: by conferences or by members; Geneva Health Forum 4. Novartis through NVGH 5. DNDI, MMV, NITD: most of the activities are done in cooperation
2.1 b		(b) provide support for national health research programmes in developing countries through political action and, where feasible and appropriate, long-term funding	Governments; regional organizations; WHO (technical assistance); other relevant stakeholders	X	X			X	1. SDC: SWAPs and contribution to national health policies, support to COHRED and GFHR; SECO 2. Swiss TPH support in Tanzania, leading house scientific collaboration with South Africa, Centre Suisse de la Recherche Scientifique en Côte d'Ivoire 5. NITD in Singapore and Indonesia; DNDI in Malaysia, India, Brazil and Kenya
2.1 c		(c) support governments in establishing health-related innovation in developing countries	Governments; regional organizations; WHO (technical assistance); other relevant stakeholders	X	X				1. SDC: SWAPs and contribution to national health policies, support to COHRED and GFHR; SECO 2. Swiss TPH: support in Tanzania; SNSF: joint research projects in development cooperation programme
2.2 a	(2.2) promoting upstream research and product development in developing countries	(a) support discovery science, including where feasible and appropriate, voluntary open-source methods, in order to develop a sustainable portfolio of new products	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders	X	X			X	1. SER: WIRE study; SDC; SECO; IGE 2. Key activity of Swiss TPH; SNSF: bottom up funding; University of Lausanne through EU- and WHO-funded projects in the field of malaria, HIV and polio-vaccine 5. Key activities of DNDI, MMV, and NITD
2.2 b		(b) promote and improve accessibility to compound libraries through voluntary means, provide technical support to developing countries and promote access to drug leads identified through the screening of compound libraries	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders	X	X		X	X	1. IPI 2. Swiss TPH involved in screening of compounds in many collaborations; SNSF: bottom up funding 4. Roche through collaboration with OneWorld Health 5. DNDI, MMV, and NITD: through their collaborations with the pharmaceutical industry;
2.2 c		(c) identify incentives and barriers, including intellectual property-related provisions, at different levels – national, regional and international - that might affect increased research on public health, and suggest ways to facilitate access to research results and research tools	Governments; WHO; other international intergovernmental organizations (including WIPO and WTO); other relevant stakeholders	X	X			X	1. IPI: Legislative facilitation of access to research; SECO 2. Swiss TPH following the Global Access Policy; Uni Lausanne: cooperation with WHO 5. DNDI, MMV, and NITD: following the Global Access Policy
2.2 d		(d) support basic and applied scientific research on Type II and Type III diseases and on the specific R&D needs of developing countries in relation to Type I diseases	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders	X	X		X	X	1. SDC: Support to TDR; SER 2. Key activity of Swiss TPH; SNSF: bottom up approach in the DC programme; NCCR North-South; RPDC; EPFL-GHI; some research projects at the University of Basel and at the University of Geneva and HUG; University of Lausanne through EU- and WHO- funded projects in the field of malaria, HIV and polio-vaccine 4. Novartis through NVGH 5. Key activities of DNDI, MMV, and NITD
2.2 e		(e) support early-stage drug research and development in developing countries	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including relevant health-related industries, academia, international and national research institutions; donor agencies; development partners; nongovernmental organizations)	X	X		X	X	1. SDC: Support to TDR; SECO 2. Key activity of Swiss TPH; SNSF 4. Novartis through NVGH 5. Key activities of DNDI, MMV, and NITD
2.2 f		(f) build capacity to conduct clinical trials and promote public and other sources of funding for clinical trials and other mechanisms for stimulating local innovation, taking into account international ethical standards and the needs of developing countries	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including relevant health-related industries; academia; development partners; charitable foundations; public-private partnerships; nongovernmental organizations)	X	X		X	X	1. SER: Participation in COST research programmes; SDC 2. Swiss TPH: conducting clinical trials in low resource settings in collaboration with local partners; SNSF 4. Roche Training Programme 5. While DNDI and MMV are involved in clinical trials of all stages, NITD's research portfolio is involving proof-of-concept clinical trial

Number	Elements and sub-elements	Specific actions	Stakeholder(s)*	Contribution of Switzerland					Activities (key word + n° - see separate list by office)
				1. Swiss Federal Offices	2. Academic sector	3. NGOs	4. Private sector	5. PPPs	
2.2 g		(g) promote the generation, transfer, acquisition upon agreed terms and voluntary sharing, of new knowledge and technologies, consistent with national law and international agreements, to facilitate the development of new health products and medical devices to tackle the health problems of developing countries	Governments; WHO; other international intergovernmental organizations, other relevant stakeholders (including: academia, international and national research institution; relevant health-related industries and development partners)	X	X			X	1. SDC: Support to COHRED; SECO 2. Swiss TPH: following the Global Access Policy; Uni Lausanne: cooperation with WHO; SNSF; Universities signing the Berlin Declaration 5. DNDI, MMV, and NITD: following the Global Access Policy
2.3 a	(2.3) improving cooperation, participation and coordination of health and biomedical research and development	(a) stimulate and improve global cooperation and coordination in research and development, in order to optimize resources	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders	X	X		X	X	1. SER: Bilateral research program with South Africa, participation in COST research programmes; SDC 2. Swiss TPH: many activities are done in cooperation; SNSF; University of Zurich; KFPE; SCOPES; NCCR North-South; RPDC; Geneva Health Forum 4. Novartis through NVGH, Roche collaboration with OneWorld Health 5. DNDI, MMV, and NITD: most of the activities are done in cooperation
2.3 b		(b) enhance existing fora and examine the need for new mechanisms, in order to improve the coordination and sharing of information on research and development activities	Governments; WHO; other relevant stakeholders	X	X			X	1. SER: Participation in COST research programmes; SDC; IGE; FOPH 2. Swiss TPH is actively involved in the Commission for Research Partnerships with developing countries and is member of various fora; ZHUAS: active participation in international networking; SNSF; SNIS; Global Health Programme of the Graduate Institute in Geneva 5. DNDI, MMV, and NITD: members of various fora
2.3 c		(c) encourage further exploratory discussions on the utility of possible instruments or mechanisms for essential health and biomedical R&D, including inter alia, an essential health and biomedical R&D treaty	Interested Governments; [WHO]; other relevant stakeholders (including nongovernmental organizations)	X	X	X		X	1. SER; SDC; SECO; IPI; FOPH 2. ZHUAS: active participation in international networking; Swiss TPH; Geneva Health Forum 3. BD, MMS 5. MMV, DNDI, and NITD
2.3 d		(d) support active participation of developing countries in building technological capacity	Governments; WHO; other relevant stakeholders	X	X	X	X	X	1. SDC: Support to TDR, ANDI, COHRED (new initiative in Africa) 2. Swiss TPH: Contribution through collaborations with local organizations and institutions and through support academic carriers; SNSF 3. Collaboration with local staff in many NGO projects 4. Roche Technology Transfer Initiative 5. DNDI and NITD contribute through collaborations with local organizations and institutions and through supporting academic carriers (PhD students, etc); MMV collaborates in the South mainly with universities in South Africa, except for running clinical trials where it collaborates with universities in disease endemic countries
2.3 e		(e) promote the active participation of developing countries in the innovation process	Governments; WHO; other relevant stakeholders	X	X			X	1. SDC; SECO 2. Swiss TPH: Contribution through collaborations with local organizations and institutions and through support academic carriers; SNSF; Universities: hosting of PhD and post-doctorate students 5. DNDI and NITD contribute through collaborations with local organizations and institutions and through supporting academic carriers (PhD students, etc); MMV collaborates in the South mainly with universities in South Africa, except for running clinical trials where it collaborates with universities in disease endemic countries
2.4 a	(2.4) promoting greater access to knowledge and technology relevant to meet public health needs of developing countries	(a) promote the creation and development of accessible public health libraries in order to enhance availability and use of relevant publications by universities, institutes and technical centres, especially in developing countries	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia, research institutions, relevant health-related industries; nongovernmental organizations; publishers)	X	X				1. SER; IPI; FOPH 2. Universities and academic institutions which have signed the Berlin Declaration
2.4 b		(b) promote public access to the results of government funded research, by strongly encouraging that all investigators funded by governments submit to an open access database an electronic version of their final, peer-reviewed manuscripts	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia and research institutions)	X	X				1. SER; IPI; FOPH 2. Universities and academic institutions which have signed the Berlin Declaration; SNSF: support of open access
2.4 c		(c) support the creation of voluntary open databases and compound libraries including voluntary provision of access to drug leads identified through the screening of such compound libraries	Governments; WHO; other international intergovernmental organizations (including WIPO); other relevant stakeholders (including relevant health-related industries)	X	X		X		1. SER; IPI; FOPH 2. SNSF 4. Roche through its collaboration with OneWorld Health.

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				1. Swiss Federal Offices	2. Academic sector	3. NGOs	4. Private sector	5. PPPs	
2.4 d		(d) encourage the further development and dissemination of publicly or donor-funded medical inventions and know-how through appropriate licensing policies, including but not limited to open licensing, that enhance access to innovations for development of products of relevance to the public health needs of developing countries on reasonable, affordable and non-discriminatory terms	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia and national research institutions)	X	X			X	1. IPI 2. Swiss TPH: Intellectual property issues are in general dealt with on a case by case basis; the basic guiding principle is to follow the Global Access Policy; ZHUAS: Cooperation project with Health Sciences University of Mongolia 5. DNDI, MMV, and NITD: following the Global Access Policy
2.4 e		(e) consider, where appropriate, use of a "research exception" to address public health needs in developing countries consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights	Governments;	X					1. IPI: Adoption of research exemption; SECO
2.5 a	2.5 establishing and strengthening national and regional coordinating bodies on research and development	(a) develop and coordinate a research and development agenda	Governments; regional organizations; WHO; other relevant stakeholders	X	X			X	1. SER; SDC 2. Swiss TPH; EPFL-GHI; ZHUAS; SNSF 5. Key activities of DNDI, MMV, and NITD
2.5 b		(b) facilitate the dissemination and use of research and development outcomes	Governments; regional organizations; WHO; other relevant stakeholders	X	X			X	1. SER; SDC 2. Scientific publications 5. Publication of results
3	Element 3. Building and improving innovative capacity								
3.1 a	(3.1) building capacity of developing countries to meet research and development needs for health products	(a) support investment by developing countries in human resources and knowledge bases, especially in education and training including in public health	Governments; other international intergovernmental organizations; other relevant stakeholders (including development partners)	X	X	X	X		1. SDC: Support to TDR; SECO 2. Swiss TPH world-renowned institution for teaching and training; ZHUAS: Cooperation project with Health Sciences University of Mongolia; University of Basel with research projects in collaboration with the Swiss TPH; projects of HUG (RAFT, training in Bamako); SNSF: in the framework of the SCOPES programmes; Graduate Institute Geneva 3. Many NGOs involved in training activities 4. Roche skills transfer and education support programmes, NVGH strong focus on capacity building
3.1 b		(b) support existing and new research and development groups and institutions, including regional centres of excellence, in developing countries	Governments; other international intergovernmental organizations; other relevant stakeholders (including research and development groups, relevant health-related industries and development partners)	X	X	X		X	1. SDC: Support to TDR, contribution to national health systems, prioritization of health care agenda in several countries; SECO 2. Swiss TPH has a strong engagement in Ifakara (TTCIH), Tanzania; SNSF 3. mediCuba-Suisse (national cancer clinic); Novartis Foundation support of TTCIH in Tanzania; SRC in Ghana 5. DNDI and NITD collaborate with different research institutions in the South; MMV mainly works with universities in South Africa
3.1 c		(c) strengthen health surveillance and information systems	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including nongovernmental organizations, research institutions, academia)	X	X	X	X		1. SDC; SECO 2. Swiss TPH: large experience in Demographic Surveillance Systems 3. NGOs running in-country programs with data collection such as MFS, SolidarMed 4. Roche collaboration with google.org
3.2 a	(3.2) framing, developing and supporting effective policies that promote the development of capacities for health innovation	(a) establish and strengthen regulatory capacity in developing countries	Governments; WHO; other relevant stakeholders (including national and regional regulatory agencies)	X	X			X	1. SECO: Financing of capacity strengthening projects, financing of an investment and capacity building project in Azerbaijan; SDC; Swissmedic 2. New development within Swiss TPH 5. DNDI: Conduction of a regulatory workshop in Nairobi in June 2009
3.2 b		(b) strengthen human resources in research and development in developing countries through long-term national capacity building plans	Governments; other international intergovernmental organizations; other relevant stakeholders (including development partners; international and national research institutions)	X	X				1. SDC: Support to TDR; FOPH 2. Swiss TPH: Project on medical education in Tajikistan; SNSF: more short term activities (3 years)
3.2 c		(c) encourage international cooperation to develop effective policies for retention of health professionals including researchers in developing countries	Governments; WHO; other international intergovernmental organizations (including International Organization for Migration and ILO); other relevant stakeholders	X	X				1. SDC: Support to TDR; FOPH: Thematic document on migration of health workers 2. Swiss TPH: Mandate from BAG to formulate recommendations on effective and efficient practices in Switzerland to counteract migration of staff working in the health sector; SNSF: in the framework of DC programmes, membership in International Foundation for Science in Stockholm

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				1. Swiss Federal Offices	2. Academic sector	3. NGOs	4. Private sector	5. PPPs	
3.2 d		(d) urge Member States to establish mechanisms to mitigate the adverse impact of the loss of health personnel in developing countries, particularly researchers, through migration, including by ways for both receiving and originating countries to support the strengthening of national health and research systems, in particular human resource development in the countries of origin, taking into account the work of WHO and other relevant organizations	Governments	X					1. FOPH: Thematic document on migration of health workers; SDC
3.3 a	(3.3) providing support for improving innovative capacity in accordance with the needs of developing countries	(a) develop successful health innovation models in developing innovative capacity	Governments; WHO; other international intergovernmental organizations (including WIPO, OECD and UNCTAD); other relevant stakeholders (including academia; research institutions; health related industries and developmental partners)	X	X				1. SDC 2. ZHUAS: Cooperation project with Health Sciences University of Mongolia
3.3 b		(b) intensify North-South and South-South partnerships and networks to support capacity building	Governments; WHO; other International intergovernmental organizations; other relevant stakeholders (including academia, research institutions, relevant health-related industries)	X	X	X	X	X	1. SER: Support to the Swiss TPH; SECO: Financing of capacity strengthening projects, realisation of the Swiss Vietnamese Intellectual Property Project; SDC 2. Swiss TPH; ZHUAS: Cooperation project with Health Sciences University of Mongolia; University of Basel: Competence centre "Africa"; University of Zurich: building up partnerships with the Makerere University in Uganda and the National University of Rwanda; SNSF; RPDC; SCOPES; KFPE; HUG 3. North-South and South-South partnerships are part of many programmes of NGOs 4. Novartis through NVGH 5. Most activities done through such partnerships
3.3 c		(c) establish and strengthen mechanisms for ethical review in the research and development process, including clinical trials, especially in developing countries	Governments; WHO; other relevant stakeholders (including academia and research institutions)	X	X		X	X	1. SER: Participation in EDCTP; FOPH: Draft Federal Law on human research; SDC 2. Conducted research follows international accepted ethical standards 4. Conducted research follows international accepted ethical standards 5. Conducted research follows international accepted ethical standards
3.4 a	(3.4) supporting policies that will promote innovation based on traditional medicine within an evidence-based framework in accordance with national priorities and taking into account the relevant provisions of relevant international instruments	(a) establish and strengthen national and regional policies to develop, support, promote traditional medicine	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including concerned communities)	X		X			1. SDC 3. medico international schweiz, BD
3.4 b		(b) encourage and promote policies on innovation in the field of traditional medicine	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including international and national research institutions, concerned communities)	X					1. SDC
3.4 c		(c) promote standard setting to ensure the quality, safety and efficacy of traditional medicine, including by funding the research necessary to establish such standards	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including national and regional regulatory agencies; international and national research institutions; development partners; concerned communities)	X	X	X			1. SDC, Swissmedic 2. SNSF 3. Swiss Red Cross in Paraguay, mediCuba-Suisse
3.4 d		(d) encourage research on mechanisms for action and pharmacokinetics of traditional medicine	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including academia; international and national research institution; relevant health-related industries; concerned communities)	X	X	X			1. SER; FOPH 2. SNSF 3. Esperanza Medicines Foundation
3.4 e		(e) promote South-South collaboration in traditional medicine	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including research institutions, regional bodies, academia)	X					1. SDC
3.4 f		(f) formulate and disseminate guidelines on good manufacturing practices for traditional medicines and laying down evidence-based standards for quality and safety evaluation	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including national and regional regulatory agencies, relevant health-related industries)	X					1. SDC, FOPH, Swissmedic

Number	Elements and sub-elements	Specific actions	Stakeholder(s)*	Contribution of Switzerland					Activities (key word + n° - see separate list by office)
				1. Swiss Federal Offices	2. Academic sector	3. NGOs	4. Private sector	5. PPPs	
3.5 a	(3.5) developing and implementing, where appropriate, possible incentive schemes for health-related innovation	(a) encourage the establishment of award schemes for health-related innovation	Governments: [WHO]/[WHO]/[WHO]; other international intergovernmental organizations [(including WIPO)]; other relevant stakeholders (including academia; international and national research institution; development partners; charitable foundations)	X	X				1. SER; SDC, SECO 2. ZHUAS
3.5 b		(b) encourage recognition of innovation for purposes of career advancement for health researchers	Governments: WHO; other international intergovernmental organizations; other relevant stakeholders (including academia; international and national research institution; development partners; charitable foundations)	X	X			X	1. SDC: Support to TDR; SER; SECO 2. Joint publications 5. Joint publications
Element 4. Transfer of technology									
4.1 a	(4.1) promoting transfer of technology and the production of health products in developing countries	(a) explore possible new mechanisms and make better use of existing mechanisms to facilitate transfer of technology and technical support to build and improve innovative capacity for health-related research and development, particularly in developing countries	Governments: WHO; other international intergovernmental organizations (including WTO, UNCTAD, UNIDO, WIPO); other relevant stakeholders (including; international and national research institution; relevant health-related industries)	X	X	X			1. SECO: targeted aid at health infrastructure in Egypt 2. Swiss TPH: Through collaboration with local organisations; University of Geneva with RAFT 3. NFSD with eLearning programmes such as ICATT and eLearning project in Ghana 5. DNDI and NITD: through collaboration with local organisations; MMV works mainly in the field of clinical trials with universities in the disease endemic countries.
4.1 b		(b) promote transfer of technology and production of health products in developing countries through investment and capacity building	Governments; WHO; other intergovernmental organizations; other relevant stakeholders (including health-related industries)	X	X	X	X	X	1. SER: Support to the Swiss TPH; SECO: Investment and capacity building projects, targeted aid at health infrastructure in Jordan and Egypt, financing of an investment and capacity building project in Ghana 2. Swiss TPH: SNSF 3. mediCuba-Suisse (transfer of raw material) 4. Roche Technology Transfer Initiative 5. DNDI has the strongest focus on technology transfer
4.1 c		(c) promote transfer of technology and production of health products in developing countries through identification of best practices, and investment and capacity building provided by developed and developing countries where appropriate	Governments: WHO; other international intergovernmental organizations; other relevant stakeholders (including relevant health-related industries; academia; nongovernmental organizations; development partners; charitable foundations)	X	X	X	X	X	1. SDC: Support to TDR and ANDI; SECO: Investment and capacity building projects, targeted aid at health infrastructure in Egypt, financing of an investment and capacity building project in Serbia 2. Swiss TPH 3. Novartis Foundation (support of the TTCIH); Swiss Aids Care International (transfer of know how and capacity building); most NGOs do capacity building in their programs 4. Roche Technology Transfer Initiative 5. DNDI has the strongest focus on technology transfer
4.2 a	(4.2) supporting improved collaboration and coordination of technology transfer for health products, bearing in mind different levels of development	(a) encourage North–South and South–South cooperation for technology transfers, and collaboration between institutions in developing countries and the pharmaceutical industry	Governments; WHO; other international intergovernmental organizations (including WIPO); other relevant stakeholders (including relevant health-related industries; international and national research institutions; academia; nongovernmental organizations; development partners)	X	X	X	X	X	1. SER: Bilateral research program with South Africa; SDC: Support to research institutions 2. Swiss TPH: ARCEAU project 3. Afro-European Medical and Research Network 4. Roche Technology Transfer Initiative 5. MMV, DNDI and NITD: through their collaborations with the pharmaceutical industry and local organisations
4.2 b		(b) facilitate local and regional networks for collaboration on research and development and transfer of technology	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including relevant health-related industries, national research institutions, academia, nongovernmental organizations)	X	X			X	1. SDC: Support to TDR, ANDI, and COHRED 2. Swiss TPH: Member of the EANETT (Eastern African Network for Trypanosomiasis), ARCEAU project, SNSF: potential effect of joint research projects in the DC and SCOPES programme 5. DNDI: Involved in three regional networks for research capacity strengthening
4.2 c		(c) continue to promote and encourage technology transfer to least-developed country members of the WTO consistent with Article 66.2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights	Governments	X					1. IPI and SECO
4.2 d		(d) promote the necessary training to increase absorptive capacity for technology transfer	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including research institutions)	X	X	X			1. SECO: targeted aid at health infrastructure in Egypt 2. Swiss TPH: Egypt - Swiss radiology project, sponsored by the Egyptian and Swiss governments; SNSF: potential effect of joint research projects in the DC and SCOPES programmes 3. SRC in Egypt, Entrea, Zimbabwe: strengthening national blood transfusion services
4.3 a	(4.3) developing possible new mechanisms to promote transfer of and access to key health-related technologies	(a) examine the feasibility of voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical devices	Governments; WHO; other international intergovernmental organizations (including WIPO); other relevant stakeholders (including international and national research institution; relevant health-related industries, nongovernmental organizations; academia)	X		X			1. SECO and IPI 3. Strong support for the UNITAID patent pool by MSF

Number	Elements and sub-elements	Specific actions	Stakeholder(s)*	Contribution of Switzerland					Activities (key word + n° - see separate list by office)
				1. Swiss Federal Offices	2. Academic sector	3. NGOs	4. Private sector	5. PPPs	
4.3 b		(b) explore and, if feasible, develop possible new mechanisms to promote transfer of and access to key health-related technologies of relevance to public health needs of developing countries especially on Type II and III diseases and the specific R&D needs of developing countries in respect of Type I diseases, which are consistent with the provisions of the TRIPS agreement and instruments related to that agreement, which provide flexibilities to take measures to protect public	Governments; WHO; other international intergovernmental organizations (including WIPO, WTO); other relevant stakeholders (including health-related industries)	X	X			X	1. SECO and IPI 2. Swiss TPH: following the Global Access Strategy 5. DNDI, MMV, and NITD: following the Global Access Strategy
5	Element 5. Application and Management of intellectual property to contribute to innovation and promote public health								
5.1 a	(5.1) support information sharing and capacity building in the application and management of intellectual property with respect to health related innovation and the promotion of public health in developing countries	(a) encourage and support the application and management of intellectual property in a manner that maximizes health-related innovation and promotes access to health products and that is consistent with the provisions in the TRIPS agreement and other WTO instruments related to that agreement and meets the specific R&D needs of developing countries	Governments; WHO; other international intergovernmental organizations (including WIPO, WTO, UNCTAD); other relevant stakeholders (including international and national research institutions and development partners))	X	X	X		X	1. IPI: Carrying out of cooperation projects, start of a new project with Ghana and a new one with Serbia 2. Swiss TPH: following the Global Access Strategy 3. MSF 5. DNDI, MMV, and NITD: following the Global Access Strategy
5.1 b		(b) promote and support, including through international cooperation, national and regional institutions in their efforts to build and strengthen capacity to manage and apply intellectual property in a manner oriented to public health needs and priorities of developing countries	Governments; WHO/[WHO]; other international intergovernmental organizations (including [WIPO]/[WIPO], [WTO]/[WTO], UNCTAD); other relevant stakeholders (including international and national research institutions and development partners)	X	X			X	1. IPI: Carrying out of cooperation projects, offering free patent searches, start of a new project with Ghana 2. Swiss TPH: ARCEAU project; ZHUAS: Cooperation project with Health Sciences University of Mongolia 5. DNDI: strong focus on capacity transfer
5.1 c		(c) Facilitate widespread access to, and promote further development of, including, if necessary, compiling, maintaining and updating, user-friendly global databases which contain public information on the administrative status of health-related patents, including supporting the existing efforts for determining the patent status of health products, in order to strengthen national capacities for analysis of the information contained in those databases, and improve the quality of patents.	[Governments]/[Governments]; [WHO]/[WHO]; other international intergovernmental organizations (including [WIPO]/[WIPO], [WTO]/[WTO], [UNCTAD]); other relevant stakeholders (including international and national research institutions and development partners))	X					1. IGE
5.1 d		(d) stimulate collaboration among pertinent national institutions and relevant government departments, as well as between national, regional and international institutions, in order to promote information sharing relevant to public health needs	Governments; WHO; Other international intergovernmental organizations; Other relevant stakeholders (including academia; international and national research institutions; development agencies; nongovernmental organizations; relevant health-related industries)	X	X			X	1. IPI: Interministerial expert group on health and intellectual property; FOPH: interministerial expert group on health and intellectual property; SECO 2. Swiss TPH support in Tanzania, leading house scientific collaboration with South Africa, Centre Suisse de la Recherche Scientifique en Côte d'Ivoire, ARCEAU project in DRC 5. NITD in Singapore and Indonesia; DNDI in Malaysia, India, Brazil and Kenya

Number	Elements and sub-elements	Specific actions	Stakeholder(s)*	Contribution of Switzerland					Activities (key word + n° - see separate list by office)
				1. Swiss Federal Offices	2. Academic sector	3. NGOs	4. Private sector	5. PPPs	
5.1 e		(e) strengthen education and training in the application and management of intellectual property, from a public health perspective taking into account the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement	Governments; [WHO]/[WHO]; other international intergovernmental organizations (including [WIPO]/[WIPO], [WTO]/[WTO], [UNCTAD]/[UNCTAD]); other relevant stakeholders (including international and national research institutions and development partners)	X		X			1. IPI: support of WTO and WIPO seminars 3. BD; different campaigns supported by a number of NGOs
5.1 f		(f) facilitate, where feasible and appropriate, possible access to traditional medicinal knowledge information for use as prior art in examination of patents, including, where appropriate, the inclusion of traditional medicinal knowledge information in digital libraries	Governments; [WHO]; other international intergovernmental organizations; other relevant stakeholders (including concerned communities)	X					1. IPI
5.1 g		(g) promote active and effective participation of health representatives in intellectual property-related negotiations, where appropriate, in order that such negotiations also reflect public health needs	Governments;	X					1. IPI and FOPH
5.1 h		(h) strengthen efforts to effectively coordinate work relating to intellectual property and public health among the Secretariats and governing bodies of relevant regional and international organizations to facilitate dialogue and dissemination of information to countries	Governments; WHO; other international intergovernmental organizations (including WIPO, WTO, and UNCTAD)	X					1. IPI and FOPH
5.2 a	(5.2) providing as appropriate, upon request, in collaboration with other competent international organizations technical support, including, where appropriate, to policy processes, to countries that intend to make use of the provisions contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including the flexibilities recognized by the Doha Ministerial Declaration on the TRIPS Agreement and Public Health and other WTO instruments related to the TRIPS agreement, in order to promote access to pharmaceutical products	(a) consider, whenever necessary, adapting national legislation in order to use to the full the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights, including those recognized by the Doha Declaration on TRIPS Agreement and Public Health and the WTO decision of 30 August 2003	Governments; WHO; Other international intergovernmental organizations (including WIPO, WTO and UNCTAD)	X					1. IPI
5.2 b		(b) Take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights, without prejudice to the sovereign rights of Member States	Governments; [WHO]; Other international intergovernmental organizations (including WIPO, WTO and UNCTAD)]	X	X			X	1. IPI 2. Swiss TPH: following the Global Access Strategy 5. DNDI, MMV and NITD: following the Global Access Strategy
5.2 c		(c) take into account in trade agreements the flexibilities contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights and including those recognized by the Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference (Doha, 2001) and the WTO decision of 30 August 2003	Governments	X					1. IPI and SECO

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				1. Swiss Federal Offices	2. Academic sector	3. NGOs	4. Private sector	5. PPPs	
5.2 d		(d) consider, where appropriate, taking necessary measures in countries with manufacturing capacity to, facilitate through export, access to pharmaceutical products in countries with insufficient or no manufacturing capacity in the pharmaceutical sector in a manner consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights, the Doha Declaration on the TRIPS Agreement and Public Health and the WTO decision of 30 August 2003	Governments	X					1. IPI: Implementation of WTO General Council decision of August 30, 2003.
5.2 e		(e) encourage finding ways, in ongoing discussions, to prevent misappropriation of health-related traditional knowledge, and consider where appropriate legislative and other measures to help prevent misappropriation of such traditional knowledge	Governments; WHO; other international intergovernmental organizations (including WIPO, WTO, UNEP/Secretariat of the Convention on Biological Diversity); other relevant stakeholders (including concerned communities)	X		X			1. IPI: obligation of declaration for the source of genetic resources and traditional knowledge 3. medico international schweiz, BD
5.3 a	(5.3) exploring and, where appropriate, promoting possible incentive schemes for research and development on Type II and Type III diseases and on developing countries' specific research and development needs in relation to Type I diseases	(a) explore and, where appropriate, promote a range of incentive schemes for research and development including addressing, where appropriate, the de-linkage of the costs of research and development and the price of health products, for example through the award of prizes, with the objective of addressing diseases which disproportionately affect developing countries	[Governments; (WHO)/WHO]; other international intergovernmental organizations; other relevant stakeholders (including international and national research institutions; development partners; charitable foundations; relevant health related industries; nongovernmental organizations)]	X					1. SDC; SECO; IPI; FOPH
6	Element 6. Improving delivery and access								
6.1 a	(6.1) encouraging increased investment in the health-delivery infrastructure and financing of health products in order to strengthen the health system	(a) invest in developing health-delivery infrastructure and encourage financing of health products	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including development partners, charitable foundations, private sector and relevant health-related industries)	X	X	X	X	X	1. SDC: Support to national health programmes; FOPH: Premium for innovation 2. Swiss TPH is partner in different access programs 3. several NGOs 4. Access programmes of Novartis and Roche 5. DNDI focus on advocacy for access but is not directly involved in access programs, MMV has access programs
6.1 b		(b) develop effective and sustainable mechanisms in least-developed countries in order to improve access to existing medicines, acknowledging the transitional period until 2016[1]	Governments; WHO; other international intergovernmental organizations (including WTO); other relevant stakeholders	X	X	X	X	X	1. SDC: support to prioritize health care in national agendas; IPI; SECO 2. Swiss TPH is partner in different access programs; ZHUAS: Cooperation project with Health Sciences University of Mongolia 3. Novartis Foundation access programmes 4. Access programmes of Novartis and Roche 5. DNDI focus on advocacy for access but is not directly involved in access programs, MMV has access programs
6.1 c		(c) prioritize health care in national agendas	Governments	X					1. SDC; FOPH
6.1 d		(d) encourage health authorities to improve domestic management capacities in order to improve delivery and access to medicines and other health products with quality, efficacy, safety and affordability and, where appropriate, to develop strategies to promote rational use of medicines	Governments; WHO	X					1. SDC: Contributions to TDR; FOPH

Number	Elements and sub-elements	Specific actions	Stakeholder(s)*	Contribution of Switzerland					Activities (key word + n° - see separate list by office)
				1. Swiss Federal Offices	2. Academic sector	3. NGOs	4. Private sector	5. PPPs	
6.1 e		(e) increase investment in human resource development in the health sector	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including development partners; nongovernmental organizations; charitable foundations)	X	X	X	X	X	1. SDC: SWAp and Health sector budget support 2. Investment through capacity building/training 3. Investment through capacity building/training, through creating work opportunities in developing countries 4. Roche skills transfer and capacity building programmes, NVGH strong focus on capacity building 5. Investment through capacity building/training, through creating work opportunities in developing countries
6.1 f		(f) develop effective country poverty reduction strategies that contain clear health objectives	Governments; other relevant stakeholders (including development partners)	X	X				1. SDC 2. Swiss TPH contributes through development programmes, for example health systems strengthening in Tanzania
6.1 g		(g) encourage pooled procurement mechanisms for health products and medical devices, where appropriate	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders	X				X	1. IPI 5. MMV: close alignment with AMFm initiative
6.2 a	(6.2) establishing and strengthening mechanisms to improve ethical review and regulate the quality, safety and efficacy of health products and medical devices	(a) develop and/or strengthen the capacity of national regulatory authorities to monitor the quality, safety and efficacy of health products while sustaining ethical review standards	Governments; WHO; other relevant stakeholders (including national and regional regulatory agencies and development partners)	X	X			X	1. FOPH, Swissmedic 2. Swiss TPH involvement in AMASA FP7 project 5. DNDI: regulatory workshop in Nairobi in June 2009
6.2 b		(b) promote operational research to maximize the appropriate use of new and existing products, including cost-effective and affordable products in high disease-burden settings	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including international and national research institutions; nongovernmental organizations, development partners and charitable foundations)	X	X	X		X	1. SDC; FOPH 2. Swiss TPH actively involved in different access programs; ZHUAS: Cooperation project with Health Sciences University of Mongolia 3. Several NGOs such as SolidarMed, Novartis Foundation, Swiss Red Cross, MSF, etc. 5. MMV: Access programs
6.2 c		(c) comply with good manufacturing practices for safety standards, efficacy and quality of health products	Governments; WHO; other relevant stakeholders (including national regulatory bodies; relevant health-related industries; development partners)	X			X	X	1. SDC; FOPH; Swissmedic 4. Novartis and Roche 5. DNDI, MMV: through the careful selection of their private partners for the production of the medicines
6.2 d		(d) strengthen the WHO pre-qualification programme	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including development partners)	X				X	1. FOPH; Swissmedic 5. WHO prequalification of product developed by DNDI and MMV
6.2 f		(f) where appropriate, initiate programmed actions on regional and sub-regional levels with the ultimate goal of harmonization of processes employed by the regulatory authorities for drug marketing approvals	Governments; [WHO]/[WHO]; other relevant stakeholders (including national and regional regulatory agencies, regional bodies and development partners)	X				X	1. Swissmedic 5. DNDI: regulatory workshop in Nairobi in June 2009
6.2 g		(g) promote ethical principles for clinical trials involving human beings as a requirement of registration of medicines and health-related technologies, with reference to the Declaration of Helsinki, and other appropriate texts, on ethical principles for medical research involving human subjects, including good clinical practice guidelines	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including national and regional regulatory agencies)	X	X		X	X	1. SER: Participation in EDCTP; FOPH Draft Federal Law on human research; SDC; IPI 2. Swiss TPH: clinical trials are conducted according to international approved standards; 4. Clinical trials are conducted according to international approved standards 5. Clinical trials are conducted according to international approved standards; NITD only conducts proof-of-concept clinical trials
6.2 h		(h) support regional networks and collaborative efforts to strengthen the regulation and implementation of clinical trials using appropriate standards for medicines evaluation and approval	Governments; WHO; other relevant stakeholders (including national and regional regulatory agencies, international and national research institutions, regional bodies and development partners)	X	X		X	X	1. SER: Participation in EDCTP; SDC; FOPH; Swissmedic 2. Swiss TPH: Clinical trials are conducted according to international approved standards; the clinical trials are conducted in collaboration with local partners; 4. Roche: internship programme at the clinical pharmacology unit 5. Clinical trials are conducted according to international approved standards; the clinical trials are conducted in collaboration with local partners

Number	Elements and sub-elements	Specific actions	Stakeholder(s)*	Contribution of Switzerland					Activities (key word + n° - see separate list by office)
				1. Swiss Federal Offices	2. Academic sector	3. NGOs	4. Private sector	5. PPPs	
6.3 a	(6.3) promoting competition to improve availability and affordability of health products consistent with public health policies and needs	(a) support the production and introduction of generic versions, in particular of essential medicines, in developing countries, through the development of national legislation and/or policies that encourage generic production and entry, including a "regulatory exception" or "Bolar"-type provision, and which are consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights and instruments related to that agreement	Governments	X					1. IPI: Implementation of a bolar-type provision; SDC; SECO; FOPH
6.3 b		(b) frame and implement policies to improve access to safe and effective health products, especially essential medicines, at affordable prices, consistent with international agreements	Governments; WHO; other international intergovernmental organizations (including WTO and WIPO); other relevant stakeholders	X	X	X		X	1. FOPH 2. Geneva Health Forum 3. MSF 5. MMV: close alignment to AMFm initiative
6.3 c		(c) consider where appropriate, inter alia, the reduction or elimination of import tariffs on health products and medical devices and the monitoring of supply and distribution chains and procurement practices to minimize cost and increase access	Governments	X					1. SECO
6.3 d		(d) encourage pharmaceutical companies and other health-related industries to consider policies, including differential pricing policies, that are conducive to promoting access to quality, safe, efficacious and affordable health products in developing countries, consistent with national law	Governments; WHO; other international intergovernmental organizations; other relevant stakeholders (including relevant health-related industries)	X	X	X		X	1. SECO; FOPH 2. Swiss TPH: following the Global Access Policy 3. MSF 5. DNDI, MMV and NITD: following the Global Access Policy
6.3 e		(e) consider, where appropriate, the development of policies to monitor pricing and to improve affordability of health products; further support WHO's ongoing work on pharmaceutical pricing	Governments	X					1. FOPH
6.3 f		(f) Consider, where necessary, and provided that they are consistent with the provisions of the Agreement on TRIPS, taking appropriate measures to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology, in the field of health products	Governments	X					1. IPI; SECO
6.3 g		(g) increase information among policy makers, users, doctors and pharmacists regarding generic products	Governments; WHO other relevant stakeholders (including nongovernmental organizations and relevant health related industry)	X	X				1. FOPH 2. Swiss TPH: strong involvement in the health sector in Tanzania
7	Element 7. Promoting sustainable financing mechanisms								

Number	Elements and sub-elements	Specific actions	Stakeholder(s)*	Contribution of Switzerland					Activities (key word + n° - see separate list by office)
				1. Swiss Federal Offices	2. Academic sector	3. NGOs	4. Private sector	5. PPPs	
7.1 a	(7.1) endeavoring to secure adequate and sustainable financing for research and development, and improve coordination of its use, where feasible and appropriate, in order to address the health needs of developing countries	(a) establish a results-oriented and time-limited expert working group under the auspices of WHO and linking up with other relevant groups to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of financing to stimulate R&D related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases	Governments; WHO ; other international intergovernmental organizations; other relevant stakeholders	X					1. SER; SDC
7.1 b		(b) consider channelling additional funds to health-oriented research organizations as appropriate in both the private and public sector of developing countries and promote good financial management to maximize its effectiveness as recommended by the resolution WHA58.34	Governments; WHO ; other international intergovernmental organizations; other relevant stakeholders (including development partners, charitable foundations, international and national research institutions, academia, private sector and relevant health-related industries)	X					1. SER; SDC
7.1 c		(c) create a database of possible sources of financing for R & D	Governments; WHO ; other relevant stakeholders	X	X				1. SER; SDC 2. SNSF
7.2 a	(7.2) facilitating the maximum use of, and complementing as appropriate, existing financing, including that through public-private and product development partnerships, in order to develop and deliver safe, effective and affordable health products and medical device	(a) document and disseminate best practices in public-private and product development partnerships	Governments; WHO ; other relevant stakeholders (including research institutions, public-private and product development partnerships)	X	X	X	X	X	1. SER; SDC; SECO 2, 3 and 4. As partners in PPPs and PDPs: annual/biannual reports 5. Information sharing through the open publication of annual/biannual reports
7.2 b		(b) develop tools to periodically assess performance of public-private and product development partnerships	Governments; WHO ; other relevant stakeholders (including research institutions; public-private and product development partnerships; charitable foundations)	X					1. SDC; SECO
7.2 c		(c) support public-private and product development partnerships and other appropriate research and development initiatives in developing countries	Governments; WHO ; other international intergovernmental organizations; other relevant stakeholders (including relevant health-related industries, charitable foundations, development partners, nongovernmental organizations; academia; research institutions)	X	X	X	X	X	1. SER; SDC 2. Swiss TPH: many activities are conducted in PPP/PDPs; SNSF 3. NFSD 4. Roche and Novartis 5. DNDI; MMV; NITD
8	Element 8. Establishing monitoring and reporting systems								
8.1 a	(8.1) measuring performance and progress towards objectives contained in the strategy and plan of action	(a) establish systems to monitor performance and progress of the implementation of each element of the global strategy and plan of action	Governments; WHO	X					1. FOPH: Secondment of an IP expert at WHO; SER; SDC; SECO; IPI; Swissmedic
8.1 b		(b) monitor and report periodically to WHO's governing bodies on the gaps and needs related to health products and medical devices in developed and developing countries	Governments; WHO	X					1. FOPH: Secondment of an IP expert at WHO; SDC
8.1 c		(c) to continue to monitor, from a public health perspective, in consultation as appropriate with other international organizations, the impact of intellectual property rights and other issues addressed in the report of the Commission on Intellectual Property Rights, Innovation and Public Health, on the development of, and access to, health care products, and to report thereon to the Health Assembly	Governments; WHO ; other international intergovernmental organizations (including WIPO and WTO); other relevant stakeholders	X					1. FOPH: Secondment of an IP expert at WHO; IPI

Number	Elements and sub-elements	Specific actions	Stakeholder(s)*	Contribution of Switzerland					
				1. Swiss Federal Offices	2. Academic sector	3. NGOs	4. Private sector	5. PPPs	Activities (key word + n° - see separate list by office)
8.1 d		(d) monitor and report on the impact of incentive mechanisms on innovation of and access to health products and medical devices	Governments; WHO; other international intergovernmental organizations (including WIPO and WTO); Other relevant stakeholders	X					1. FOPH; Secondment of an IP expert at WHO; SECO
8.1 e		(e) monitor and report on investment in research and development to address the health needs of developing countries	Governments; WHO; other relevant stakeholders	X					1. SER; SDC

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