Ministry of Foreign Affairs – (Department for Green Diplomacy and Climate)

Meeting in the Council for Development Policy on 14 September 2023
Agenda Item No. 4

1. Overall purpose:	For discussion and recommendation to the Minister
2. Title:	Framework Programme on the Strategic Sector Cooperation with the Ministry for the Interior and Health, 2024-2027
3. Amount:	DKK 60 million (2024-2027)
4. Presentation for Programme Committee:	14 March 2023
5. Previous Danish support presented to UPR:	Presented to UPR on 22 June 2023

28-08-2023

Cover

For discussion and recommendation to the minister

Adjustments to the Framework Programme for the Strategic Sector Cooperation with the Ministry of the Interior and Health (2024-2027) addressing points raised by the Council for Development Policy on 22 June 2023

During the meeting on 22 June 2023, the Council for Development Policy requested adjustments of the Framework Programme in the following areas:

(i) changes of the result framework to reflect the broader development purpose of the programme in the form of indicators on poverty-orientation,
(ii) a clearer description of criteria for selecting new countries, including selection of at least one African country during the framework period,
(iii) more convincing arguments for focusing on non-communicable diseases.

The changes will be presented to the Council at the next Council meeting on 14 September 2023. This note summarizes the changes made and their impact on programme implementation.

Ad (i): The result framework has been adjusted at the level of objective, outcome and output. Objective is changed to *Enable partner countries to increasingly ensure healthy lives and promote well-being for all at all ages with an emphasis on a poverty and human rights-based approach through improved (1) coherent, efficient and quality healthcare services for NCDs, (2) regulation of pharmaceuticals and medical devices and (3) prevention and management of health threats*. Outcome 1 is changed to: *Number of regulatory and institutional systems addressed and improved within the three thematic areas of the SSC cooperation based on a multidimensional poverty analysis.* Output 1 indicator (a) is changed to: *Number of verifiable improvements in partner institution systems or capacities for furthering equal access to health services*.

The changes are reflected in the Theory of Change to emphasize that that SSC projects are entered with partner authorities in developing countries who aim to improve the health systems to improve access to health. Furthermore, it is clarified that the SSC programme aims to strengthen partners' capacity to act as duty-bearers.

The changes are made on the basis of the definitions in the *How-to-note on Fighting Poverty and Inequality* and will be operationalized in line with the guidance provided by the note. Introducing a multidimensional poverty analysis as a basis for identifying the regulatory and institutional systems, which will be addressed under output 1, contributes to ensuring that the development purpose remains a central part of project design at the country level and for each thematic area.

Ad (ii): The criteria for country selection have been adjusted in accordance with the request from the Council. It is clarified that country selection will happen in accordance with the Policy for Development Cooperation, and that special attention shall be given to supporting developing countries, particularly in Africa. As was explained during the meeting on 22 June, the programme currently includes projects with several middle-income countries as a result of *previous* country selection procedures. We wish to underline that *future* country selection will be based on the criteria on page 20-21.

Ad (iii): The analysis of Global Health Challenges has been expanded with the objective of providing a clearer explanation of the burden of non-communicable diseases (NCDs) in developing countries and the detrimental effect of NCD's on the health systems and socio-economic development in these countries. The

Council expressed a belief that NCDs was primarily a 'rich world problem'. The revised text seeks to address this concern by including data on prevalence of NCDs in developing countries and the WHO's assessment of the importance of addressing NCD in developing countries as "the rapid rise in NCDs is predicted to impede poverty reduction initiatives in low-income countries". The text in section 2.1 and 2.2 underlines the fact that NCDs are on the rise and already a major cause of premature deaths and loss of productivity and life quality in developing countries and the cause of 86% of premature deaths in low- and middle-income countries. It further documents the fact that within countries, NCD risk factors are more prevalent among the poor, further underlining the relevance of the focus area. Drawing from the WHOs and leading scientific research, the section explains the challenge that this epidemiological change places on health systems, especially in countries without well-functioning primary health care systems. Adapting and adjusting health care systems to NCDs is a challenge in these countries because, among other, of the need for long-term care that is proactive, patient-centred, community-based and sustainable. This is a major concern for health authorities in developing countries and an area where Denmark's experiences and competences are in high demand.

Finally, as a consequence of the delays in the approval process, the commencement date of the Framework Programme has been changed from 1st October 2023 to 1st January 2024.

Ministry of the Interior and Health &

The Department for Green Diplomacy and Climate (GDK)

Framework Programme on Strategic Sector Cooperation with Ministry of the Interior and Health

Key results:
The health sector cooperation with five countries aims to enable partner countries to increasingly ensure healthy lives and promote well-being for all at all ages in three thematic areas:

- Coherent, efficient and quality healthcare services for non-communicable diseases (NCDs),
- regulation of pharmaceuticals and medical devices, and
- combatting health threats from infectious diseases and AMR.

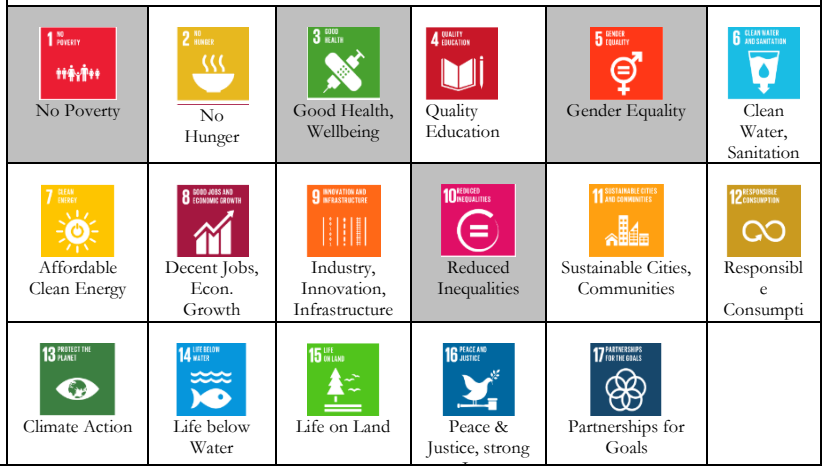
Within these three focus areas the programme contributes to the longer-term improvement of framework conditions and increased ambitions of partner institutions in relation to SDG 3 and equitable universal access to healthcare.

Justification for support:
The FP promotes the Danish Government's policies on advancing good health and well-being for all by targeting growing global diseases and health issues and ensuring access to safe and quality medicines and medical devices. Promoting SDG 3 is closely linked with and contributes to poverty alleviation, gender equality and empowerment as well as reducing inequality. The FP delivers on the Government's intention for the Strategic Sector Cooperation to be a core instrument to promoting sector diplomacy and to engage the Danish private sector in meeting the SDGs.

Major risks and challenges:
The risks include that the bilateral relations with one or more SSC countries could evolve negatively or that national partner authorities' internal processes delay implementation. It should furthermore be emphasised that the scope of the SSC projects is limited, and they can at best contribute to national processes which are driven by national institutions and interests and in this way contribute to better access to more equitable health systems. The approach to strengthening national capacities is therefore key to sustaining the results of the SSC projects.

File No.	2022-30894				
Country	Brazil, China, India, Mexico and Vietnam				
Responsible Unit	GDK				
Sector	12110 Health policy and administrative management.				
DKK million	**2024**	**2025**	**2026**	**2027**	**Total**
Commitment	15.3	14.15	16.2	14.35	60.0
Projected Disbursement	15.3	14.15	16.2	14.35	60.0
Duration	2024-2027				
Finance Act code.	06.38.02.14				
Head of unit	Karin Poulsen				
Desk officer	Charlotte Laursen				
Reviewed by CFO	YES: Katja Thøgersen Staun				

Relevant SDGs *[Maximum 5 – highlight with grey]*



Objectives for stand-alone programme:

Enable partner countries to increasingly ensure healthy lives and promote well-being for all through improved i) coherent, efficient and quality healthcare services for NCDs, 2) regulation of pharmaceuticals and medical devices and 3) combatting health threats from infectious diseases and AMR.

Environment and climate targeting - Principal objective (100%); Significant objective (50%)

	Climate adaptation	Climate mitigation	Biodiversity	Other
Total green budget (DKK)	N/A	N/A	N/A	N/A

Project 1 Brazil	**Partner**	**Total thematic budget:**
Total	Brazilian Ministry of Health and Brazilian Health Regulatory Authority	9,500,000
Project 2 China	**Partner**	
Total	National Health Commission, Peking University Sixth Hospital, Guangdong Province National Medical Products Administration and Jiangsu Province	10,839,328
Project 3 India	**Partner**	
Total	Ministry of Health and Family Welfare	12,250,000
Project 4 Mexico	**Partner**	
Total	Secretariat of Health and Federal Commission for Protection against Health Risks (COFEPRIS)	8,900,000
Project 5 Vietnam	**Partner**	
Total	Vietnam Ministry of Health and Provincial Department of Health in Thai Binh Province	9,784,180
Project 6 New countries	**Partner**	
Total	Tbc	3,000,000
Project 7 Unallocated	**Partner**	
Total	Tbc	3,426,492
Results monitoring and learning		1,100,000
Communication		600,000
Midterm review		600,000
	Total	**60,000,000**

Framework Programme on Strategic Sector Cooperation with Ministry of the Interior and Health (2024-2027)

Framework Programme Document
August 2023

Abbreviations

AMG	Aid Management Guidelines
AMR	Antimicrobial Resistance
AMU	Antimicrobial Use
BMoH	Brazil Ministry of Health
DFC	Danida Fellowship Centre
DHA	Danish Health Authority
DKMA	Danish Medicines Agency
DMOH	Danish Ministry of the Interior and Health
FP	Framework Programme
GP	SSC Guiding Principles
HRBA	Human Rights-Based Approach
ICARS	International Centre for Antimicrobial Resistance Solutions
IFU	Investment Fund for Developing Countries
LNOB	Leave no-one behind
MEAL	Monitoring, Evaluation and Learning
MFA	Ministry of Foreign Affairs
NCD	Non-communicable diseases
PANT	Participation, accountability, non-discrimination, transparency
PMG	Programme Management Group
RFI	Results Framework Interface
SDG	Sustainable Development Goals
SMG	Strategic Management Group
SSC	Strategic Sector Cooperation
TC	Trade Council
TOR	Terms of Reference
UHC	Universal Health Care
UN	United Nations
WHO	World Health Organisation

1. Introduction

This document outlines the Framework Programme (FP) implemented by the Danish Ministry of the Interior and Health (DMOH) and its agencies under the Strategic Sector Cooperation (SSC), an instrument launched in 2015 engaging Danish authorities in cooperation with partner authorities in developing countries to improve framework conditions for a green, inclusive transition and key development priorities.

The FP covers the four-year period from January 2024 to December 2027, within a budget of DKK 60 million, and it replaces the single-project agreements between the Danish Ministry of the Interior and Health and the Ministry of Foreign Affairs (MFA).

Guided by the Danish Government's policies, *The World We Share* and the Action Plan for Economic Diplomacy, the FP focusses the SSC-partnerships on global health challenges in five countries, targeting areas where the DMOH through its core competencies can contribute to strengthening national partner country capacities to sustainably address important international health challenges in the context of national priorities in the partner countries.

In contrast to the previously approved sector FPs, the health FP does not target the green transition but has distinct focus on Denmark's overall aims in global health related to the three thematic areas selected for the FP:

1. Coherent, efficient and quality healthcare services for non-communicable diseases;
2. Regulation of pharmaceuticals and medical devices; and
3. Combatting health threats from infectious diseases and AMR.

The FP document describes the thematic focus and expected results, the guiding considerations and the management mechanisms of the Framework Programme and will be the basis of an agreement between the MFA and the DMOH and its agencies for the SSC-programme in a four-year period from 1 January 2024. It will include SSC projects in five countries, which are all on-going, and subsequent project phases initiated during the programme period. When SSC-countries are phased out after a maximum of three project phase, new SSC countries will be selected under the Framework Programme in accordance with the criteria mentioned in this document and in relevant guidelines.

What is a strategic sector cooperation?

- A peer-to-peer, long-term cooperation between a Danish sector authority or municipality and an authority in a developing country.
- Tackles selected capacity challenges where the Danish authorities' competences can further significant improvements – but may not tackle all partner capacity constraints to fundamental reform.
- Consists of 1) project-based technical cooperation between the two peer authorities, and 2) a Sector counsellor stationed at the Danish Embassy to facilitate the project and its linkages.
- Typically uses instruments like study tours, seminars, workshops, training courses, and direct engagement of experts for drafting regulations, policies, guidelines, or processes.
- Main inputs consist of Danish authorities' staff time, travels, consultancies, and expenses for workshop/seminars, studies, trainings.
- Projects run in phases and have an inception phase (DKK 1.5 million) for in-depth needs assessment and project design with the peer authority, followed by up to three 3-years phases; each phase with a maximum budget of DKK 10 million.

2. Context, strategic considerations and justification

2.1 Global health challenges

The 2030 Agenda for Sustainable Development was adopted to guide global development, with health embodied in Sustainable Development Goal 3 "Ensure healthy lives and promote well-being for all at all ages". Health systems strengthening for universal health coverage was identified by WHO as one of the key instruments for the change offered by the 2030 Agenda, and universal health coverage can only be achieved within a functional health system. This entails integration of good governance/stewardship, adequate financing, qualified and motivated health workforce, access to quality medicines and health products, functional health information systems and people-centred service delivery systems.[1]

Substantial improvements have been made in population health outcomes over the past 25 years but overall progress towards meeting SDG 3 has been disrupted by the direct and indirect effects of the global COVID-19 pandemic. According to the UN, global life expectancy has dropped and progress towards global health coverage has been halted[2]. Meanwhile, a growing burden of non-communicable diseases (NCDs) and increasing risk of emerging and re-emerging health threats threaten to overwhelm health systems in low and middle-income countries, which lack capacity to tackle these complex health challenges.

Non-communicable diseases (NCDs) cannot be defined as a health problem of the rich and developed countries, associated with economic development. NCDs have long been on the rise in developing countries and today NCD's contribute a higher number of mortalities in these countries than communicable diseases. In fact, 86% of premature deaths in low- and middle-income countries are due to NCDs[3]. According to WHO, NCDs threaten progress towards the 2030 Agenda for Sustainable Development, which includes a target of reducing the probability of death from any of the four main NCDs between ages 30 and 70 years by one third by 2030. The enormous rise in NCDs in low- and middle-income countries has serious socio-economic consequences both at the societal and individual level.

WHO states that "Poverty is closely linked with NCDs. The rapid rise in NCDs is predicted to impede poverty reduction initiatives in low-income countries, particularly by increasing household costs associated with health care. […] In low-resource settings, health-care costs for NCDs quickly drain household resources. The exorbitant costs of NCDs, including treatment, which is often lengthy and expensive, combined with loss of income, force millions of people into poverty annually and stifle development."[4]. Because NCDs tend to affect people living in developing countries at a younger age than in wealthier economies, the economic effects are substantially larger in developing countries, due to the reduced productivity and the increased health care costs.[5] This has caused the World Health Organization

[1] Framework For Health Systems Development Towards Universal Health Coverage In The Context Of The Sustainable Development Goals In The African Region, WHO, 2017
[2] https://sdgs.un.org/goals/goal3
[3] https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases
[4] https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases
[5] Rachel A. Nugent and Andrea B. Feigl: Where Have All the Donors Gone? Scarce Donor Funding for Non-Communicable Diseases, 2010

(WHO) to term NCDs as an 'invisible pandemic'. Furthermore, social and structural determinants of health play a significant role in NCDs, meaning that people with lower socio-economic status face a higher risk of suffering from NCDs compared to the rest of society.

The emergence of NCDs as a major global health challenge is linked to the global demographic and epidemiological transition. This transition is characterised by lower birth rates and longer life expectancy combined with lower mortality due to epidemics, but higher frequency of non-communicable and chronic diseases. Many middle-income countries are currently undergoing this epidemiological transition and therefore experience a double burden of both communicable and non-communicable diseases. This double burden puts additional strain on the countries' health systems which have traditionally been focused on communicable diseases and maternal health. The need to include prevention and management of chronic diseases results in a strain on financial and human resources, and ultimately threatens to overwhelm the health systems, and negatively impact the ability of governments to provide universal health care and access to safe and affordable medicine to their citizens.

This challenge is exacerbated in countries without well-functioning primary health care systems. As pointed out by the WHO, "people with noncommunicable diseases, or at risk of developing one, require long-term care that is proactive, patient-centred, community-based and sustainable. Such care can be delivered equitably only through health systems based on primary health care".[6] In the absence of public primary health care, the specialised health care system (hospitals) becomes overburdened with consequences for patients and an economic burden for governments, since primary health care is more cost effective than hospital centric care. In 2017, WHO estimated that at least half of the world's population cannot obtain essential health services and that large numbers of households are being pushed into poverty because they must pay for health care out of their own pockets[7]. Primary health care therefore plays a crucial role with respect to the interlinked global health challenge of increased prevalence of non-communicable and chronic diseases, access to health and poverty alleviation in developing countries.

Another challenge for achieving SDG 3 is availability of safe, effective and quality pharmaceutical products in many low- and middle-income countries as a result of weak regulatory systems. Countries with weak regulatory systems lack the capacity to control the import, export, manufacturing, and use of pharmaceutical products. This is often caused by the fact that legal and regulatory frameworks have developed over time causing overlapping or incoherent regulations and mandates. As a result, countries face significant delays in getting pharmaceuticals and medical devices on the market and at the same time lack capacity to control the quality and safety of drugs that enter the market. Low-quality and unsafe drugs are a major public health problem and contributes to delinking the enormous effort in therapeutic research from improvements in patient health and safety. Finally, pharmaceutical production can have severe negative environmental effects due to effluents from manufacturing facilities amongst others. This issue is increasingly gaining attention as an area of concern in relation to poor regulatory systems in countries with pharmaceutical production.

[6] WHO EMRO | Management of noncommunicable diseases in primary health care | Publications | NCDs

[7] https://www.who.int/news/item/13-12-2017-world-bank-and-who-half-the-world-lacks-access-to-essential-health-services-100-million-still-pushed-into-extreme-poverty-because-of-health-expenses

The COVID-19 pandemic served as a stark reminder that although global prevalence of infectious diseases has been falling for years, the world is not yet safe from pathogens and other health threats that can travel between humans, animals and across borders. The pandemic not only reversed progress towards SDG 3, it also pushed about 75-95 million additional people into extreme poverty according to the UN[8]. Epidemics and pandemics hit unevenly and affect the poorest strata of society and those with the lowest levels of education the most, thus contributing to increased inequality and hence to the structural causes of poverty[9]. Climate change, loss of biodiversity, degradation of nature and urbanisation all add to the risk of new epidemics which – due to the interconnectedness of the world – have the potential to develop into global pandemics. The Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES) concluded in 2020 that pandemic frequency was on the rise with more than five new diseases emerging in people every year, each with potential to grow to pandemic proportions. Most of these emerging diseases are caused by microbes in animals which "spill over" after repeated contact between wildlife, livestock, and people[10].

At the same time, humanity's most important weapon against harmful microbes – antibiotics and related antimicrobial pharmaceuticals – is severely threatened by increasing levels of antimicrobial resistance (AMR). Drug-resistant infections are estimated to kill 1.27 million people each year and are rising rapidly with projections of up to 10 million annual deaths by 2050[11]. This has caused WHO Director General Dr. Tedros Adhanom Ghebreyesus to declare that *"AMR is a slow tsunami that threatens to undo a century of medical progress"*. AMR affects all countries, but the burden is disproportionately higher in developing countries due to a multitude of factors linked to poor access to health care, inappropriate use of antimicrobials and poor regulatory systems. Low educational levels and low awareness combined with poverty leave people to self-medicate against common infections, buy medications from unregulated drug dispensaries or borrow medicine from family members or social networks[12]. While antibiotics are important in treating infections, good infection prevention and control also play a key role in halting the development and spread of antimicrobial-resistant infections and multidrug-resistant bacteria. Vaccination and immunisation can reduce antimicrobial resistance by preventing infections and thereby treatment. New and improved vaccines can also prevent diseases from becoming difficult to treat due to AMR.

Against this backdrop, governments and health authorities in SSC partner countries face the task of adapting, improving and modernising their national health systems to tackle the multiple and interconnected global health challenges.

2.2 The evolving context in the five SSC countries

The FP includes the ongoing SSC projects in Brazil, China, Mexico, Vietnam and India. The latter will enter the first full project phase under the FP. All five countries have been selected through a "matchmaking" process in accordance with the SSC guidelines in which DMOH, Danish embassies and business associations expressed their interests. It is a prerequisite that the development needs of the

[8] https://unstats.un.org/sdgs/report/2022/goal-01/
[9] https://www.imf.org/en/Blogs/Articles/2020/05/11/blog051120-how-pandemics-leave-the-poor-even-farther-behind
[10] Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis - The Lancet.
[11] https://healthpolicy-watch.news/no-time-to-wait-amr-could-cause-10-million-deaths-annually-by-2050-warns-un-report/
[12] Tackling antimicrobial resistance in low-income and middle-income countries | BMJ Global Health

individual SSC-countries match the areas of strength of the Danish authorities. This requires that the partner countries and their public health authorities have a certain base-level in terms of organisational capacity in order to be able to successfully apply the solutions that the Danish authorities can contribute with. Countries with poorly developed public health systems would require more comprehensive assistance not necessarily based on solutions applied in Denmark.

Two of the current SSC projects (Brazil and Vietnam) are expected to conclude their third and final phase in 2027. The future of the programme in China beyond 2026 is uncertain, because China will at some point no longer be eligible for development aid according to the OECD/DAC criteria. It is DMOH's ambition to remain with five SSC-countries for the duration of this FP: The emerging project portfolio in the last year of the FP (2027) will therefore include inception phases in two-three new partner countries. The new partner countries are selected on the basis of several criteria and within the framework of Danish strategy for development aid and humanitarian assistance "The World 2030" and within the strategic priorities and strengths of the DMOH. In accordance with the government's focus on support to Africa, specific consideration will be paid to potential partner countries from this region (see further in Section 5).

The current SSC countries are facing several of the above-mentioned global health related challenges and are undergoing the above-mentioned transition from struggling predominantly with communicable diseases to a higher prevalence of NCDs, placing a double burden on the health systems. The key health data in Table 1 below indicate that each country faces its individual (and often interlinked) health challenges.

Table 1: Key health data for five SSC-countries and Denmark

	Mexico	China	India	Vietnam	Brazil	Denmark
Life expectancy at birth (2020)[13]	75	78	70	75	74	82
Total expenditure on health as % of GDP (2019)[14]	5.4	5.4	3.0	5.3	9.6	10.0
Cause of death, by NCDs (% of total)	80	90	66	81	75	90
Premature NCD death rate (of all NCD deaths) (SDG 3.4) (2019) [15]	45.3	37.1	53.9	41.5	43.7	21.4
UHC Service Coverage Index (SDG 3.8.1) (2019)[16]	74	82	61	70	75	85

[13] Life expectancy at birth, total (years) | Data (worldbank.org) (for Mexico: Health status - Life expectancy at birth - OECD Data

[14] Current health expenditure (% of GDP) | Data (worldbank.org)

[15] Premature deaths due to noncommunicable diseases (NCD) as a proportion of all NCD deaths (who.int)

[16] UHC Service Coverage Index (SDG 3.8.1) (who.int)

Share of households with health expenditure above 10 % (SDG 3.8.2)[17]	1.6 (2016)	24.0 (2016)	17.3 (2017)	8.5 (2020)	11.8 (2017)	2.9 (2010)

Overall, India lags behind the other countries due to a number of interlinked factors such as under-investment in health, low universal health coverage, lack of health professionals and a pronounced double burden (high levels of both communicable and non-communicable diseases). Vietnam has a far-reaching system of health care, but the health service delivery system is hospital-centric. This is both expensive and not well suited to prevent, diagnose or manage NCDs, which account for 81% of all deaths (of which 41,5% are premature deaths).

Socio-economic advancements in Brazil, Mexico and China over the past decades have resulted in lower levels of poverty and longer life expectancy overall. NCDs, such as cardiovascular diseases, neoplasms, chronic respiratory disease and diabetes have become a leading cause of the death in all three countries, which threatens the socio-economic development especially for the poorer strata of society due to the interconnectedness between poverty and prevalence of NCDs. For example smoking rates differ 5-fold in Brazil between uneducated and secondary-school educated adults, and 3.4-fold in Mexico between workers and professionals[18]. Meanwhile, NCDs place a tremendous economic burden on both governments and patients, as explained in section 2.1.

As Table 1 above indicates, out-of-pocket expenses related to health constitute an important share of many households' expenses in most of the countries. In China and India 24 % and 17 % of the households, respectively, report spending more than 10 % of their income on health. This underlines the relevance of increasing access to quality public health care for prevention and treatment of NCDs for poverty alleviation in the SSC-countries.

[17] Population with household expenditures on health greater than 10% of total household expenditure or income (SDG 3.8.2) (%) (who.int),

[18] file:///C:/Users/B245374/AppData/Local/Temp/MicrosoftEdgeDownloads/ce7e4d62-9dd9-4c74-a762-0d35e6ff9d1c/paho-policy-brief-2-En-web1.pdf

Access to quality and safe pharmaceuticals and medical devices is a general problem in most LMICs, among other as a result of poor regulatory systems. China and India are major pharmaceutical producing countries, which, in addition to supplying their home markets, also play a global role as major exporting nations. India's role as the largest global producer of affordable and generic drugs has earned it the title as 'pharmacy of the world', yet the sector is characterised by weak regulations, overlapping mandates, poor quality control and enforcement, and IP protection issues amongst others. China has made considerable progress in strengthening the regulatory framework over the past decades, but there are still areas in which China can improve and build up capacity. In particular, approval of medicines or medical devices remains a challenge, affecting not least the import.

National plan or policy which the SSC projects contribute to:

Brazil:
- New Strategy for Digital Health 2020-2028
- Law 13.411/2016 (ANVISA)
- Strategic Plan 2020-2023 (BMoH)

China:
- Healthy China 2030

India:
- Pradhan Mantri Ayushman Bharat Health Infrastructure Mission (PM-ABHIM)
- Presidential target of the pharmaceutical industry growing to 130 billion USD by 2030

Mexico:
- Mexican National Development Plan 2019-2024

Vietnam:
- National Strategy for the Prevention and Control of Non-communicable Disease 2015-2025.

Regulation of pharmaceuticals and medical devices in Mexico is an area that is undergoing various administrative and political changes. Status is that approval processes are very long and communication with relevant authorities is complicated. Mexico has recently experienced shortage of some medicines. Backlog of approvals of new and generic drugs has long been a major obstacle in Brazil and lowering back logs has been a major political priority, which Denmark has and continues to support through the SSC.

The risk of emerging or re-emerging health threats (including AMR) is present in all five SSC-countries, due to urbanization, human-animal interaction and high population density among others. In India, where the level of communicable diseases remains high there is special attention to the issue. India's health system was overwhelmed by the COVID-19 pandemic, specifically the second wave in 2021. As a result, pandemic preparedness has gained increased attention as a matter of strategic importance.

It is estimated that countries such as India and Vietnam have some of the highest levels of AMR in Asia. However, due to the absence of comprehensive surveillance it is impossible to substantiate. Both countries have an overuse of antimicrobial drugs both in animals and humans. In Vietnam, evidence suggests that around 90% of drug stores dispense antibiotics without a prescription despite the fact that it is prohibited by Vietnamese law. There is significant political attention to the issue in both countries and good frameworks for Danish support.

The relevant sector strategies and legislation in relation to strengthening national efforts within the three FP thematic areas have been identified for each of the five countries (see box and further information in

Annex). These have guided the alignment of the current SSC projects and the information will be updated as new phases are prepared.

2.3 Danish priorities and the role of the SSC

Denmark is committed to the realisation of the SDGs, and Danish priorities on global health are fully aligned with the goal and sub-goals on health (SDG 3). The achievements of the SDGs are all interlinked. Hence, due to the cross-sectoral nature of global health challenges, efforts towards SDG 3 are particularly interlinked with and contribute to SDG 1 on poverty alleviation, SDG 5 on gender equality and empowerment, and SDG 10 on inequality. Ultimately, good health and wellbeing allows people to live life to the fullest and being valuable members of their community, which is a strong driver in achieving all of the SDG's. As described in Denmark's strategy for development cooperation "the World We Share", Denmark aims to "focus and expand the strategic sector cooperation through comprehensive, integrated programmes where Danish strengths are greatest, such as […] health".

In line with Denmark's green agenda ambitions, global SSC guidance suggests the framework programmes should establish relevant greening targets. However, climate and environment are not considered a principal or significant objective of the DMOH FP and there is therefore no greening target as part of the FP. The priorities of the Ministry of the Interior and Health in relation to the SSC-programme are aligned with the priorities in "the World We Share" and the How-to Note for the social sectors and derives from Denmark's long-standing international focus on universal health coverage, strengthening public health and ensuring people-centred health systems that are universal, equitable and sustainable and of high quality. As indicated in the How-to note, it is a priority for Denmark to strengthen health security and pandemic preparedness for – and in response to – health emergencies and strengthened preparedness against emerging and re-emerging health treats. These areas are increasingly strategic priorities for the DMOH and are reflected in Denmark's political priorities in international health fora, such as the WHO and in the EU. The Ministry's international health priorities guide engagements with partner countries and organisations on important areas such as non-communicable diseases, antimicrobial resistance, vaccines and immunisation and health emergencies.

Building on the previous strategy on Internationalisation of Health and Life Science from 2019 and the over-all global health priorities outlined above, the Ministry of the Interior and Health is considering publishing a strategy for international cooperation on health which will outline the international health priorities and underpin the strategic focus areas of the SSC Framework Programme.

The Strategic Sector Cooperation (SSC) plays an important role in DMOH's international engagement as a mechanism for engaging directly with health authorities in LMICs to support their efforts towards achieving the SDGs. Recognising the limited scope of the SSC framework, Denmark prioritises collaborations aimed at strengthening national partner capacities to tackle the global health issues described above, and thereby contribute to progress towards SDGs 3.4 and 3.8 while concretely delivering against SDG 3.D:

- *3.4 By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being;*

- *3.8 Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all;*
- *3.D Strengthen the capacity of all countries, in particular developing countries, for early warning, risk reduction and management of national and global health risks.*

Under the Strategic Sector Cooperation, the DMOH can contribute to strengthening national progress towards these SDG targets via peer-to-peer collaboration with health authorities in partner countries. This can, among other things, inspire and catalyse national partner-led reform processes, ultimately enabling them to adapt, improve and reshape their health systems by drawing on Danish best practices and strongholds.

The strategic focus of the SSC framework programme will contribute to collective health-systems strengthening efforts in partner countries by addressing critical capacity gaps and needs in:

1. Coherent, efficient and quality healthcare services for non-communicable diseases; and
2. Regulation of pharmaceuticals and medical devices; and
3. Combatting health threats from infectious diseases and AMR.

Coherent, efficient and quality healthcare services for non-communicable diseases

Denmark is internationally recognised for the efficient and data-driven public healthcare system and unique organisation of the primary healthcare system as well as an efficient uptake of digital solutions promoting coherence throughout the health system. A strong and coherent primary healthcare system is a cornerstone in ensuring universal health coverage and access to high quality care for all. Patients with chronic and/or multiple NCDs have varying and individual needs and are often in contact with various parts of the healthcare system. The Danish approach includes prevention, quality of care, and disease management. The aim is to strengthen coherent patient pathways with people-centred care as a central principle. Denmark has significant experience in developing and implementing the use of disease management programmes, standardised treatment programmes, and quality standards for care. The Danish approach also hinges on a national IT infrastructure, national registers and the development of digital solutions, which make relevant data available at the point of treatment and care, efficient logistics as well as solutions promoting transparency in the course of treatment of individual citizens or patients. These initiatives aim to ensure continuity of care across the different levels of the healthcare system as well as a more uniform practice of the same high quality of care – from early detection, diagnostics, investigation and treatment, to follow-up, rehabilitation and palliation.

Regulation of pharmaceuticals and medical devices

Strengthened regulatory frameworks and processes as well as increased capacity to implement and enforce the rules in the regulatory authorities are necessary to meet the challenges related to access to safe and affordable medicines. Strong regulatory frameworks and efficient processes for approval, monitoring, control and enforcement are important for all partner countries. The Danish support takes on an extra dimension for countries with domestic production of medicines and medical devices, such as India and China, especially concerning good manufacturing practices, active pharmaceutical ingredients (APIs), clinical trials, etc.

The Danish Medicines Agency has a strong position in the European cooperation on pharmaceuticals and medical devices and can draw on both Danish and European regulatory best practices in the collaboration with regulatory agencies in partner countries. With the establishment of the Data Analysis Center (DAC), the Danish Medicines Agency has become a spearhead in relation to the use of data analysis in the EU. Analysis of data is and will increasingly become a significant component in regulatory affairs, e.g. in relation to approval and pharmacovigilance of medicines, not least in relation to complex pharmaceuticals, medical devices and personalised medicine for treatment of NCDs. In connection with the strengthening of the regulatory processes, the Danish Medicines Agency will also be able to support in relation to quality management and digital transformation, which are both significant factors in relation to strengthening the regulatory processes for the benefit of the Danish companies that wish to enter market in these countries.

Combatting health threats from infectious diseases and AMR

Denmark has a robust healthcare system, where Statens Serum Insititut and the Danish Health Authority complement each other, respectively providing data from surveillance and diagnostics early warning, and developing informed, anticipatory action to prevent and mitigate health threats.

Surveillance is the backbone of public health. Knowing which infections are circulating, which pathogens are emerging, the antimicrobial use (AMU) and the prevalence of antimicrobial resistance (AMR) as well as reduced vaccine coverage are key to developing and implementing the appropriate public health responses.

Effective, continuous and cross-sectoral surveillance is essential for identifying emerging health threats and assessing their potential burden. Building institutional capacity in cross-sectoral surveillance will enable integrated surveillance systems, which provide new and improved data for better public health preparedness and response – both nationally and globally. An example of this is Denmark's comprehensive surveillance of AMU and AMR. With its long tradition for involving multiple sectors in public health work, integrating digital solutions and drawing on expertise from a wide variety of professionals for surveillance and research, Denmark is uniquely placed to provide this support and act as a sparring partner for institutions as they further develop their evidence-based public health management.

When combating health threats today, we have to recognise that the health of humans, animals and the environment is intrinsically linked. This is called a One Health approach. Most emerging and re-emerging health threats are zoonotic (viruses able to infect both humans and animals) and certain geographic areas, such as Asia, tropical Africa and Latin America, are more likely to experience emerging infectious disease events[19]. Denmark is one of only a few countries in the world that has a public health institute – Statens Serum Institut – which also has veterinary preparedness functions: i.e. a One Health institute. Denmark can therefore provide an added layer to capacity building efforts as Danish authorities bring practical experience in implementing the One Health approach in our public health responses to combating health threats.

[19] Spernovasilis N, Tsiodras S, Poulakou G. Emerging and Re-Emerging Infectious Diseases: Humankind's Companions and Competitors. Microorganisms. 2022 Jan 4;10(1):98. doi: 10.3390/microorganisms10010098. PMID: 35056547; PMCID: PMC8780145.

Example: SSC China phase 1

In the SSC project between Denmark and China within primary health and mental health, Danish and Chinese health authorities collaborate on the destigmatisation of mental disorders. People with mental disorders are an exposed and vulnerable group in China, as due to stigma they risk being excluded from e.g. education or the labour market, just as stigma can prevent people with symptoms of a mental disorder from seeking help from the healthcare system in time. In the cooperation between the authorities, Denmark and China exchange experiences and best practice examples of destigmatisation initiatives, which can help break down prejudice, shame and taboos associated with mental disorders and thus make it easier for people with mental disorders to seek relevant treatment in time and remain active members of society.

In the SSC project, Denmark and China are also collaborating on digital solutions within mental health, including online psychological treatment of anxiety and depression (also called iCBT, internet-based cognitive therapy). In the project, there is a particular focus on making mental health services more accessible to the young target group via digital solutions. The young target group is important, as many young people in China suffer from mental distress, and there is not enough capacity in the healthcare system to reach and treat all the young people who have symptoms of anxiety and depression. Therefore, digital solutions can contribute to mental health services reaching more young people in need of treatment.

2.4 Results and lessons from on-going and previous phases of support

In 2020, an independent evaluation of the Strategic Sector Cooperation confirmed that the SSC delivers relevant and effective results, although the long-term effects and outcomes are still to be verified. The programme has in a short time succeeded in mobilising Danish public sector expertise, which would not have been accessible on commercial terms or otherwise and initiated relevant contributions to the SDGs. Based on the preliminary results, the evaluation considered the programme in many ways to be "punching above its weight" compared to the resources invested. The evaluation also found that the SSC programme contributes to stronger bilateral relations and cooperation between Denmark and SSC partner countries.

The experience of the health SSC projects to a large extent confirms the overall findings of the evaluation. The Strategic Sector Cooperation is a relevant tool that has substantial potential to contribute to global health challenges in the partner countries and at the same time strengthen Danish diplomacy and engage Danish companies.

The embassies in Vietnam, China, Brazil and Mexico[20] consider the SSC projects important for their diplomatic work in the partner countries. The projects provide multiple entry points to the national political and administrative systems at various levels, which are sector specific and therefore an important and relevant addition to the general diplomatic efforts of the embassies. Furthermore, the cooperation with Denmark within the health sector provides valuable "political capital" for Denmark, thereby improving relations and branding of Denmark as a trusted partner.

The SSC projects have contributed to a number of specific results in relation to strengthening national capacity and systems and changing framework conditions, both from the current phase 1 projects (in China and Mexico) and from the phase 2 projects in Brazil and Vietnam (see box). However, programme implementation has been severely impacted by Covid-19. Both due to travel restrictions and because the pandemic has dominated the agenda of the health authorities, both in Denmark and in the partner countries.

Selected results from on-going SSC health sector projects

- Key health indicators identified and adopted at national level for enhanced digitalisation of health data (Mexico)
- Development and adoption of pilot for use of telemedicine in a more integrated way (Mexico)
- Implementation of national clinical guidelines for testing new medicine (Mexico)
- Adoption on a pilot basis of an app for detection of diabetes developed by the private sector (Vietnam)
- National digital health strategy elaborated and published (Brazil)
- Strengthened National Health Data Network that empowers vulnerable citizens, integrating their health data through local health agents (Brazil)
- Diagnostic Related Groups (DRG) based system developed and piloted in two clinical areas (Brazil)
- Establishment of a DRG Unit in the BMoH to study, adopt and develop a Brazilian DRG model based on Danish expertise (Brazil)
- Implementation of new legislation on approval of pharmaceuticals/equipment (Brazil)
- Backlog in pharmaceutical approval reduced and shorter case handling time (Brazil)
- Implementation of European guidelines for clinical tests of new pharmaceuticals (China)

The SSC projects are very susceptible to delays if the selected partners are not appropriate or if they change priorities during implementation. Although local level partners may be relevant for the thematic area of the SSC project, e.g. primary health care may be the responsibility of local administration, the experience with working directly with local level partners is mixed, because the Danish partner knowledge does not necessarily match the needs of partners at the local level. Going forward, the primary partners of the SSC projects will be agencies on central level and if pilot activities take place at local level, it will be in close collaboration with the primary partner authority.

The thematic focus areas of the SSCs are selected on the basis of Danish international strongholds, but it is recognised that without a genuine demand from the partner authority, the SSC projects may risk implementation delays and ultimately low effectiveness. When entering new phases, the effort to align the SSC projects to national programmes and ambitions will be further strengthened.

[20] The collaboration with the fifth country, India, was only initiated with an inception phase in 2022.

The objectives and scope of the SSC projects are generally quite broad and some of the current SSC projects include many different work streams within the thematic areas. Given the modest size of the SSC projects, focusing the efforts on a few work streams provide better possibilities of inducing changes in national framework conditions. Unless it is deliberately controlled, there is a tendency for projects to proliferate during implementation, perhaps due to direct demand from partners or the specific interest and capabilities of Danish partners. This will be observed in the further implementation and in the formulation of new SSC project phases. There have also been valuable lessons learned on effective country-level enabling factors, which could provide guidance to project implementation in general. These include, for example, establishing robust relations with local administrations as well as key decision-makers, recognising that key counterparts may be highly qualified practitioners which means relations must be collaborative and demand-driven and maintaining flexibility in engagements to accommodate evolving stakeholder priorities.

The implementation of the current SSC projects has provided valuable lessons in terms of the organisation of the programme on the Danish side where multiple authorities are involved in the implementation of the projects. Staff rotation is a given condition of the public sector, which means that project knowledge and experience is intermittently lost. The DMOH FP management will ensure that the necessary support for project implementation is available.

Linkages to the Danish private sector

Engagement of the private sector is crucial to deliver sustainable solutions to the SDGs and framework conditions in low- and middle-income countries are often a hindrance to market entry and establishing a level playing field.

The experience from the health sector SSC-projects provides lessons as to how the embassies benefit from the SSC projects to provide linkages to commercial cooperation, the work of the Trade Council (TC) and Danish companies:

- The cooperation has a branding value for Denmark as a competent and trusted partner in the health sector. These are indirect and medium to long-term effects.
- The SSC counsellors and other staff involved in the SSC projects may, with their knowledge and networks, provide valuable information to the TC and of general information for commercial cooperation between Denmark and the country.
- The SSC projects aim to induce changes in the framework conditions for the health sector, thereby providing a level playing field and opportunities also for Danish companies.
- The SSC projects may engage solutions provided by Danish companies directly in the SSC projects providing giving them exposure in the market.

The Embassies benefit from the SSC counsellors' knowledge by integrating them in or ensuring a close collaboration with the commercial teams in the Embassy and there are a number of examples of direct collaboration between SSC counsellors and the Embassy trade officers. Furthermore, spin-off projects are pursued when possible. For example, it has been possible to organise activities on diabetes and obesity with participation of the private sector in Brazil. DMOH and its agencies can directly support commercial events by organising thematic seminars or participating in round tables in connection with trade delegations in partner countries. In Denmark, collaboration with Healthcare Denmark provides a professional setup for displaying Danish commercial and public-private solutions as an integrated part of

SSC-study tours for partner authorities to Denmark. DMOH is furthermore strengthening its network to the industry in Denmark, including the Confederation of Danish Industry (DI) and the Danish Association of the Pharmaceutical Industry (LIF).

So far, the full potential of this aspect of the programme has not yet materialised, not least due to the lower-than-expected level of activities. The potential for leveraging commercial collaboration varies between the thematic areas and this experience has been used when selecting the thematic areas for the FP.

Linkages to multilateral and civil society organisations in partner countries

The SSC projects are relatively modest in size compared to large scale multilateral or civil society interventions. However, due to the unique intervention modality of peer-to-peer cooperation between key health and medicine agencies, the SSC can play an important complimentary role. DMOH and embassies in the partner countries keep a close dialogue with multilateral and civil society organisations who are engaged in the same thematic areas in the partner countries. Sector counsellors continuously monitor international engagements of relevance and seek synergies when possible. Examples of other interventions of special relevance to the current SSC projects are provided in Annex 6.

The sector counsellors engage actively in the dialogue with other countries and donors through existing donor working groups in the health sector and in Team Europe. In Vietnam, for example, the sector counsellor participates in the Health Partnership Group (HPG), which is co-chaired by WHO and the Vietnamese Ministry of Health. In China, the embassy participates in an informal network of health adviser – the Diplomatic Health Partners Network – with like-minded countries, multilateral organisations and international finance institutions.

2.5 Alignment with SSC principles and global results

Through the strategic sector cooperation, the Danish authorities support national partners addressing their own legislative, regulative and policy challenges and needs through promotion of Danish sustainable solutions. The long-term objective for the overall SSC programme is:

> *To promote a socially just green transition and contribute to sustainable growth and resilient development for people in partner countries through Strategic Sector Cooperation.*

For the health FP, this is translated into a contribution to the partner countries' achievement of the SDGs, primarily selected targets under SDG 3, as indicated above.

It should be emphasised that the SSC is aiming at improving the sector framework conditions, which includes policies, legislation, regulation and their implementation. This is reflected in the global intermediate objective of the SSC, which is *to contribute to conducive framework conditions in partner countries focusing on the green and inclusive transition and selected development priorities through contributions from the strategic sector cooperation*. Defining relevant framework conditions and the national capacity gaps for the effective administration of these are therefore a priority in the formulation of the country-level SSC-projects.

In line with the SSC Guiding Principles, the FP focusses on areas where Denmark has special strengths and shows international best practice in public-private partnerships, not least by using digital and data driven solutions furthering a coherent and client-centred health system.

The FP outcome 1 contributes to the SSC global Outcome 1 (*Strengthened partner countries capacity to develop, implement and enforce conducive framework conditions for green transition and selected development priorities*) through its country level projects which support strengthening of partner countries' capacities within the three thematic areas. The intervention areas of the specific SSC projects will be targeting institutional capacity development of specifically identified framework conditions, e.g. sector specific policies, legislation, regulation, plans or tools and the systems for implementing these. The DMOH will base its approach to capacity development on lessons learnt from the SSC programme, international best practice, with integration of HRBA and non-government actors, as summarised in the text box below.

The FPs approach to Capacity Development

- The overall aim of capacity development of DMOHs FP is to strengthen the ownership, engagement and effectiveness at national and local level in the partner countries which is necessary to make sustainable improvements and developments within the healthcare systems.
- The SSC aims to support planning and implementation processes through which partner organisations and stakeholders in partner countries adapt, strengthen and maintain the capability to define, plan and achieve their own sector development objectives on a cross-sectoral, holistic, inclusive and sustainable basis.
- Capacity development is often addressed at three different levels, namely the enabling environment, the organizational level and the individual level. Interventions at each level are often mutually supportive.
- For the enabling environment the SSC e.g. works directly or indirectly with laws and policies by engaging and bringing together public or private stakeholders and related partners and civil society.
- At the organizational level the SSC e.g. advise and promotes change processes that relates to structures, systems (digital and non), procedures and policies that determine sector institutions and other stakeholders impact, accountability and effectiveness.
- At the individual level, the SSC aims to develop and strengthen the skills, experience and knowledge that allow each person to perform.
- In the interests of capacity development outcome sustainability, efforts also aim to enable partner organisations and stakeholders to sustain newly acquired behaviours and practices, by facilitating capacity retention, modernisation, utilisation and institutionalisation over time.
- Capacity development can contribute to changes in specific institutional capacities, but can also contribute to wider systems-strengthening efforts by supporting complementary and/or inter-dependent capacities (either simultaneously or in collaboration with other enabling actors)
- Capacity development is always undertaken with due respect to the national context, priorities and the resources available for the FP. Capacity development is often undertaken with the involvement of both public and private sector, both in Denmark and partner countries.
- The SSC aims to ensure that the capacity development in health administration benefits poorer and marginalised groups of society by a) including interventions that directly target these groups (see examples in text boxes) and b) emphasising LNOB-principles in dialogue with partner authorities.

The FP outcome 2 contributes to the SSC global Outcome 2 (*Increased climate ambitions and ambitions for green transition and sustainable development through strong bilateral relations and green diplomacy*) by strengthening the embassies' network at country level in relation to the health sector. Embassies, sector advisers and the Danish agencies engaged in the SSC projects will be responsible for sharing knowledge, networks, and lessons between the SCC projects and the Danish bilateral diplomacy efforts, which will enable linkages to broader Danish policy agendas.

The FP outcome 3 contributes to the SSC global outcome 3 (*Enhanced engagement of the Danish private sector in identifying sustainable development solutions and opportunities).* The potential to demonstrate public-private solutions has been an important factor in the selection of the three thematic focus areas of the FP. The SSC projects will aim to enhance the engagement of the Danish private sector in identifying sustainable development solutions and opportunities for strengthening access to health care and medicine and prevent health threats.

2.6 Poverty reduction and human rights-based approach

The health sector is central to human development and health issues are closely linked to poverty. Poor and marginalised populations are more susceptible to infections and in general they have poorer access to reliable and safe medical treatment. Poor and marginalised populations, particularly women and girls, are the most at risk of getting sick, also from non-communicable diseases, and the worst hit economically by epidemics, as was witnessed during the COVID-19 pandemic.

Thematic areas 1 and 3 of the FP (healthcare services for NCDs and combatting health threats from infectious diseases and AMR) provide good opportunities for working with access to health services and a human rights-based approach. Thematic area 2 – Regulation of pharmaceuticals and medical devices – does not to the same extent provide opportunities for addressing these issues. Optimising market approval processes may drive increased market penetration, but other factors are equally important in relation to access to pharmaceuticals.

The WHO Constitution of 1946 affirms that the enjoyment of the highest attainable standard of health is a fundamental human right. The obligation to provide access to health services, medicine and vaccinations and the right to health is enshrined in the Article 12 of the Covenant on Economic, Social and Cultural Rights. Non-discrimination and equality are fundamental human rights principles and critical components of access to health services. States have an obligation[21] to prohibit and eliminate discrimination on all grounds (race, age, ethnicity or other factors) and to ensure equal access to health care and medicine. This is reflected in SDG 3, *Ensure healthy lives and promote well-being for all at all ages*, and especially SDG target 3.8 *Achieve universal health coverage including access to quality health-care services, medicines and vaccines*.

In pursuing a human rights-based approach, national health policy, strategies and programmes should be designed explicitly to improve the enjoyment of all people to the right to health, with special considerations to the principle of leaving no one behind. An important factor influencing this is the extent to which a universal healthcare system is rolled out in the country.

The FP will address multidimensional aspects of poverty and the human rights-based approach by integrating the principles of participation, accountability, transparency and non-discrimination (the "PANT" principles). DMOH's work under the FP will be based on these core values, while recognising that the relevant issues to integrate in the SSC projects depend largely on the national context, policies and the partner institutions responsible for national health sector framework conditions. Relevant recommendations of the Special UN Rapporteur on Health will be observed, including the upcoming report on the increased use of digital technologies in the planning and delivery of health information and

[21] International Convention on the Elimination of All Forms of Racial Discrimination. UN General Assembly resolution 2106.

services. DMOH will implement a human rights-based approach and further initiatives to reduce poverty by observing and promoting the following issues in the formulation and implementation of SSC projects:

- Promote universal access to health services, including aspects of physical access, affordability and access to information by analysing ex-ante the consequences of initiatives supported by the SSC on the goal of universal access.
- Work towards avoidance of discrimination in the delivery of health services and address discrimination in policies and practices, e.g. relating to the implementation of health regulations.
- Include a focus on gender differences and disadvantaged populations who are often underserved in relation to access to primary healthcare and neglected in national health data collection systems.
- Promote fair access to participation in technical training and capacity development to support empowerment of women and marginalised groups.
- Promote accountability and participation in partner authorities, for example in relation to including civil society and the private sector in the processes of developing and monitoring the implementation of new policies and regulations.
- Promoting quality, which is an important aspect of universal health coverage and includes aspects such as safety, effectiveness, timely and people-centred treatments.
- Respect human rights in relation to data management and digital technologies, for example on issues related to privacy, equality and autonomy.

Furthermore, the potential for furthering equal access to health services and for working with the principles of a human-rights based approach will be considered when selecting the new countries under the FP.

Women are underrepresented in the formal health sector, particularly in complex technical job roles, despite being overrepresented in underpaid frontline jobs. According to the World Bank, women in the health sector, for example in India, have limited access to trainings and career advancement opportunities. The SSC projects include capacity strengthening and training and the project in India, for example, focuses on the exchange of knowledge and know-how in the areas of epidemiology and surveillance, including One Health, where women are under-represented in complex, technical positions. As a preliminary measure to increase awareness of the disparity and to increase women's access to training, including DFC training courses, the SSC project in India will strive to ensure a high representation of women among its training participants. To the extent possible, this may serve as an entry point for dialogue with the relevant national institutions around additional capacity development to help address the underlying root causes for the gender disparity across the public health system and in complex, technical positions specifically.

3. Framework Programme objectives and Theory of Change

In line with the long-term objective of the overall SSC programme, the programme objective of the FP is:

> *Enable partner countries to increasingly ensure healthy lives and promote well-being for all at all ages through improved (1) Coherent, efficient and quality healthcare services for NCDs, (2) regulation of pharmaceuticals and medical devices and (3) prevention and management of health threats from infectious diseases and AMR.*

The FP is guided by the Theory of Change (ToC) below which aligns with the SSC's global ToC. The critical assumptions behind the ToC include: Partner authorities' political and institutional commitment to agreed reform processes is maintained during the FP; DMOH capability to address partners' weaknesses in the relevant practices, legislation and systems, including systematic learning from proven

capacity development approaches and basic market conditions in countries are conducive to Danish private sector actors to offer health sector solutions.

The Strategic Sector Cooperation has three outcomes, which are different in nature. Financed by official development assistance (ODA) Outcome 1 is the principal outcome and the basis for unfolding the following two; the three outcomes combined deliver the programme objective. Outcomes 2 and 3 cannot stand alone and must support the transition and development priorities of Outcome 1.

Theory of change for DMOH SSC Framework Programme

If the MFA and DMOH select developing countries for the SSC where non-communicable diseases, regulation of pharmaceuticals and medical devices and health threats from infectious diseases and AMR are critical challenges for attainment of SDG3 and SDG 1		
And if DMOH and Embassies identify and establish SSC partnerships with relevant national authorities who demand such collaboration and strongly prioritise addressing such challenges to improve access to health, yet with regulatory and institutional capacity constraints that match the core competences of Danish authorities		
And if DMOH - and other involved Danish authorities - use learning-based capacity development approaches to share their core expertise and best-practice knowledge with partners and facilitate them in identifying new approaches to strengthening key framework conditions in one or more of the three focus areas in an inclusive and equitably manner, as relevant to context	**And if** Danish Embassies, DMOH and the MFA make use of the insights, processes, and networks obtained through the SSC projects to inform Danish bilateral diplomatic initiatives to promote SDG 3 and universal access to healthcare	**And if** Danish Embassies, DMOH and the MFA (including the Trade Council) jointly use knowledge and networks from the SSC projects on partner country health sector to inform the engagement with the Danish private sector to provide health sector solutions that can address the countries' challenges
Then, partner institution awareness, systems or competencies across the three focus areas and their capacity to act as duty-bearers will be strengthened (output 1)	**Then** there will be an increased engagement with partner country health sector institutions at technical and political level (output 2)	**Then** there will be an increased exposure of Danish commercial solutions to partner countries (output 3)
Which will inform or contribute to the longer-term improvement of framework conditions related to one or more of the three focus areas in an inclusive and equitable manner furthering equal access to quality health services, as relevant (outcome 1)	**Which will inform or contribute to** increased partner country national and international ambitions in relation to SDG 3 and equitable universal access to healthcare (outcome 2)	**Which will contribute to** an enhanced engagement of the Danish private sector in providing health sector solutions in the partner country (outcome 3)
And then Denmark contributes to *enabling partner countries to increasingly ensure healthy lives and promote well-being for all at all ages* (SDG3) with an emphasis on a poverty and human rights based approach through improved (1) coherent, efficient and quality healthcare services for NCDs, (2) regulation of pharmaceuticals and medical devices and (3) combatting health threats from infectious diseases and AMR in a way that strengthens the participation, accountability, non-discrimination and transparency of health sector institutions		

4. Results framework

Monitoring and reporting of the FP will be based on the results framework below, which should inform the results frameworks of future SSC-projects. The outputs of the SSC-projects are diverse and may not all be captured in the FP results framework, but all SSC-projects should contribute to the FP-level output and outcome indicators. The proposed targets are preliminary and will be revisited and discussed in the Programme Management Group (PMG) and approved by the first Strategic Management Group (SMG) of the FP. Moreover, they will be reviewed in the mid-term review of the program. DMOH and Embassies are jointly responsible for results especially related to outcomes 2 and 3.

The FP builds on a multidimensional poverty concept and a human rights based approach. The FP will especially address poverty through the dimension of improved opportunities and choices for all, encompassing the principles of participation, accountability, transparency and non-discrimination in the work of the individual SSC project.

Project/Programme Objective	Enable partner countries to increasingly ensure healthy lives and promote well-being for all at all ages with an emphasis on a poverty and human rights based approach through improved (1) coherent, efficient and quality healthcare services for NCDs, (2) regulation of pharmaceuticals and medical devices and (3) prevention and management of health threats.

Outcome (1)		Longer-term improvement of framework conditions to (1) provide coherent, efficient and quality healthcare services for NCDs, (2) regulate pharmaceuticals and medical devices and (3) combat health threats from infectious diseases and AMR in an inclusive and equitable manner, as relevant.	
Outcome indicator		Number of regulatory and institutional systems addressed and improved within the three thematic areas of the SSC cooperation based on a multidimensional poverty analysis.	
Baseline	Year	2023	0
Target	Year	2027	18 (two for each of the applied thematic areas in each country)
Outcome (2)		Increased partner country national and international ambitions in relation to SDG 3 and equitable universal access to healthcare.	
Outcome indicator		Number of partner institution public declarations of new initiatives and/or targets in thematic areas linked to the FPs work.	
Baseline	Year	2023	0
Target	Year	2027	9 (one for each of the applied thematic areas in each country)
Outcome (3)		Enhanced engagement of the Danish private sector in providing health sector solutions in the partner country.	
Outcome indicator		Number of companies indicating that the SSC programme has had a positive impact on their engagement in the country.	
Baseline	Year	2023	13
Target	Year	2027	35
Output 1		Strengthened awareness, systems or competencies of partner institutions in relation to (1) coherent, efficient and quality healthcare services for NCDs, (2) regulation of pharmaceuticals and medical devices and (3) combatting health threats from infectious diseases and AMR.	

Output indicator		a. Number of verifiable improvements in partner institution systems or capacities for furthering equal access to health services (composite of specific indicators at country and focus area output level). b. Number of publications/notes, road maps or action plans jointly developed.	
Baseline	Year	2023	a: 0 b: 0
Target	Year 1	2024	a: 5 b: 2
Target	Year 2	2025	a: 10 b: 3
Target	Year 3	2026	a: 15 b: 5
Target	Year 4	2027	a: 20 b: 10
Output 2		Increased Danish engagement with partner country health sector institutions at political level	
Output indicator		Number of high-level meetings between the Danish embassy/DMOH and partner country institutions where international or national initiatives or targets linked to the FP work are on the agenda (annually).	
Baseline	Year	2023	10
Target	Year 1	2024	12
Target	Year 2	2025	19
Target	Year 3	2026	19
Target	Year 4	2027	15
Output 3		Increased embassy-led exposure of Danish commercial solutions to partner countries	
Output indicator		Number of embassy/TC workshops and events exposing Danish commercial solutions in which the FP has contributed with technical knowledge (annually).	
Baseline	Year	2023	11
Target	Year 1	2024	25
Target	Year 2	2025	27
Target	Year 3	2026	30
Target	Year 4	2027	20

Note: Final project year in China is expected to be 2026.

5. Emerging project portfolio: Context and design features

In line with the SSC Guiding Principles, the FP enables the Danish Ministry of the Interior and Health to develop and manage a portfolio of projects over four years, based on agreed objectives, outcomes, outputs and overall budget. The FP is established on the basis of the existing SSC projects and includes new project phases, which are not yet fully defined. As the third and last phase of the SSC projects in Vietnam and Brazil are planned to be finalised within the four-year period of this FP, it is envisaged that two new countries will be identified, and pilot projects will be initiated in these in the last year of the FP. The two new countries will be identified in a joint process between the MFA and the DMOH.

Criteria for country selection include:

- The country should express a clear demand for Danish support both at national level and at the level of the potential partner institutions
- In accordance with the Policy for Development Cooperation, special attention shall be given to supporting developing countries, particularly in Africa.
- There should be a Danish embassy in the country.

- The thematic focus areas of the FP and the competencies offered by the DMOH and its agencies should be relevant for the national health sector, and the institutional capacity should be sufficient to ensure sustainability of the results
- Furthering equal access to health services and medicine for all and the principles of a human rights-based approach, including promoting gender equality, should be considered feasible with the relevant national institutions
- Relevance in relation to Danish commercial interests

The SSC projects are based on a thorough identification of needs and demands of the partner countries matched with the Danish authorities' core competences in an international perspective, health system weaknesses which are structural causes or catalysts of poverty and inequality, Danish bilateral interests and commercial interests and opportunities. The challenges of the national health systems in relation to the SSC thematic focus areas are generally well known, and it is important that the SSC-projects assess the potential of national strategies and targets within the specific political economy of the country to contribute to the LNOB and HRBA agenda and to ensure a high degree of national ownership. It is a pre-requisite for the SSC projects that the partner authorities are committed to establishing improved framework conditions or strengthening the implementation and management of existing policies, laws and regulations within shared objectives and are requesting international cooperation to achieve these objectives. To maintain focus of the SSC-projects, each country level SSC project will as a maximum include two of the three thematic areas of the FP.

In connection with the preparation of a new SSC project or a new phase, a thorough background and context analysis is prepared or updated. The document includes a country-level analysis of the relevant thematic health issues and a capacity assessment of the potential partners involved. The context analysis furthermore includes an analysis of opportunities for addressing specific HRBA and development issues in the SSC projects, such as increasing access to health services for underserved population groups, enhanced public transparency and accountability and human rights aspects in relation to data management and digital technologies. Although not part of this appropriation, the Sector Counsellors are central to the implementation of the SSC projects. The Sector Counsellor is a specialist posted to the Danish Embassy to facilitate and support the individual SSC project, facilitate knowledge sharing, add technical dimensions to the bilateral diplomacy. The Sector Counsellor works closely together with the Danish Authority, the Partner Authority, other Embassy staff and the private sector.

The SSC projects and the Sector Counsellors collaborate with a range of institutions in Denmark. The Danida Fellowship Centre (DFC) offers training and scholarships, including master studies, to partner authority staff. The DFC has been offering four different training courses in health. Due to Covid-19, the DFC training activities have been limited since 2020 but going forward, the SSC projects will work to include DFC training activities more coherently in the relevant projects, as they become available. DFC is also organising the Danida alumni network in the partner countries and thereby maintaining the network of professionals having been trained in Denmark.

The SSC projects are increasingly collaborating with Healthcare Denmark. Collaboration with Healthcare Denmark is especially relevant in relation to study tours to Denmark, where Healthcare Denmark

supports the planning and execution of study tour programmes with a combination of public and private elements.

Combatting health threats from infectious diseases and AMR, including AMR is a new thematic focus area of the SSC projects. Collaboration and coherence with other Danish initiatives linked to AMR/One Health will be sought as part of this engagement, including SSC projects in the same partner countries under agriculture and food systems, such as the Danish Veterinary and Food Administration and the National Food Institute at the Technical University of Denmark as well as the International Centre for Antimicrobial Resistance Solutions (ICARS) in Copenhagen, which provides access to international research-based knowledge on AMR and One Health.

Table 2: Project phases in SSC Health Framework Programme 2024 – 2027

Country and phase	**Time period**	**Status**	Thematic **Focus**	Partner Authority
Vietnam phase II	2020 (Jan) – 2024 (Jul)	Current	Disease prevention, diagnostics and monitoring of non-communicable diseases with a focus on the primary healthcare system	Ministry of Health of Vietnam Provincial Department of Health in Thai Binh Province (Thai Binh DoH)
Vietnam phase III	2024 (Aug) – 2027 (Jul)	Future	Coherent, efficient and quality healthcare services for NCDs	Ministry of Health of Vietnam
Brazil phase II	2020 (Oct) – 2024 (Oct)	Current	Health data and digitisation & pharmaceuticals and medical devices	Brazilian Ministry of Health, including DataSUS Brazilian Health Regulatory Agency
Brazil phase III	2024 (Nov) – 2027 (Oct)	Future	Regulation of pharmaceuticals and medical devices, and continued work on health data and digitalization as key tools for coherent, efficient and quality healthcare services for NCDs.	Brazilian Ministry of Health, including DataSUS Brazilian Health Regulatory Agency
China phase I	2019 – 2024 (Jun)	Current	Pharmaceuticals and the primary healthcare system, including mental health and chronic diseases	National Medical Products Administration; National Health Commission, Peking University Sixth Hospital; Wuxi Mental Health Centre; Guangzhou Huiai Brain Hospital Jiangsu Province
China phase II	2024 (Jul) – 2027 (Jun)	Future	Regulation of pharmaceuticals and medical devices, & coherent, efficient and quality healthcare services for NCDs, including mental health	National Medical Products Administration of the People's Republic of China National Health Commission of the People's Republic of China
Mexico phase II	2023 (Jan) – 2025 (Dec)	Current	Regulation of medicines and medical devices, and prevention and treatment of NCDs in the primary sector	Secretariat of Health in Mexico Federal Commission for Protection against Health Risks

Country and phase	Time period	Status	Thematic Focus	Partner Authority
Mexico phase III	2026 (Jan) – 2028 (Dec)	Future	Regulation of pharmaceuticals and medical devices & coherent, efficient and quality healthcare services for NCDs	Secretariat of Health in Mexico
India Inception	2022 (Nov) – 2023 (Dec)	Current	Regulation of pharmaceuticals and medical devices & Pandemic preparedness, AMR and digital solutions	Ministry of Health and Family Welfare, India and underlying agencies
India Phase I	2024 (Jan) – 2026 (Dec)	Future	Regulation of pharmaceuticals and medical devices & Combatting health threats from infectious diseases and AMR (depending on outcome of inception phase)	Ministry of Health and Family Welfare National Centre for Disease Control The Central Drugs Standard Control Organisation
India phase II	2027 (Jan) – 2029 (Dec)	Future	To be defined based on inception phase and phase I	

6. Budget

Figures in the indicative budget below are preliminary and subject to Parliamentary approval. This budget overview reflects the expected support as indicated in the 2023 Finance Act. The current SSC projects only include funding of activities under Outcome 1 of the FP whereas future SSC project phases could also include budgets for activities related to outcome 2 and 3. The allocation of funds in pursuit of Outcomes 2 and 3 must always have the realisation of Outcome 1 as the prime objective.

Table 3: Disbursement budget for SSC Health Framework Programme 2024 – 2027 (DKK)

	2024	2025	2026	2027[1]	Total 2024-2027
Vietnam phase II Vietnam phase III	2,284,180 1,250,000	 2,500,000	 2,500,000	 1,250,000	2,284,180 7,500,000
Brazil phase II Brazil phase III	2,000,000 1,000,000	 2,750,000	 2,500,000	 1,250,000	2,000,000 7,500,000
China phase I China phase II	2,339,328 1,250,000	 2,750,000	 3,000,000	 1,500,000	2,339,328 8,500,000
Mexico phase II Mexico phase III	2,300,000	2,200,000	 2,200,000	 2,200,000	4,500,000 4,400,000
India Inception India Phase I India phase II	2,750,000	3,500,000	3,250,000	 2,750,000	0 9,500,000 2,750,000
Two new countries inception phase				3,000,000	3,000,000
Projects total					**54,273,508**
Communication	150,000	150,000	150,000	150,000	600,000

Results monitoring, learning and preparatory studies[II]		300,000	800,000		1,100,000
Mid-term review			600,000		600,000
Unallocated funds			1,176,492	2,250,000	3,426,492
Total	**15,323,508**	**14,150,000**	**16,176,492**	**14,350,000**	**60,000,000**

Notes: No budget for 2023 is reflected since payment from MFA to SUM takes place in beginning of year 2023.

[I] Budget for full year 2027 since payment from MFA to SUM will take place in March 2027 for the full year.

[II] Preparatory studies with the aim of identifying thematic focus and pilot phase design in new partner countries.

In order to allow the FP and the individual SSC projects to adapt to an evolving context and in line with the principles of Doing Development Differently, DKK 3.25 million has been reserved as unallocated funds. These will be used to adapt to new situations for the individual project phases, including in relation to the cooperation with China. The funds will in particular be allocated to support relevant exit activities to be identified under each individual project based on an agreed strategy for transition that aims at sustainability of main project results after project completion. As indicated above, possible activities under outcome 2 and 3 will also be funded from unallocated funds.

7. Governance and management arrangements

The management arrangements will follow SSC's Guiding Principles and Administrative Manual. The DMOH will be overall responsible for implementing the FP in partnership with the national partner authority, working in close collaboration with Danish Embassies and MFA and following relevant Danish Government policies/strategies and MFA's Aid Management Guidelines.

In the DMOH, a team of dedicated project managers oversee planning and implementation of activities as well as financial follow-up and reporting for each of the five SSC projects. The project managers liaise closely with the sector counsellors at the embassy and with the coordinators at the agencies.

The agencies are responsible for the technical expertise and detailed planning of activities and missions under the respective project outcomes. A project coordinator is responsible for identifying and liaising with the relevant technical experts at the agency and maintaining close dialogue with the project manager and the sector counsellor.

At the level of each SSC-project, a Steering Committee is established. Members of the Steering Committee are, in addition to the Danish Authority, comprised of a representative of the Danish Embassy and a high-level representative of the partner authority along with the Sector Counsellor acting as secretary. The Steering Committee will review and approve the final SSC Project Document and work plan. It will monitor progress in delivering on agreed work plan and outputs. Discuss and suggest changes to the work plan relative to changes in context, risks and identified critical assumptions. The Steering Committee will approve annual work plans.

DMOH and MFA will engage at two levels in the governance and management of the overall FP:

Strategic Management Group (SMG is composed of senior representatives from DMOH and MFA, with the Chair rotating between DMOH and MFA. The SMG will meet annually in April/May. TOR for SMG to be developed in the Procedure Manual.

The SMG has the following overall mandate and scope of work:

- Provide overall policy and strategic guidance and direction for the Programme, building on general health-, development- and foreign policies;
- Assess overall results achieved and Programme performance;
- Decide on new countries or projects to be included in the Programme, as well as early closure of projects, if relevant;
- Decide on major changes to the programme budget;
- Ensure that all stakeholders are adequately informed; and
- Other topics of relevance for the Programme.

Programme Management Group (PMG) is composed of DMOH and MFA senior staff involved in FP management and implementation with DMOH as Chair.

The PMG has the following overall mandate and scope of work:

- Assess and discuss overall progress, results, learnings and challenges of the Programme and its projects;
- Approve annual work plans, budgets, accounting, and status reports for the Programme;
- Discuss relevant sector themes and issues, implementation modalities and lessons learned of relevance for the Programme and its Projects; if needed;
- Assess financial status and recommend major adjustments under the programme budget to the SMG; if needed;
- Decide on reallocation of funds between projects and the use of unallocated funds within the programme budget;
- Approve new projects and phases as planned by the Programme and guided by the SMG; and
- Other topics of relevance for the Programme.

The PMG meets bi-annually as follows: In February-March to address the annual progress reporting and the annual financial expenditure report, incl. deviations and challenges encountered during the implementation of the individual SSC projects under the Framework. In October-November the PMG will meet to address the coming years' programme and budget planning, incl. capacity and contributions of all involved stakeholders. The PMG will endorse programme and project changes and ensure that all stakeholders are informed and in compliance with all requirements.

DMOH will organise and facilitate all meetings and follow-up of the SMG and PMG. Meeting documentation will be circulated by DMOH at least 14 days in advance of the meeting and summary of meetings will be circulated within one week and finalised within 2 weeks from the meeting.

To ensure full integration of SSC projects with Embassies, bi-annual regional meetings will be held with all Embassies administering SSC projects. TOR for the meetings will be developed in the Procedure Manual

Preparation of new projects and new phases will be discussed in the SMG well in advance. Proposals for such must be agreed upon in the Project Steering Committee and submitted for initial screening, discussion, and recommendations for approval from the PMG, before submission to the SMG. New and adjusted outcomes will be discussed with partners and a new project document and work-plan agreed upon. The new phases or new projects must be described in project documents aligned with the requirements in the AMG.

A mechanism will also be established at Embassy level to jointly monitor, share lessons, and coordinate activities in support of the project-level contributions to the three FP outcomes on capacity development, bilateral/climate diplomacy, and private sector engagement. It will be responsible for monitoring progress, agreeing and coordinating activity plans, and compiling monitoring data for results reporting relevant to the three FP outcomes at the specific project/country level. It will be chaired by the Embassy and include DMOH, Sector Counsellor as Secretary, Trade Council, relevant Embassy diplomatic/development staff and other relevant members to be defined. It will meet on a needs-basis to enable timely input to annual progress reports and annual work plans.

Annual FP planning, budgeting, and reporting cycle: DMOH will prepare and submit a consolidated FP workplan and budget for the coming year in October/November, for discussion and approval in the PMG. The work plan and budget will describe planned FP-level activities and highlight significant project-level activities that impact on overall FP progress and expected results, priorities and budgets, and main deviations from previously approved plans. Proposed new phases and projects will be reflected in the work plans.

In February/March, DMOH will submit to the PMG the annual FP progress report and financial expenditure report, highlighting deviations and challenges in implementation of individual projects with significance or impact on the overall progress and results of the FP. The annual progress and expenditure reports will be reviewed as basis for directions on adjustments or approval by the PMG. Based on the annual progress report, financial expenditure report and work-plan and budget subsequent annual transfer of funds from MFA to DMOH will be decided. Templates for annual planning and reporting have been developed in the MYNSAM Procedure Manual.

In addition, the FP will include processes for systematic sharing of knowledge and lessons. There will be regional meetings (virtual) between DMOH, MFA, relevant Embassies, and DFC with focus on sharing information and knowledge on issues, challenges, and opportunities, across all three FP outcome areas. Generally during implementation, DMOH will facilitate relevant opportunities for Embassies to engage at high-level with partner authorities; and in connection with Danish high-level visits to the countries, MFA/Embassies will engage with DMOH early-on regarding relevant opportunities in connection with such visits; all will explore opportunities through DFC to enhance learning outcomes.

8. Financial management, planning and reporting

DMOH will provide an **Annual Progress Report**, assessing progress, developments, risks, and lessons in relation to the FP Results Framework, FP Theory of Change, and which also provides a synthesis of progress across the outcomes and outputs defined in the individual projects under the FP, structured in

terms of outcomes and main areas of work under the FP in a template included in the Procedure Manual). The report will address assumptions to the Theory of Change, risks, and learning as basis for adjustments to the individual projects. The narrative programmatic annual reports are prepared by DMOH in close cooperation with Sector Counsellors and the Embassies. The Annual Progress Report is main basis for discussion of progress in the PMG and SMG and for reporting on MFA's Results Framework Interface (RFI).

DMOH will follow the MFA Guidelines for Financial Management and the SSC Annex on financial implications for a Danish Authority engaging in Danish officially financed Development Assistance. Budgeting and financial accounting and reporting to MFA will be at Programme level in similar format as the FP budget and at project-level, including output-based reporting at project level, following the template developed fir the Procedure Manual. DMOH will provide accounting for use of inputs including staff time at output-level. The funds will be disbursed by MFA to DMOH annually in one tranche based on approved reporting. Standard best-practice accounting procedures apply.

9. Monitoring, learning, and risk management

DMOH is responsible for monitoring of the projects under the FP based on the FP results framework and the project specific results frameworks, risks matrix, and guided overall by Danida Aid Management Guidelines (AMG). DMOH will ensure internal quality assurance systems for preparing project documents, annual and mission reporting on new and on-going SSC projects and others. DMOH will establish a MEAL system adequate for meeting the monitoring, learning and reporting requirements across the SSC projects and FP results framework. The MEAL system should ensure accountability, inform decision-making, capture lessons learned and provide information for external communication. It will follow the MYNSAM guidelines and consist of three integrated components of monitoring, review and learning. The learning component will include both sharing knowledge, results, and lessons of SSC cooperation with other relevant donor programmes and Danish engagements in-country and knowledge-sharing with Danish firms and business associations.

DMOH will be responsible for reporting on the RFI. Monitoring will be based on the MEAL plan, which will be developed by DMOH and include final results frameworks, roles, and approach to aggregating project level results for the FP. The MEAL plan will include outcome harvesting undertaken to capture wider results of the FP.

The QA system, learning, and competence development will include a focus on the HRBA and poverty reduction, including based on the FP's annual reporting on HRBA related activities. MFA will commission a **mid-term review** of the FP in 2025 with focus on progress towards results, lessons learned; organizational management capacity of DMOH and partner authorities; and lessons on cooperation and dialogue with main relevant private sector actors; and implementation of programme monitoring and learning system (MEAL plan); operationalization of the HRBA and poverty reduction in the capacity development efforts. The mid-term review will also revisit the result framework and targets.

DMOH will adequately in time for the mid-term review undertake an outcome harvesting- and lessons learned study across the projects of the FP. The outcome harvesting will focus on capturing broader

effects of changes of the healthcare framework conditions, the bilateral relations and diplomacy and the commercial effects.

Annex 3 describes the **main risks** facing the FP. DMOH will annually review and update the risk assessment for discussion in the PMG and SMG meetings. Risks at the level of the individual projects will be identified and monitored based on the project documents. The main overall risks are related to the risk of political instability or worsened bilateral relations with Denmark. There is also a distinct risk of implementation delays, which many be caused by a number of factors, as indicated in Annex 3.

DMOH and the Embassies will collaborate with **Danida Fellowship Centre (DFC)** to maximise results of the FP and support joint identification of needs, co-creation of opportunities, and coordinated evaluation of results. To this end, DMOH will ensure that possibilities for relevant collaboration are considered under the individual projects and discussed across the FP annually in the PMG, and that DFC is included as relevant in the formulation of new phases under each project, and the evaluation of such phases upon their conclusion. Decisions on collaboration are made at project level, with Sector Counsellor as initiators. DMOH and DFC will strive to have an annual meeting for information and lessons sharing.

10. Closure and exit

The process for closure and exit will follow the procedures defined in the SSC guidelines and Danida's AMG. All projects are expected to end no later than phase 3, corresponding to 10 years, but can be ended after any phase if decided by the SMG.

Any project entering phase 3 should include, as part of the project documentation for approval, an outline strategy for transition that ensures sustainability of main project results after project completion. The strategy should describe how results are planned to be sustainable within the partner authority systems, for instance, through focus on particular partner reform processes that the partner is committed to sustain, and relevant plans for how project results will be transferred to be managed by the partner. It should also describe how the SSC project's synergies with the wider Danish engagement in the country will be sustained, for instance, through contribution to other Danish aid and business instruments and/or further commercial or investment cooperation in that country. To further sustainability of the results, phase 3 projects should concentrate efforts in thematic areas that have proven to be in high demand from the partner country and have seen good progress in terms of partner capacity and commitment during previous phases.

A final results report based on AMG's format should be submitted by DMOH for discussion and approval by the SMG. The closure of accounts should follow the principles in the AMG.

Annexes:

Annex 1: Project contexts and summaries

Current Phases

Brazil

Project title	Strategic Sector Cooperation between Brazil and Denmark on supporting efficient healthcare management in Brazil – Phase 2
Project period	October 2020 – October 2023
Country	Brazil
Main sector development issues	**The Health Sector** In Brazil, the healthcare system is composed of both a public (SUS) and a private sector (SSAM). Healthcare management is decentralised and municipalities are responsible for most primary care services, as well as some hospitals and other facilities. Primary care clinics and emergency units are mainly public, whereas hospitals, outpatient clinics as well as diagnostic and therapeutic services are mainly private. **Poverty, vulnerability, inequality** SUS's service network is insufficient to meet the current demand for healthcare, which impedes the access to many services offered by the system. Only around 69,7 pct. of the Brazilian population depends entirely on SUS. The remaining 30,3 pct. is also partly covered by SSAM, which is funded by out-of-pocket treatments, health plans or public resources. The decentralised nature of SUS is reflected and reproduced by a variety of non-interoperable health information systems, which do not support a national and common health data platform for collecting and sharing data. The health data provided is therefore of limited use in supporting clinical and administrative healthcare management hindering e.g. efficient use of available resources, optimised supply, increased patient safety and coherent patient pathways across health professionals, health units and governance levels. Although access to medicine is relatively high and in principle free of charge, 26 pct. of the medicines obtained by the bottom income quintile of the population are paid from their own budget. Furthermore, an increased demand for pharmaceuticals has given rise to a substantial backlog on handling applications for authorization of pharmaceuticals, posing long waiting times for approval of medicines and hence barriers for better and faster access to new medicines.
Thematic focus	The SSC has two focus areas: 1. A Diagnostic Related Groups (DRG); System and Digital Transformation 2. Regulation of pharmaceuticals and medical devices
National partner authority (recipient country)	Brazilian Ministry of Health (BMoH) Brazilian Health Regulatory Agency (ANVISA)
Danish authorities engaged	Danish Ministry of Health Danish Health Data Authority Danish Medicines Agency

Other Danish partners	MedCom (Indirect partner)
Objective	The SSC between Brazil and Denmark aims to support the improvement of healthcare management in Brazil through better use of data, digital transition and more efficient, faster and transparent approval processes of pharmaceuticals and medical devices.
Main components (outcome areas)	**<u>Pillar I – Improving healthcare by better use of data</u>** Main national partner: Brazilian Ministry of Health Two work areas 1) a continued cooperation on Diagnostic Related Group System (DRG) building on the cooperation from phase I; and 2) a new cooperation on digital transformation healthcare. The objective is to support BMoH in reviewing and developing a new Digital Health Strategy, including the development of large-scale investment projects in digital transformation of the healthcare sector in Brazil alongside the establishment of a Brazilian DRG system. **<u>Pillar II – Improving healthcare by more efficient and transparent administrative processes on new pharmaceuticals</u>** Main national partner: Brazilian Health Regulatory Agency (ANVISA). The objective is to support more efficient, faster and transparent approval processes of pharmaceuticals and medical devices. Special focus on improved and more agile case handling.
Results	Pillar 1: 1. The SSC has supported Brazil in developing its Digital Health Strategy 2020-2028 based on the Danish strategy and approach to addressing health issues with technology. 2. Political decision to implement a DRG system in Brazil and request for support from Denmark for the development of a Brazilian DRG system, involving new funding models and models for allocation of resources to regions and municipalities. Pillar II: - Number of pharmaceutical products authorised doubled from 187 in 2017 to 375 in 2019. - Significant lowering of rejected requests by 2019 reflecting a greater interaction and dialogue between the Agency and the regulated sector, which improved the quality and adequacy of approval requests. - Reduced the backlog of requests for approval of new products from 589 in December 2018 to 233 in in December 2019.
Significant implementation issues or delays	Due to the Covid-19 pandemic many activities were cancelled or transformed into a virtual format, especially during the 2021 where resources at both sides were under extreme pressure. Specifically pillar 2 was affected by cancellations. Consequently, significant delays are expected.
Danish priorities, interests, and coherence	The SSC Health is an integrated part of the Embassy's strategy and a tool to engage Brazilian authorities in Danish solutions, as well as to promote political - and to some extent - commercial priorities. Alignment, synergies, spin off, funding options and possible joint projects are explored jointly across departments at the embassy. The Danish commercial priorities in Brazil include: new drugs/medical equipment, digital health, mental health, management of chronic diseases (e.g. obesity, diabetes), innovation, diagnostics and genomics.

	The strong relations created over the years make it possible to reach out directly to both the Brazilian Ministry of Health and Brazilian Health Regulatory Agency (ANVISA). Collaboration and integration of the health agenda is also taking place at a Latin American level, as the sector advisors participation the yearly regional LATAM meetings, which contains "health" breakout sessions with LATAM colleagues.

Main other relevant instruments, engagements, and initiatives managed by the Embassy

Instrument	**Main relevant linkage to SSC project (**in a few words)
SSC project 1 Energy	From 2023, the Embassy will start a new SSC project within Energy. Synergies will be explored.
SSC project 2 IPR/Digitalization/Innovation	This SSC (2018-) also includes health activities. Synergies/joint initiatives are on the agenda at monthly meetings.
Sustainable Agricultural Supply Chain	Project conducted by the Embassy (no obvious synergies to health).
SDG Grants	1 SDG grant: Political Climate Leadership – Denmark and Brazil (no obvious synergies to health)
Green Front Mission	Since 2020, the Embassy has acted as Green Front Mission in Brazil.
Research projects	Supported by the DANIDA Grants of the Windows 2 call, two research projects have been established: • Digital Health Monitoring and Telemedicine (2018-) • AMR: One Health (2019-)
DFC courses	DFC courses are very efficient supplementary tools for in depth knowledge sharing on SSC areas - e.g. the courses on: • Efficient and transparent approval processes for Pharmaceuticals • Health Economics and Digital Health • Organisational Change Management • Private Public Partnerships Further, the DFC course activities are beneficial for: • Enhancing network, e.g. to hospitals (private/public) with commercial potentials • Adding other Danish interest areas on the political and commercial agendas in BR

China

Project title	Strategic Sector Cooperation between China and Denmark within health – Phase I
Project period	January 2019 – June 2024 (extended to Q2 2024)
Country	China
Main sector development issues	**The Health Sector** The Chinese healthcare sector is under pressure due to the socioeconomic and demographic development, i.e. an ageing population and changing lifestyle patterns. Additionally, there is an increased prevalence of mental disorders. There is a general lack of capacity and financial resources in the Chinese healthcare system, especially in the primary sector. Moreover, the Chinese healthcare system is to a large extend hospital-centric, meaning that many healthcare services are delivered by the hospitals, leading to inefficiency and to many public hospitals being overburdened.

	In China, progress has been made in recent years in terms of improving the regulation of medicines and medical devices. However, there are still areas in which China can improve and build up capacity, thereby enabling timely access to innovative medicines and medical devices for the population. In 2016, the Chinese government released *Healthy China 2030* (*HC 2030*), which is the national strategy for the future development of the healthcare sector. One of the major points in this plan is a shift from disease treatment to health promotion and health management. Developing a universal healthcare system and ensuring universal access to primary medical and healthcare services are among the key goals of the plan. Furthermore, *HC 2030* specifically mentions mental health as a priority area: *"Common mental disorders, psychological behavior problems, such as depression and anxiety, will be targeted and intervened with, and more emphasis placed on early detection and intervention for mental disorders"* (HC 2030). Finally, *HC 2030* has an explicit goal to further advance the medicines and medical devices review and approval system reform. **Poverty, vulnerability, inequality** Over the past decades, China has increased basic health insurance coverage to the majority of the population, and many people have been lifted out of poverty. However, the inequality in access to and quality of healthcare remains high between urban and rural areas and between the eastern and western part of China. In the rural areas and less-populated parts of western China, many people have poor access to health services. Moreover, people with mental disorders in China are often subject to stigmatization, and are in risk of being excluded from the educational system, the labor market, and society.
Thematic focus	Medicines and medical devices (SP1) and primary healthcare including mental health and chronic diseases (SP2). In the signed Project Document of SP2, equal emphasis has been placed on primary healthcare and mental health. During the implementation of phase I, SP 2 has ended up focusing mainly on mental health, more specifically digital psychiatry, anti-stigmatization and management of mental health disorders in the primary care sector.
National partner authority (recipient country)	SP1: National Medical Products Administration. SP 2: National Health Commission, Peking University Sixth Hospital, Jiangsu Province (Wuxi Mental Health Centre) and Guangdong Province (Guangzhou Huiai Brain Hospital).
Danish authorities engaged	SP1: Danish Medicines Agency SP2: Danish Ministry of Health, Danish Health Authority (incl. ONE OF US national anti-stigma campaign), Region of Southern Denmark
Other Danish partners	SP2: University of Copenhagen
Project objective	SP1: In the area of medicines and medical devices, the collaboration focuses on regulatory improvement and policy exchange. The project contributes to capacity development to safeguard public health in China and to inspire process optimization enabling timely access to innovative medicines. SP2: The overall focus of the project is to support increased access to care through effective management of healthcare systems in China.
Main components (outcome areas)	SP1: - Outcome A: Contribute to optimizing processes for authorization of clinical trials and medicines in order to provide better and faster access to innovative medicines in China

	o Examples of activities: Workshop on quality documentation in clinical trials; Workshop on documentation and assessment of biological and biosimilar pharmaceuticals; Workshop on API-dossiers; Medical assessment training in Denmark - Outcome B: Safeguard public health in China and Denmark by ensuring medicines and medical devices of good quality through sharing of experience in good laboratory control and inspections o Examples of activities: Inter-laboratory comparison on laboratory control of radiopharmaceuticals; Workshop on medical device frameworks in Denmark, field visit to Denmark to observe GCP inspection SP2: - Outcome A: Strengthening capacity in relevant entities involved in policy-making and support to the primary healthcare sector o Output A: Share experiences within internet-based treatment of common mental health disorders o Output B: Share experiences with the development and implementation of anti-stigmatization campaigns o Output C: Share experiences in primary sector policy-development
Results	SP1: - Access to and close bilateral relations with the National Medical Products Administration (NMPA), which is an important Chinese regulatory authority for the Danish life science sector - DKMA experts have delivered technical in-depth knowledge on regulatory matters to the NMPA, thereby supporting China in the future development of regulatory assessment and authorization procedures SP2: - The cooperation on mental health has been initiated, and relations to Chinese stakeholders within mental health has been established. Due to the pandemic, the collaboration has mainly been virtual, and specific results are still pending
Significant implementation issues or delays	Due to the COVID-19 pandemic and the fact that China until January 2023 applied strict measures of pandemic control, including international travel restrictions, the full potential of the project has not been realised, and the implementation has been heavily affected. Thus, in a substantial part of the project period, it has been necessary to change the format of activities from physical to virtual and to cancel some activities. Moreover, the project period has been extended from January 2022 to March 31 2024.
Danish priorities, interests, and coherence	Denmark has strong commercial interests in China within the health and life science sector. In this regard, strong relations to Chinese health authorities are crucial. The SSC Project is a way to maintaining and strengthening these bonds. More broadly, the SSC Project is a diplomatic tool used to build up and maintain Sino-Danish bilateral relations, including within the framework of a possible new Joint Working Program.

Main other relevant instruments, engagements, and initiatives

Instrument	**Main relevant linkage to SSC project (**in a few words)
Strategic Sector Cooperation	SSC Healthcare (Medicines and medical devices; Primary healthcare and mental health), January 2019 – March 2024
On-going research projects	N/A
Investment Counsellor	N/A
SDG Grants	N/A

Green Front Mission	Yes

India

Project title	Strategic Sector Cooperation in Health and Medicine between Denmark and India – Inception phase
Project period	November 2022 – December 2023
Country	India
Main sector development issues	**The Health Sector** Public health is one of India's major developmental challenges. Key areas of concern to the Indian government include: shortage of well-trained health personnel; access to health services in rural areas; absence of an integrated system for medical records and health data; prevalence of antimicrobial resistance (AMR); and regulatory challenges in the pharmaceutical sector. The COVID-19 pandemic had severe socio-economic impact across the country, especially for the poor and marginalised. As a result, pandemic preparedness has gained increased attention as a matter of strategic importance. This includes efforts to prevent future pandemics and other major threats to public health, such as antimicrobial resistance; as well as efforts to ensure a robust and agile system to manage any such situation, e.g. through improved data management and digital solutions, in addition to the broader measures to strengthen the public health system. Known as 'pharmacy of the world', India plays a significant role in ensuring accecss to safe and accessible medicine both nationally and globally. However, India's pharmaceuticals sector is faced which distinct challenges – most significantly of regulatory nature, but also with regards to R&D investment, price control and IP protection. Domestic and foreign companies alike have called for reform, and recently the government has taken incremental steps to meet the industry's requests and not least increase investments in the sector. **Poverty, vulnerability, inequality** In general and in India in partucular, health is intrinsically linked to poverty, and poverty is both a cause and consequence of poor health. Poor, marginalised and/or rural populations are more susceptible to bacterial infection and more likely to receive counterfeit and unsafe drugs due to poor access to reliable and safe medical treatment, which result in prolonged and potentially increased illness and hence negatively affect the ability to work and lead a full life. Poor and marginalised populations are also the most at risk of getting sick and the worst hit economically by epidemics or pandemics, as was witnessed during the recent COVID-19 pandemic. Improved capacity to tackle health threats and improved regulation of pharmaceutical and medical devices will therefore directly impact the poor and indirectly impact poverty alleviation.
Thematic focus	The inception project between India and Denmark within health has two primary thematic focus areas of mutual interest: 1. Cross-border health threats: AMR, pandemic preparedness and digital potential 2. Pharmaceuticals and medical devices: regulatory aspects
National partner authority (recipient country)	Ministry of Health and Family Welfare, India and underlying agencies
Danish authorities engaged	Ministry of Health, The Danish Health Authority, Statens Serum Institut, Denmark, The Danish Health Data Authority and The Danish Medicines Agency
Other Danish partners	N/A

Project objective	The main output of the Inception Project Phase is the formulation of a full SSC project – based on relevant activities during the inception phase clarifying and gathering the required information and knowledge using an approach of mutual understanding and close dialog with the Partner Authority. Another output will be a background/sector document.
Main components (outcome areas)	Output 1: Exploration of technical areas of cooperation In order to build mutual understanding and explore pre-identified areas of potential collaboration, experts from DKMA, DHDA, SSI and DHA will engage with their relevant Indian counterparts within the two thematic focus areas: 1. Cross-border health threats: AMR, pandemic preparedness and digital potential 2. Pharmaceuticals and medical devices: regulatory aspects Output 2: Background document and full SSC project proposal Based on the experience and knowledge gained under Output 1, the project leader and the Strategic Sector Counsellor will be responsible for developing the Background Document and the full SSC project proposal.
Results	N/A – since the inception phase has just been initiated, it is too early to document results.
Significant implementation issues or delays	N/A – since the inception phase has just been initiated, it is not relevant to describe implementation issues or delays.
Danish priorities, interests, and coherence	The SSC project on health with India contributes to the implementation of the Green Strategic Partnership between India and Denmark, and more specifically to the MOU on Health and Medicine. The SSC is anchored in the joint working group on Health under the India-Denmark joint commission and is this part of the formal bilateral framework for collaboration between the countries. As a result of the COVID-19 pandemic, the health sector is the subject of serious reassessment internally within the Indian government, which has a strong desire to strengthen efforts. The assessment is that health will be the most important security policy challenge in the next 10 years and India is looking for good, strong partners in the health sector. The Strategic Sector Cooperation will contribute significantly to meeting the Indian interest and make a significant contribution to further strengthening the bilateral relationship. The cooperation areas mentioned in the MOU are a good match with Danish competencies and can pave the way for Danish commercial opportunities. At the same time, trusting and close cooperation with the Indian authorities is a prerequisite for being able to influence regulatory challenges that affect particularly innovative and international companies (hereunder not least Danish companies). There is potential for strong synergies between the SSC project and the work of ICARS in India. At the same time, the SSC project can support leveraging India's public-sector engagement in ICARS. There is furthermore potential for synergies with the Novo Nordic Foundation's initiatives in India focused on public health as well as Novo Nordisk India's CSR projects (carried out by Novo Nordisk Education Foundation)

Main other relevant instruments, engagements, and initiatives	
Instrument	**Main relevant linkage to SSC project (**in a few words)
Strategic Sector Cooperation / Export start packages	SSC Collaboration: • Energy – Runs until end of 2023 and will then continue under the INDEP programme. • Environment / Water - Phase 1 running until 31.12.23 (expect no cost extension of one year) • Smart Cities / Urban development – Works under cost extension of phase 1 while defining phase 2.

	• Intellectual property rights – Phase 1 running until 31.12.23 (expect no cost extension of one year) • Maritime – Awaiting new counsellor to commence inception phase, similar to health collaboration. • Green investments – anchored in the Danish Ministry of Foreign Affairs, and is currently projected until 31.07.24. Export start packages Export start packages 2: • Food & Agriculture – 31.12.23 • Water – 31.12.23 • Trade policy / trade barriers – 31.12.23
On-going research projects	*Indicate titles of sector relevant research projects in the country with involvement of Danish researchers* • Akademiet for Tekniske Videnskaber (ATV) One Health collaboration with Indian counterparts. • Novo Nordic Foundations have gotten approval to operate in India and is expected to commence/or have already started health related research projects.
Investment Counsellor	Yes, with a focus on green investments.
SDG Grants	SDG Facility project with IIT Delhi regarding AMR.
Green Front Mission	Yes

Mexico

Project title	Strategic Sector Cooperation between Mexico and Denmark on strengthening primary healthcare – Phase two
Project period	Jan 2023 – Dec 2025
Country	Mexico
Main sector development issues	**The Health Sector** Mexico's healthcare system has undergone major restructuring by the current administration of President Andrés Manuel López Obrador (2018-2024). The National Development Plan, objective 2.4 focusses on health: *Promote and guarantee effective, universal and free access of the population to health services, social assistance and medicines, under the principles of social participation, technical competencies, medical quality, cultural relevance and non-discriminatory treatment.* To reach this goal the Mexican government is restructuring the national healthcare system. In 2019 the National Health Institute of Welfare (INSABI) was established and recently a new structure for securing social security for the 69 million people without social security was introduced (MAS-bienestar), dismantling policies that have been in place since the early 2000's. **Poverty, double disease burden, access to healthcare** Poverty is a challenge in Mexico. The percentage of poor people in Mexico has increased from 41.9% in 2018 to 43.9% in 2020, which equals 55.7 million Mexicans[1]. Mexico faces a health challenge with double disease burden, where non-communicable diseases, such as diabetes and ischemic heart diseases, are leading causes of years lost to premature death and at the same time, Mexico struggles with the elimination of communicable diseases. Injuries, mental health issues, accidents, addiction and violence are persistent challenges for Mexico.

[1] Mexico poverty reduction will require policy overhaul - Oxford Analytica Daily Brief (oxan.com)

	Not all Mexicans have access to health services and the goal of the current government is that the percentage of citizens lacking access to health services is reduced from 15.5 % in 2016 to 11.5% in 2024. Mexico's total health spending as a share of GDP was 5.4% in 2019 which was lower than the OECD average of 8.8%. In comparison, total health expenditure in Denmark was 10.0% of GDP in 2019. The public share of total health expenditure in 2019 was 49.3% in Mexico and 83.3% in Denmark. The out-of-pocket share of total health expenditure is relatively high in Mexico and amounted in 2019 to 42.1% compared to 14.2% in Denmark[2].
Thematic focus	The SSC has two focus areas: 1. Strengthening capacity in primary healthcare, with focus on chronic diseases, such as diabetes, and mental health (including through the use of telemedicine and national policy planning.) 2. Strengthen regulatory processes in relation to pharmaceuticals at national level.
National partner authority (recipient country)	• Secretariat of Health in Mexico (The Secretariat) • Federal Commission for Protection against Health Risks (COFEPRIS)
Danish authorities engaged	• Danish Ministry of Health (DMoH) • Danish Medicines Agency (DKMA) • Danish Health Authority (DHA)
Other Danish partners	• MedCom • Telepsychiatry center in Southern Region of Denmark
Project objective	*To strengthen primary healthcare, prevention and treatment, by improving access to effective and safe medicines in Mexico*
Main components (outcome areas)	OUTCOME A: *To strengthen the primary healthcare sector in regards to diabetes, maternal health and mental health.* Main national partner: Secretariat of Health in Mexico OUTCOME B: *To strengthen regulatory processes relating to pharmaceuticals at national level* Main national partner: Federal Commission for Protection against Health Risks (COFEPRIS)
Results	The SSC project in health between Mexico and Denmark has resulted in close cooperation between the countries in the field of health also more broadly. The Mexican Government mentions the Danish healthcare system often as a source of inspiration to the ongoing restructuring of the healthcare system in Mexico. In particular, the aspects of a public health system, a strong primary healthcare sector, the focus on prevention, the mechanisms for central planning, the referral system and high quality of care are mentioned as relevant areas of inspiration for the Mexican healthcare system. During phase one, a strategy for implementing clinical practice guidelines through the use of algorithms from primary health care clinics was developed with the purpose to reduce inequality between municipalities and states. A whitepaper for the use of telemedicine in Mexico was developed and presented at state level in a joint effort between Mexico and Denmark The evaluation model for the use of telemedicine (MAST) was developed to fit a Mexican context through workshops and joint work at federal and state level. Joint work on using existing data on chronical diseases to develop and improve the use of indicators to monitor the health status at primary healthcare level. As a result of the fruitful exchanges during first phase of the SSC, the cooperation was extended to include the Mexican Agency for Medicine (Cofepris).

[2] OECD (2021), Health spending (indicator). doi: 10.1787/8643de7e-en

Significant implementation issues or delays	*The Mexican health sector is a very high political priority for the current government. The sector is characterised by continuous adjustments and administrative changes which creates a need for flexibility in the implementation of the SSC. This flexibility has been crucial for the continuous very close relations between the countries in the health sector.*
Danish priorities, interests, and coherence	*SSC cooperation in the health sector focuses on strengthening the primary health sector, as well as improving access to medicines, by supporting health care development plans in Mexico. In addition, as an integrated part of the Embassy's strategy to promote Danish solutions, we work jointly to support Danish commercial priorities in Mexico which includes innovation in new drugs/medical equipment, digital health, mental health, management of chronic diseases (e.g. obesity, diabetes), among others.*
Main other relevant instruments, engagements, and initiatives	
Instrument	**Main relevant linkage to SSC project (**in a few words)
Strategic Sector Cooperation	*The SSC in agriculture and food between Denmark and Mexico is intended to include an AMR focus, where there will be possibilities for synergies to the SSC in health.*
On-going research projects	*There are ongoing research projects between The University of Copenhagen and Ibero University in Mexico in the field of diabetes.*
Investment Counsellor	*Is there an investment counsellor at the embassy? No*
SDG Grants	*SDG Facility 2022 projects on 1) Strengthening gender equality at the workplace in Mexico and 2) Sustainability and environment aid roadmap for the private sector. No synergies to health but for 2023 projects are envisaged.*
Green Front Mission	*Is the Embassy appointed a Green Front Mission? Yes*
	DFC courses are very efficient supplementary tools for in depth knowledge sharing on SSC areas - e.g. the courses on: • Efficient and transparent approval processes for Pharmaceuticals • Health Economics and Digital Health • Organisational Change Management • Private Public Partnerships

Vietnam

Project title	Strategic Sector Cooperation on Health Phase 2
Project period	August 2020 – June 2023 (ambition for no-cost extension until July 2024)
Country	Vietnam
Main sector development issues	Along with the general socio-economic development over the past 30 years, Vietnam has achieved significant progress in health outcomes, including increased life expectancy, reduced child and maternal mortality. Access to health services has expanded and the current per capita health expenditure is relatively high and increasing. However, Vietnam is also one of the most rapidly ageing countries in Asia and over the past 20 years there has been a change in the morbidity and mortality patterns from communicable diseases (CDs) to non-communicable diseases (NCDs). This implies a shift in the health needs of Vietnam's population away from acute episodic care, toward long-term interventions to prevent, detect and manage, particularly, NCDs. Despite a far-reaching system of health care facilities at primary, secondary and tertiary levels, Vietnam's health service delivery system is hospital-centric. In 2016, almost half of all outpatient visits took place in a hospital. This is both expensive and not well suited to the management of NCDs. Many medical conditions currently treated in hospitals could be better managed in ambulatory, community and home settings, with appropriate support from hospitals and relevant health technologies.[3] However, the capacity to diagnose and manage NCDs at local level health facilities, such as the

[3] Improving efficiency in the health sector: An assessment of Vietnam's Readiness for Integration of Care. Hui Sin Teo, Dao lan Huong. Health, Nutrition and Population Practice World Bank Group, 2020.

	Commune Health Stations (CHSs) remains low. More than 60% of individuals with diabetes and 50 % with hypertension are not diagnosed, and only 20% of NCD patients receive long-term management in accordance with the guidelines issued by the Vietnamese health authorities. Even though more than 90% of the population is covered by health insurance[4] and out of pocket payment (OPP) for health services has decreased, OPP still accounts for about 41% of total health expenditure (2016) and about 70% of health insurance funds are spent at secondary and tertiary levels. [5] Finally, despite free health insurance for the poor and ethnic minorities, access to health services remains uneven between different socio-economic and ethnic groups.[6]
Thematic focus	Strengthening primary healthcare (PHC) for prevention, detection and management of non-communicable diseases with a focus on diabetes and hypertension. The work plan is currently being revised due to delays, primarily caused by Covid-19. The thematic areas will remain the same, however the scope of activities will be reduced in order to be able to implement all activities within the current timeframe of phase 2.
National partner authority (recipient country)	General Department of Preventive Medicine (Vietnam Ministry of Health, VN MOH) International Cooperation Department (VN MOH) Provincial Department of Health in Thai Binh Province (Thai Binh DoH)
Danish authorities engaged	Danish Ministry of Health (DK MOH) Danish Health Authority
Other Danish partners	Steno Diabetes Center Copenhagen
Project objective	To strengthen PHC in Vietnam for prevention, detection and management of non-communicable diseases by supporting the development of policies, plans and guidelines, and continuing implementation of a pilot in Thai Binh province.
Main components (outcome areas)	**Outcome A:** Support for strengthening policy development and implementation on PHC for NCDs. **Outcome B:** Support to continue strengthening a PHC in the Thai Binh province with a focus on prevention, early detection and management of NCDs and generating experiences of PHC reform at local level to feed into the national policy dialogue. **Outcome C:** Improve quality of diabetes and hypertension related health services at selected Commune Health Stations (CHS) in the Thai Binh province, including the engagement of Village Health Workers and selected community-based organisations (note: outcome potentially under revision).
Results	Overall, the SSC has contributed to place Denmark as a significant actor in the area of NCD prevention, detection and management in Vietnam. The strategic and long-term Danish commitment serves as a platform to promote Danish health cooperation and provides a valuable bridging instrument following the phase-out of other bilateral development assistance. While travelling to and from Vietnam has been limited by travel restrictions in 2021, several partners have been included in virtual seminars, workshops and presentations, such as General Department of Preventive Medicine (GDPM) , Vietnam Social Security (VSS), The Danish Medicines Agency, AMGROS, University of Copenhagen etc.

[4] Viet Nam Social Security News (vss.gov.vn)
[5] Health financing in Viet Nam (who.int)
[6] research-report-multidimensional-inequality-vietnam (1).pdf

	Following the ease of Covid-19 restrictions in both DK and VN in the first quarter of 2022, a policy dialogue tour to Denmark with representatives from Vietnam Social Security (VSS), was held in June 2022. While a number of project activities were on hold during Covid-19, the Sector Counsellor was actively involved in providing input to the pharma law in VN to fully harmonise with global and regional practice as it has strong influence on PHC, and remove unnecessary administrative burdens for the authorities and industry.
Significant implementation issues or delays	There have been significant delays due to Covid-19, leading to cancellation of activities and transformation of selected activities into virtual format. The activity plan is, as a result thereof, currently being revised together with partners in Vietnam. Lessons learned includes the need for a preparedness plan for the SSC project in case partners in VN must redirect their work towards a specific health issue (such as Covid-19) or international and local travel is limited due to a health crisis.
Danish priorities, interests, and coherence	In the process of revising the current activity plan to realistically reflect the remaining project period (end December 2023/July 2024), DK will have a strengthened focus on policy dialogue between DK and VN and promoting policy dialogue between different levels of government in VN. Key activities will include central level consultation meetings, technical inputs and policy dialogue tours for development of national policies on primary health care and NCDs and provincial and district level policy- and implementation dialogue. In addition to activities carried out separately at different levels of government and health service facilities, the project aims to create opportunities for dialogue between the different levels of government and health service facilities, in order strengthen focus on policy implementation needs in the development of national policies. This reflects technical strengths at the DK Health Authority and Steno Diabetes Center, DK MoH policy priorities, and provides opportunities for Danish commercial priorities within the field of NCDs. The revision is further based on the general understanding that change should happen at the policy level (local, regional and national) in order to sustain after the SSC project has been finalised.

Main other relevant instruments, engagements, and initiatives

Instrument	**Main relevant linkage to SSC project** (in a few words)
Strategic Sector Cooperation	Education and Statistics, phase 2: 2021-2023 Food and Agriculture, phase 2: 2020-2023 Energy Sector, phase 3: 2020-2025 Synergies explored on an ongoing basis through local organization of Sector Counsellors in the Trade Department of the Embassy. Areas to be explored may for instance include the "Decent Work" and the "One Health" agendas locally.
On-going research projects	University of Copenhagen research project, VALID I (terminated November 2022). University of Copenhagen research project, VALID II (starting December 2022).
Investment Counsellor	N/A
SDG Grants	Supporting Vietnamese Ministry of Health in enhancing primary healthcare in Vietnam (2018) Enhancing primary healthcare and sustainability of the healthcare insurance fund in Vietnam (2020)
Green Front Mission	Yes

DFC Courses	The SSC on Health in VN has previously provided the opportunity for VN health professionals to engage in DFC courses in DK, particularly through the University of Copenhagen School of Global Health courses.

Future Phases

Brazil

Project title	Strategic Sector Cooperation between Brazil and Denmark – phase 3
Project period	October 2024 - October 2027
Country	Brazil
Budget	7.500.000 DKK
Thematic focus	1. Regulation of medicines and medical devices, and 2. continued work on health data and digitalization as key tools for coherent, efficient and quality healthcare services for Non-Communicable Diseases (NCDs)
National partner authority (recipient country)	Brazilian Ministry of Health, including DataSUS (BMoH) Brazilian Health Regulatory Agency (ANVISA)
Danish authorities engaged	As in Phase II: Danish Ministry of Health, Danish Health Data Authority, Danish Medicines Agency
Other Danish partners	
Objective	Support equal access to health and quality services/products through: - Improvement of healthcare management regarding prevention and treatment of NCDs; and - More efficient, faster and transparent approval processes of pharmaceuticals and medical devices. To be developed further with the Brazilian partners. Options for continued work on health data and digitalization as key tools for NCD management should be explored, building on phases I and II.
Main possible or expected components (outcome areas)	**Outcome 1:** TBD **Outcome 2**: Continue supporting more transparent, faster and agile approval processes. **Exit strategy:** Develop an exit strategy based on Phase I-II outcomes and involving tools such as educational activities and public-private-partnerships.
Significant outstanding questions or critical steps in the process	Due to the general elections in 2022, a new political situation is emerging. We expect a very positive attitude towards the existing SSC projects, but priority areas might be supplied further.
Danish priorities, interests, and coherence	Danish commercial priorities in Brazil include SSC relevant areas such as new drugs/medical equipment, innovation, digital health and management of chronic diseases/NCDs. Together with the TC at the Consulate in São Paulo, we will seek synergies, develop joint PD activities and incorporate results into the future Phase III and into the exit strategies.
Previous lessons or changes in the context giving cause to changed design	Cf. results and lessons learned from previous phases.

China

Project title	Strategic Sector Cooperation on regulation of medicines and medical devices and healthcare services for non-communicable diseases and mental health disorders in the primary sector.
Project period	July 2024 – June 2027
Country	China
Budget	DKK 8.500.000
Thematic focus	1. Regulation of medicines and medical devices, and 2. Coherent, efficient and quality healthcare services for non-communicable diseases and mental health disorders in the primary healthcare sector
National partner authority (recipient country)	National Medical Products Administration of the People's Republic of China (NMPA) and relevant sub-agencies, including the Center for Drug Evaluation (CDE) National Health Commission of the People's Republic of China (NHC) *And secondary partners (TBD)*
Danish authorities engaged	Danish Medicines Agency Danish Health Authority Region of Southern Denmark (TBD)
Other Danish partners	*TBD*
Objective	To support capacity development for prevention and treatment of non-communicable diseases (NCDs) in the primary sector and increased access to safe, innovative medicines and medical devices in China
Main possible or expected components (outcome areas)	**Outcome A: Regulation of medicines and medical devices** • Contribute to optimizing processes for authorization of clinical trials, medicines and medical devices in order to support faster access to innovative medicines and medical devices in China • Contribute to ensuring safe medicines and medical devices of high quality through sharing of experiences with inspections **Outcome B:** Coherent, efficient and quality healthcare services for non-communicable diseases and mental health disorders in the primary sector • Strengthening capacity development in the primary care sector through exchanges of knowledge and experiences with policy-making, organization of primary health services, and cross-sector collaboration in relation to Primary healthcare including mental health and non-communicable diseases.
Significant outstanding questions or critical steps in the process	**Re. Outcome A:** China and Denmark have a long history of close collaboration within the field of regulation of medicines and medical devices. Phase I includes a broad range of areas of collaboration. For phase II, it will be relevant to narrow the number of areas of collaboration and deepen the collaboration within the areas that are considered most important and valuable by the project partners. **Re. Outcome B:** The project initially focused on both primary sector development and mental health. Due to the COVID-19 pandemic and a shift in the interest of the Chinese project partners, phase I has mainly focused on mental health. For phase II, the Danish partners intend to propose that prevention and treatment of both mental disorders and non-communicable

	diseases in the primary care sector remain an area of collaboration. In the collaboration on mental health, a possible pilot project focusing on digital mental health solutions inspired by Danish experiences is currently being discussed, but decision is pending on how/whether to proceed with this pilot project in phase II. .
Danish priorities, interests, and coherence	• Government-to-government collaboration within health and life science is expected to be a part of a new Green China-Denmark Joint Work Programme • The project supports the objective to increase export of Danish life science solutions through enhanced government-to-government collaboration, as stated in the Strategy for Life Science 2021. In this regard, China is an important market for Danish life science companies, who benefit from close bilateral relations within the area of regulation of medicines and medical devices • The project supports the implementation of the Action Plan for Economic Diplomacy, including sustainable development of the Chinese healthcare sector and better framework conditions for Danish life science companies on the Chinese market • The project is an important diplomatic tool for the Danish missions in China in terms of keeping an open and constructive dialogue with the Chinese health authorities on matters of mutual interest • The project has enabled a closer dialogue between the Danish embassy and other multilateral and bilateral missions in China on global health issues
Previous lessons or changes in the context giving cause to changed design	Phase I has been heavily affected by the COVID-19 pandemic, and the project has been extended until Q2 2024. Despite the no-cost extension, it is expected that the project as a whole will not be able to fully accomplish the stated objectives and outcomes. This will also affect phase II, which will both include activities that build on the results of phase I and activities related to outcomes that have not been possible to fulfil in phase I.

India

Project title	Strategic Sector Cooperation between India and Denmark on Health phase 1
Project period	January 2024 – December 2026
Country	India
Budget	7.500.000 DKK
Thematic focus	Regulation of pharmaceuticals and medical devices & combatting health threats from infectious diseases and AMR (depending on outcome of inception phase)
National partner authority (recipient country)	Ministry of Health and Family Welfare *(Primary partner)* National Centre for Disease Control (NCDC) The Central Drugs Standard Control Organisation (CDSCO) *And possibly other secondary partners as agreed during inception phase*
Danish authorities engaged	Ministry of the Interior and Health (*primary partner)* National Health Authority Danish Medicines Agency Statens Serum Institut

	Danish Health Data Authority (TBD) *Secondary partners to be finally decided during inception phase*
Other Danish partners	none
Objective	Robust and effective public health systems for regulation of pharmaceuticals and medical devices & combatting health threats from infectious diseases and AMR
Main possible or expected components (outcome areas)	Outcome 1: Increased public health system capacity for regulation of pharmaceuticals and medical devices Outcome 2: Increased public health system capacity for combatting health threats from infectious diseases and AMR
Significant outstanding questions or critical steps in the process	Collaboration is still in its early phases, and relations are in the process of being established between the relevant agencies. Despite commitment at Ministry level, further capacity assessment at agency level is needed as part of the inception phase. Furthermore, technical discussions and analyses during the inception phase will serve to identify agreed outputs and outcomes under each thematic area. There is significant international interest and a high level of international support to the Indian agencies, which are intended to be involved in the SSC project. Therefore, engagement with other international partners and donors is necessary to ensure alignment of support. This may impact the detailed planning of the project phase 1. Finally, Indian priorities within the thematic areas are likely to mature during 2023 as a result of the G20 presidency which includes a focus on pandemic preparedness and AMR. This may result in new or more ambitious areas of collaboration, which are not evident today.
Danish priorities, interests, and coherence	-
Previous lessons or changes in the context giving cause to changed design	N/A

Mexico

Project title	Strategic Sector Cooperation (SSC) between Denmark and Mexico on strengthening primary healthcare – Phase three
Project period	2026-2028
Country	Mexico
Budget	6.600.000 DKK (2026-27 (4.400.000))
Thematic focus	Coherent, efficient and quality healthcare services for Non-Communicable Diseases (NCDs) & regulation of pharmaceuticals and medical devices
National partner authority (recipient country)	Secretariat of Health in Mexico (SALUD)
Danish authorities engaged	Danish Ministry of Health (DMoH)
Other Danish partners	Danish Medicines Agency (DKMA) Danish Health Authority (DHA)
Objective	To strengthen primary healthcare, prevention and treatment.

Main possible or expected components (outcome areas)	• Strengthening capacity in primary healthcare • Strengthening regulatory processes relating to pharmaceuticals
Significant outstanding questions or critical steps in the process	The area of regulation of pharmaceuticals is of high importance to secure sufficient and safe pharmaceuticals for the Mexican population. It has been an area of many political and administrative changes and cooperation with relevant agencies has not always been easy. Where possible, Denmark should try to secure sustainable close relations with Mexican regulatory authorities. This could be achieved through a Health Business Club and the incorporation of international agencies/organisations such as PAHO even more in the SSC activities etc.
Danish priorities, interests, and coherence	The tentative outcome areas are based on the overall strategic focus of the SSC health framework as described in Mynsam 2.0. and on an initial assessment of the needs and potential interests of the relevant mexican government agencies. The continued focus on NCDs management and prevention mirrors the Danish focus both in the EU and global health in all. Furthermore, strengthen transparent regulative process in regard to pharmaceuticals is crucial for Danish companies and export of the Danish Pharma sector.
Previous lessons or changes in the context giving cause to changed design	To secure a sustainable relation between Mexico and Denmark in areas of health different possibilities for further joint work in the area has since phase two been explored. The experiences around shift in Government in Mexico has given some indications of which type of relations that can 'survive' big political changes. • Cooperation with academia e.g. through organizing all representatives who have been joining a DFC course (Alumni network) and the DFC funded research programs. • Developing initiatives together with Danish Foundations. • Securing meetings of high relevance and high quality content for a Health Business Club.

Vietnam

Project title	Strengthening primary healthcare to prevent, detect and control non-communicable diseases (NCDs))
Project period	31.07.24-31.07.27
Country	Vietnam
Budget	7.500.000
Thematic focus	Coherent, efficient and quality healthcare services for Non-Communicable Diseases (NCDs)
National partner authority (recipient country)	Central level: Relevant departments and associated partners in the Ministry of Health of Vietnam (VN MoH) Provincial/district level: TBD
Danish authorities engaged	Danish Ministry of Health (DK MoH) Danish Health Authority
Other Danish partners	Steno Diabetes Center Copenhagen

Tentative objective	To strengthen primary healthcare in Vietnam for the prevention, detection and management of non-communicable diseases (NCDs) through strengthened institutional capacity to develop and implement policies, legislation and regulation at relevant levels of government.
Main possible or expected components (outcome areas)	**<u>Tentative</u> outcome areas:** **Outcome A:** Strengthened policy development and implementation in areas related to two selected primary healthcare challenges (based on experiences from phase I and II).
Significant outstanding questions or critical steps in the process	Consultations with partners in Vietnam have not yet been initiated, The suggested outcome areas should thus be further qualified and operationalised in close cooperation with relevant Vietnamese authorities and in dialogue with other Vietnamese and international stakeholders as well as related SSC projects in Vietnam.
Danish priorities, interests, and coherence	The tentative outcome areas are based on the overall strategic focus of the SSC health framework as described in Mynsam 2.0. and on an initial assessment of the needs and potential interests of the relevant Vietnamese government agencies.
Previous lessons or changes in the context giving cause to changed design	Experiences from the implementation of activities in phase II during the Covid-19 pandemic highlighted the need for multiple national partner authorities with different areas of responsibilities in order to maintain a flow in activities. Based on this, the preparatory work for a phase III will explore other relevant partner agencies and departments in the VN MoH,

Annex 2: Partner Assessment

Brief presentation of The Ministry of the Interior and Health, The Danish Health Authority, The Danish Medicines Agency, Statens Serum Institut and The Danish Health Data Authority

The Ministry of the Interior and Health (DMOH)'s core vision is to contribute decisively to the development of a healthy Denmark. The Ministry strives to set the framework for a well-functioning, modern and efficient healthcare system, putting the citizens at the centre.

DMOH's core responsibilities focus on administrative tasks in the area of the interior and the healthcare system. The healthcare system operates across three political and administrative levels: the state, the regions and the municipalities (national, regional and local levels). The state holds the overall regulatory and supervisory functions in health, the five regions are primarily responsible for the hospitals, the general practitioners (GPs) and for psychiatric care, while the 98 municipalities are responsible for a number of primary healthcare services as well as for elderly care.

DMOH consists of the Ministry and 11 agencies, who cover a wide range of interior- and healthcare related issues. The Ministry is responsible for policy-development, ministerial service and the overall management and development of the ministerial area. The agencies handle regulatory and administrative tasks. They also provide technical guidance to the Ministry as part of the legislative process and for policy development. The four agencies involved in the SSC-projects are the Danish Health Authority (DHA), Statens Serum Institut (SSI), the Danish Medicines Agency (DMA) and the Danish Health Data Authority (DHDA). For ease of reference, the agencies are referred to collectively as "the agencies".

The Danish Health Authority (DHA) has a national responsibility for health issues and works to ensure good public health and uniform healthcare services of high quality across Denmark. The DHA is responsible for effective health emergency management, national clinical guidelines, initiatives in health and elderly care and in major disease areas, such as cancer, heart disease, psychiatry, diabetes and infectious diseases prevention. A pivotal role of DHA is to advise the Ministry of the Interior and Health and other governmental, regional and municipal authorities on health and elderly care. **The Danish Medicines Agency (DMA)** authorises and inspects pharmaceutical companies and licenses medicinal products in the Danish market. The agency also monitors medical devices available in Denmark, appoints proprietary pharmacists, organises the pharmacy structure and supervises pharmacies and retailers. Among other tasks the DMA monitors adverse reactions from medicinal products and medical devices, authorises clinical trials and decides which medicines are eligible for reimbursement. The DMA contributes to the development of policies and regulations in the pharmaceutical area, both in Denmark and at EU level.

Statens Serum Institut (SSI)'s main duty is to ensure preparedness against infectious diseases and biological threats as well as control of congenital disorders. SSI's mission statement is to strengthen health through disease control and research. SSI engages in surveillance and research nationally and through international collaborations, and as such SSI has a strong global health profile. In the event of e.g. epidemics that demand urgent action, SSI provides counselling to the Danish healthcare system and

relevant national authorities. SSI is also responsible for the purchase and supply of vaccines to the national vaccination programme.

The Danish Health Data Authority (DHDA) works to ensure better health for the Danish citizens through the use of data and by creating digital coherence in the healthcare sector. The use of health data is a key element in the Danish healthcare system, and Denmark has some of the most comprehensive health registers in the world and is one of the globally most advanced countries when it comes to the use of health-IT. DHDA uses health data to strengthen and develop the healthcare system and at the same time to support the provision of the best possible treatment to each individual patient. DHDA runs the national eHealth infrastructure which aims at promoting coherence across sectors as well as continuity of care.

2. Summary of partner relevant capacities

ISM (including its agencies) has extensive experience with international collaboration and capacity development. ISM has participated in SSC projects since 2015 and was thus among the first Danish authorities to establish SSC projects with partner authorities. The projects have proven the ability of ISM and the agencies to develop demand driven joint activities aimed at improving capacities and framework conditions within pharmaceutical regulation, primary healthcare and data and digitalization. Danish solutions have been introduced with a focus on relevance in the local context and the particular needs of partner authorities. It follows that there today is a high level of trust established between the agencies and their sister authorities in the SSC partner countries.

In 2018, the Ministry established bilateral collaboration with partner authorities in Japan, South Korea and USA as part of the government strategy "Vækstplan for Life Science". Based on the positive results, it was decided to expand the engagement substantially in the current "Strategy for Life Science", and today ISM (including the agencies) is engaged in active collaboration with partner authorities in eight high income counties in addition to the five SSC-partner countries. The increased prioritization of bilateral collaboration has enabled ISM and the agencies to build on and further strengthen capacity for international agency-to-agency collaboration. Furthermore, experiences with economic diplomacy and engagement of the Danish life science industry in the high-income countries provides a useful source of inspiration for increased commercial engagement in the SSC countries.

ISM has a substantial international portfolio beyond the bilateral collaboration projects. As health has developed from primarily a domestic policy issue to increasingly being a highly internationalised sector, the international obligations and activities of ISM and the agencies have also increased. Currently, Denmark (represented by DMA) is a member of the Executive Board of WHO and in 2025 the Danish EU presidency and presidency of the Nordic Council of Ministers are expected to have a strong focus on health. This means that across the ISM and the agencies, international collaboration is a key priority and increasingly an area of expertise.

Certain agencies, such as the DMA and SSI, are inherently international because of their mandate and history.

DMA: A significant part of the legislation in the area of pharmaceuticals and medical devices is adopted at European level, and DMA collaborates extensively within the framework of the EU pharmaceutical framework as well as with authorities in other countries. It is essential that DMA maintains a strong international engagement to ensure high-standard and efficient administrative processes in the EU while asserting Danish influence on the regulatory framework in the EU and in other international forums, such as IMDRF, WHO etc., all having a major impact on the Danish life sciences ecosystem and on patient safety. This results in a very strong capacity for engaging with partners in SSC-countries.

SSI: Statens Serum Institut is actively involved in international collaboration within the core areas of epidemiology, special diagnostics, biological preparedness and ensuring vaccine supply. Statens Serum Institut is also the Danish contact center for the worldwide alert system under WHO and a corresponding alert system between the EU countries. Concretely, the collaboration is implemented through assignments such as participation in European and international disease surveillance coordinated by ECDC and WHO respectively; taking care of tasks for the EU and WHO, i.a. through contracts and operation of WHO collaborating centres; international research, monitoring and development cooperation; education and training, i.a. through the European Program for Training in Interventional Epidemiology, EPIET; amongst other relevant international assignments.

3. Internal coordination and management of the Framework Programme

The DMOH and its agencies work closely together under the SSC framework programme with a clear division of tasks and responsibilities.

The Ministry is the primary Danish Authority with responsibility for implementation of the Framework Programme vis-à-vis the Ministry of Foreign Affairs. It follows that the Ministry is responsible for alignment between individual project objectives and the FP objectives, planning and reporting on the FP level as well as external communication, etc. The department will represent DMOH at the Strategic Management Group (SMG) and the Programme Management Group (PMG).

In the Ministry, a team of dedicated project managers oversee planning and implementation of activities as well as financial follow-up and reporting for each of the five SSC projects. The project managers liaise closely with the sector counsellors at the embassy and with the coordinators at the agencies.

The agencies are responsible for the technical expertise and detailed planning of activities and missions under the respective project outcomes. A project coordinator is responsible for identifying and liaising with the relevant technical experts at the agency and maintaining close dialogue with the project manager and the sector counsellor.

Terms of references and back to office reports are developed jointly by the project leader, the sector counsellor and the relevant agency coordinator / technical experts in connection with implementation of project activities. This ensures a good planning process prior to activity implementation and sufficient follow-up and documentation post activity implementation.

Annex 3: Risk Matrix

Risk Factor	Likelihood	Impact	Risk response	Residual risk	Background to assessment
Contextual Risks					
Bilateral relations with one or more SSC countries evolve negatively in a way that jeopardises the bilateral relations and prevents a technical cooperation	Somewhat likely	Medium	The SSC programme is in itself aimed at strengthening bilateral relations but has little influence on overall bilateral relations.	If one or more countries are affected by this type of constraint, funds may be re-allocated to other SSC projects.	Bilateral relations with the five SSC countries have in general developed positively but for one or two countries there could be a risk for deterioration. There is also a risk that the current crisis in Ukraine evolves negatively constraining international relation and/or travel
Pandemics stall or delay project activities and travel	Unlikely	Major	Changing schedule and plans for missions, study tours and other physical events and activities; make use of virtual communication means	Some risk of delays will remain	The COVID-19 pandemic demonstrated how exposed international development activities are to travel restrictions. While these effects are no longer felt by the SSC projects, a new pandemic could arise but the likelihood is considered low.
Programmatic Risks					
Key staff of the DMOH and its agencies are not available for engaging pro-actively in project management and implementation	Somewhat likely	Low-medium	Dedicated core staff with an explicit strategy for filling key staff vacancies and introducing new staff.	This is likely to occur to some extent but if reacted upon it will not be detrimental to the implementation.	Keeping momentum in the activity implementation is important. Although the political commitment to the SSC activities is considerable, a situation could arise where key staff momentarily are not available ot the extent needed. Frequent changes in key staff could also jeopardise FP management.

Risk Factor	Likelihood	Impact	Risk response	Residual risk	Background to assessment
Lack of commitment and participation from relevant partner institution stakeholders (high-level management, other authorities, private sector).	Somewhat likely	Medium - high	Due diligence of the selection of partner authorities, emphasis on alignment to national processes and ownership will be crucial.	It is not unlikely that this will occur to some extent but it should be mitigated	If extensive, lack of commitment could jeopardise achievement of results and the sustainability of the SSC projects
Strengthened capacity is not sustained in the partner institutions	Somewhat likely	High	DMOH ensures the use of good practice and tools in relation to capacity strengthening and continues to focus on organisational results.	Some residual risk that the capacity is not sustained.	Through the SSC-projects DMOH and its agencies share experience and present the partners for tools and systems used by the National Danish health system. Even if these are adopted by partner institutions, they will need to be adapted and modified going forward in order for their sustained use to be effective.
The SSC projects under constitute a minor contribution to possible changes in framework conditions. This could mean that outcomes were only visible after the end of the cooperation or that it is not possible to attribute the effects to the SSC project.	Somewhat likely	Medium-high	The theory of change and the results framework reflect the understanding that the SSC projects may only provide a small contribution to what are in some cases comprehensive reforms that are carried forward by national institutions and interests.	None	By not promising that the FP will ensure larger changes in national health systems or policies and recognising that the SSC projects can only provide some contribution, expectations have been levelled.
The Danish private sector does not respond to the potential opportunities	Unlikely	Medium-High	Actively pursuing collaboration at the embassies and in Denmark with TC and private sector actors while seeking synergies to other aid modalities and business instruments.	There seems to be little residual risk but the export orientation of the industry is driven by many factors beyond the influence of the SSC	The showcasing Danish solutions and an active commercial engagement is essential for the SSC programme. The FP currently operates in some of the potentially largest markets for the Danish life science sector.
The strengthened capacity and the changes in systems and framework conditions would not necessarily	Somewhat likely	High	Increased emphasis on Leaving no-one behind (LNOB) and human rights as described in the FP document	There is some residual risk, especially in the existing SSC projects.	Project focus areas and activities in the current SSC projects were established as part of a process prior to this FP document.

Risk Factor	Likelihood	Impact	Risk response	Residual risk	Background to assessment
further a more equal access to health services in line with human rights			in the implementation of the existing SSC projects and in the selection of new partner countries.		
Institutional Risks					
The sector counsellors don't maintain the needed balance between advising partner authorities and linking with trade council/ Danish commercial actors	Unlikely	Medium	The Embassies and DMOH will be responsible for properly defining the expectations for the Sector Counsellor and monitor the Sector Counsellor's performance of his/her roles, also with inputs from the Partner Authority. In addition to technical skills and knowledge, Sector Counsellors will be selected for their personal skills and ability to exercise good judgement.	With good supervision, little residual risk	The sector counsellors' responsibilities include linking with Danish commercial actors as well as advising partner authorities, and it may not always be straightforward how to best manage the balance between the two roles, for instance to avoid compromising the partner authorities' long-term interests.
DMOH could omit focus on their role on capacity strengthening and how it is best supported throughout the SSC projects	Not likely	High	The role of DMOH and its agencies is central to the implementation of the programme and is an integral part of the theory of change and the results framework	Some residual risk remaining despite efforts	Frequent staff changes in DMOPH and its agencies and external pressures on staff should be counterweighted by the establishment of permanent implementation capacity in DMOH and continued focus on the SSC projects within the organisation.
The projects could risk duplicating activities and/or fail to recognise interfaces and synergies with other initiatives in a crowded and dynamic field of development partners	Somewhat likely	Small-medium	Coordination with other initiatives is to a large extent the responsibility of the partner institution but should to the extent possible be followed up by SSC project management and Sector Counsellors	Some residual risk remaining despite efforts	Coordinating with other initiatives and support to partner institutions could be challenging due to lack of full overview of other engaging programmes.

Annex 4: Plan for communication of results

The overall communication plan for DMOH's framework programme on strategic sector cooperation (SSC) aims to ensure broad knowledge about the MIH's work in international cooperation through SSC projects. This includes results, lessons, and general awareness about the significance of global health issues – and DMOH's role in addressing the key challenges through the SSC programme with clear attribution to Danish Development Cooperation.

The communication plan is dynamic and will be updated and implemented according to developments with policies, results, lessons learned and needs and opportunities identified by partners, stakeholders and staff involved in SSC cooperation. The communication plan targets a wide audience in both Denmark and globally with the use of SoMe channels, homepages, production of videos, explainers and storytelling from both Denmark and partner countries.

For Whom? Target Group/Audience	**What?** (the message)	**When?**	**How?**	**Responsible**
Target Group 1: Danish public	Stories about MIH's SSC work, the SSC projects, challenges and concrete results. Short videos for SoMe and homepage Images and other visual means MIH's homepage updated on SSC cooperation and SSC projects One long-read per year 1-2 pages on SSC programme and each of the SSC Projects (info ark) Press releases Document and disseminating results from SSC projects.	During implementation of SSC projects, i.e. minister visits, missions in-country, study tours in Denmark, major outputs produced, milestones achieved etc. Once a year	LinkedIn, Twitter Short annual SSC report MIH homepage Photos and video during missions Use of Explainers and Story-telling	Project Manager and Sector Counsellors for Health (content) Communication Focal Point (publishing on MIH's SoMe and homepage) Project managers, MFA Press Unit (press releases)
Target Group 2: Sector partners in Denmark sector associations and others	See above Articles on global health issues Newsletters from MIH with project update, news on relevant current events in SSC-countries	See above	See above	See above

For Whom? Target Group/Audience	**What?** (the message)	**When?**	**How?**	**Responsible**
	Other visual and infographic versions of documents and material			
Target Group 3: Public and institutions in partner countries and globally	As above-mentioned Stories about Danish strongholds, state-of-the-art solutions on global health issues Talks organised by DFC	As above-mentioned	As above-mentioned Make use also of other communication materials, e.g. professional journals on global health Communication channels used by the specific partners	As above-mentioned
Target Group 4: Internal communication in MIH	Results reporting and milestones for SSC programme and its projects. Outcome harvesting and reporting. SMG meetings PMG meetings Annual reporting MIH management meetings	Once a year – Strategic Management Group (SMG) Twice a year – Programme Management Group (PMG)	MIH Intranet Dedicated communication	Project Managers

Annex 5: Process Action Plan for Formulation

Version 30.5.2023

Action/product	Deadlines	Responsible/involved units	Comment/status
Identification			
Initial meeting with SUM	3.10.2022	GDK, SUM, consultant	Discuss initial PAP, who will be involved in the process, status for SUM international strategy and SUM procedure for programme approval.
Coordination and update meeting	Weekly	GDK, SUM, Consultant	By Teams
Briefing mail to embassies	12.10.2022	GDK, consultant	Heads-up on process and expected embassy involvement, including PAP
Prepare note with overview and analysis of existing portfolio (for identification note)	26.10.2022	Consultant	SSC project documents and progress reports. SSC Evaluation.
Clarify formats and documentary needs for Framework programme	27.10.2022 2-hour meeting	GDK, SUM, Consultant	Discuss deliverables based on consultant's proposed draft document template
Understand SSC role in relation to embassy priorities and national context	1.11 16.30 and 2.11 (whole day) 1-1½-hour meeting with 5 countries	GDK, SUM, Consultant Embassy management and SSC counsellor in China, Vietnam, India, Brazil, Mexico, SST, SDS, LMST, SSI	Including commercial agenda, development and diplomacy. Location: MFA Room 1ab (1.11) and M8 (2.11)
Consult commercial and health sector stakeholders / experts	9-11.11	GDK, Consultant	TC, DI, other industry association, research institutions
Experience and lessons learned from existing SSC projects *Discuss priority global health issues that SUM will address through MYNSAM 2.0*	16.11.2022 12.00 2-hour workshop	GDK, SUM including programme managers, SSC counsellors, consultant, SST, SDS, LMST, SSI	Names will be provided by SUM Location: MFA Room 1ab
Clarify/decide main issues for Identification Note	21.11.2022	GDK, consultant	
Prepare project summaries (existing projects)	Deadline 5.12.2022	SUM and SSC counsellors	Based on template provided by consultant
Review and streamlining of project summaries (Annex 1)	5-9.12.2022	Consultant	
Drafting Identification Note	21.11 - 5.12.2022	Consultant, SUM	
Comments to draft Identification Note	8.12.2022	GDK, SUM,	

Final Identification Note	12.12.2022	Consultant	
Formulation			
Initial discussion of theory of change and results framework	15.12.2022 2-hour workshop	GDK, SUM including programme managers, SST, SDS, LMST, SSI	Based on SUM core competences and other MYNSAM 2.0 ToC.
Internal hearing: interest in new project phases	15.12.22 – 23.12.22	SUM, SST, SDS, LMST, SSI	Internal hearing regarding new phases (wishes/interest)
Outline of new SSC project phases	5.1.2023 Meeting	GDK, SUM, consultant	Proposal by SUM
Theory of change discussion with embassies	9.1.2023 Joint session 2 video-meetings	GDK, SUM, SSC counsellors, Embassy management, consultant	Especially how to combine the development, commercial and diplomatic priorities
SUM input to Framework Programme Document	13.1.2023	SUM	Contents and format to be agreed
First draft FP document	31.1.2023	Consultant	
Internal discussion of first draft FP document	31.1.-7.2.2023	SUM, SST, SDS, LMST, SSI	
Comments to first draft FP document	9.2.2023	SUM and GDK	
Briefing of Minister for Health prior to Danida Programme Committee meeting	17-28.2.2023	SUM	Adjusted to PC meeting schedule
Submission of 2nd draft FP document to Programme Committee	17.2.2023	GDK	
Discuss governance, planning, monitoring, reporting and learning	21.2.2023	GDK, SUM, Consultant, SST, SDS, LMST, SSI	
Danida Programme Committee meeting	14.3. 2023	GDK, SUM	
Discuss PC recommendations	20.3.22	GDK, SUM, Consultant	
3rd draft FP document	30.3.2022	Consultant	
Discussion of third draft FP document	7.4. 2023	GDK, SUM (including programme managers), Consultant, embassies, SST, SDS, LMST, SSI	
3rd draft FP with amendments for appraisal	10.4.2023	Consultant	
Appraisal/quality assurance process			
Quality assurance: Appraisal	10.4-1.5.2023	ELQ	Consultant to prepare draft ToR for appraisal
Draft appraisal report	1.5.2022	ELQ	
Comments to appraisal report	5.5.2022	GDK, SUM, consultant, SST, SDS, LMST, SSI	
Final appraisal report	10.5.2022	ELQ	
4th draft FP Document based on appraisal recommendations	20.5.2023	Consultant	

Comments to 4th draft	27.5.2022	GDK, SUM, embassies, SST, SDS, LMST, SSI	
Minister for Health's approval of Framework Programme Document	30.5.2023	SUM	Adjusted to Council meeting schedule
Final FP document submitted to Council for Development Policy	2.6.2023		Adjusted to Council meeting schedule
Approval			
Meeting in Council for Development Policy	22.6.2023	GDK, SUM	To be adjusted to Council meeting schedule
Minister for Development Cooperation's approval of Framework Programme	August-September 2023	ELQ submits proposed Framework Agreements and minutes of CDP meeting	After Council for Development Policy meeting
Document for Finance Committee (Aktstykke), etc.	After the Minister's approval		Only if direct legal basis for the commitment is not in place at Finance Act
Initial actions following the Minister's approval			
Publish on Danida Transparency		*ELQ*	
Development of Draft Framework Agreements		*GDK*	*FRU*
Sign agreement(s)	*After Minister's approval*	*GDK*	
Register commitments	After agreement(s) are signed	GDK	

Annex 6: Examples of linkages and coordination with multilateral health programmes

Country	Organisation	Thematic area	Initiative	Link
China	WHO China	Regulation of pharmaceuticals	Strengthening China's medical products regulatory system	Strengthening China's medical products regulatory system (who.int)
WHO China has cooperated with National Medical Products Administration (NMPA) over a number of years to strengthen China's regulation of pharmaceuticals and thereby enhance the access of the Chinese people to safer and more innovative high-quality drugs. NMPA is also project partner in the SSC projects with the Danish Medicines Agency in relation to regulation of pharmaceuticals contributing to the same objectives.				
China	UNICEF China	Primary healthcare and NCG (mental health)	Improving adolescent health, especially mental health	Child Health and Development | UNICEF China
UNICEF works with the promotion of mental healthcare in China through a range of projects aiming at empowering young people to better manage stress related to their schooling. This s done through school-based programmes, on-line interventions and peer group support. Danish authorities work under the SSC project in primary healthcare and mental health, with emphasis on children and youth. The project explores the use of digital solutions in addressing mental health issues, including stigmatisation.				
Vietnam	World Bank	Primary Healthcare	The Investing and Innovating for Grassroots Health Service Delivery Project	Vietnam - Investing and Innovating for Grassroots Health Service Delivery Project (worldbank.org)
This World Bank funded project strengthens the capacity of local health stations in 13 provinces in relation to identifying and managing non-communicable diseases. The project furthermore supports political reforms aiming at improving the quality and the viability of local health services. There is a continuous dialogue between this project and the SSC project.				
Mexico	The pan-American Health Organisation (PAHO)	Primary health and NCD	PAHO promotes technical cooperation between countries and works in partnership with ministries of health and other government	México - OPS/OMS | Organización Panamericana de la Salud (paho.org)

Country	Organisation	Thematic area	Initiative	Link
			agencies, civil society organizations, other international agencies, universities, social security agencies, community groups, and other partners	
The Pan American Health Organization (PAHO) is the specialised international health agency for the Americas. It works with countries throughout the region to improve and protect people's health. PAHO engages in technical cooperation with its member countries to fight communicable and noncommunicable diseases and their causes, to strengthen health systems, and to respond to emergencies and disasters. PAHO works closely with the Mexican health authorities on a number of projects at federal and state level. The SSC project ensures a close consultation with PAHO on a number of relevant issues and there gas so far not been direct cooperation between the programmes.				
Mexico	UNOPS	Regulatory processes	Improve efficiency, transparency and value for money in the consolidated procurement of medicines and medical aid supplies for the period 2021-2024	UNOPS to support national medicine procurement in Mexico | UNOPS
In 2020, the Mexican government entered into an agreement with United Nations Office for Project Services (UNOPS) aiming to improve effectiveness, value for money and transparency in consolidated procurement of pharmaceuticals and medical devices. When the SSC project was prepared, UNOPS was therefore considered an important partner. Subsequently the Government of Mexico has cancelled the agreement with UNOPS and placed procurement with the Mexican health authorities.				
Brazil	PAHO/WHO	5 Focus areas: Public health, pharmaceutical products and medical devices	Country strategy 2022-2027: Brazil "Estratégia de Cooperação do País 2022-2027: Brasil"	Estratégia de Cooperação do País 2022-2027 - Brasil. Versão revisada (paho.org)
The Pan American Health Organization (PAHO) is the specialised international health agency for the Americas. It works with countries throughout the region to improve and protect people's health. The country programme in Brazil focus on: 1) Promote public health with particular focus on vulnerable groups: 2) Re-establish, improve and strengthen the post-Covid health services; 3) Strengthen the resilience of the health system and strengthen access for all; 4) Promote research innovation and technological knowledge, including in relation to pharma, vaccines and medtech.; 5) Strengthen participatory systems for prevention, preparedness, timely interventions and restoration in emergency and disaster situations. These areas are in large part also supported by the SSC.				

Country	Organisation	Thematic area	Initiative	Link
Of specific relevance is the recently agreed PAHO project aiming at identifying the needs and priorities in relation to the digital transformation of the Unified Health System of Brazil, which is closely related to the SSC project pillar 1.				
Brazil	Novo Nordisk	Primary healthcare and NCD	Cities Changing Diabetes	Cities Changing Diabetes
This international programme for prevention and management of type 2 diabetes is now initiated in the city of Curitiba with the possibility of expanding to other cities.				