Strategic Sector Cooperation in Health Between Denmark and Brazil, Phase II

Key results:
Improving healthcare through 1) better use of data including a digital transformation of the healthcare sector in Brazil and the establishment of a Brazilian Diagnostic Related Group (DRG) system, and 2) more efficient and transparent administrative processes on new pharmaceuticals. These are essential elements in ensuring better, faster and universal access to quality healthcare services and products.

Justification for support:
A rapidly aging population and a transition in terms of disease burden from predominantly infectious diseases to non-communicable diseases puts the Brazilian healthcare system under pressure. Despite efforts to reform the Brazilian healthcare system, challenges remain, namely in coordination of care, coverage of primary care, as well as access to medicines and to specialist and high-complexity care at secondary and tertiary level.

Phase I of the cooperation formed the political basis for developing a prototype of the DRG system in Brazil through examples proving the possible use of the system as well as essential preparations of data infrastructure. Moreover, phase I supported Brazil in enhancing and accelerating their management processes relating to approval of pharmaceutical products.

Phase II is divided in to two main pillars:
I) ensuring better, faster and universal access to quality healthcare services and products by supporting the development of more efficient healthcare management with the same resources, including by means of digitalisation and standards, and **II)** Improving healthcare management by facilitating more efficient and transparent approval processes considering the overall licensing principles of pharmaceuticals: quality, safety and efficacy.

The Danish Authorities can contribute with solid experience using digitalisation to improve efficient use of resources e.g. through the use of a DRG system as cost control to increase the activity at hospitals and reduce waiting lists. This will be even more essential in Brazil following the increased pressure on the health system following covid-19, which have hit the country hard. Moreover, Denmark has expertise in regulation of pharmaceuticals that ensure timely access to safe medicines for the Danish population.

Major risks and challenges:
The results will depend on the cooperation between the Danish and Brazilian stakeholders, political will, access to information and data, as well as the availability of relevant experts. Steering Committees are set to mitigate the risk of unfavourable conditions. Covid-19 may delay implementation of the project. To ensure progress a number of activities will be virtual.

File No.	2015-25181				
Country	Brazil				
Responsible Unit	GDI				
Sector	12110 - Health policy and administrative management				
Partner	Danish Ministry of Health				
DKK mill.	**2020**	**2021**	**2022**	**2023**	**Tot.**
Commitment	10				10
Projected ann. disb.	0.7	7.7	1.4	0.2	
Duration	2020-2023				
Previous grants	DKK 997,557 (Inception Phase); DKK 5,315, 029 (Phase I)				
Finance Act code	§06.38.02.14				
Head of unit	Rasmus Abildgaard Kristensen				
Desk officer	Signe Refstrup Skov				
Reviewed by CFO	YES: Christina Hedegård Hyttel				

Relevant SDGs *[Maximum 1 – highlight with grey]*

 No Poverty	 No Hunger	 Good Health, Wellbeing	 Quality Education	 Gender Equality	 Clean Water, Sanitation
 Affordable Clean Energy	 Decent Jobs, Econ. Growth	 Industry, Innovation, Infrastructure	 Reduced Inequalities	 Sustainable Cities, Communities	 Responsible Consumption & Production
 Climate Action	 Life below Water	 Life on Land	 Peace & Justice, strong Inst.	 Partnerships for Goals	

Strategic objectives:

The main objective of the project is to support the improvement of healthcare management in Brazil.

Justification for choice of partner:

The Danish partner was identified through a strategic match-making process in 2014 where Danish public competencies were matched with local demand. Under the SSC projects, the Danish partner typically works with its "sister organization". In Brazil, this is the Brazilian Ministry of Health and the Brazilian Health Surveillance Agency.

Summary:

A rapidly aging population as well as changes in disease patterns put the Brazilian health care system under pressure and calls for improvements of the current system. This project addresses the need for improved health care in Brazil through improved use of health data as well as more efficient and transparent approval processes for pharmaceuticals. The project is divided into two work streams: I) digitalisation and standards including the use of a Diagnostic Related Group system, and II) optimisation of the approval processes for pharmaceuticals.

Budget:

Personnel – Danish Authority	5.215.038
Reimbursable Costs for Danish Authority Staff	1.287.565
Activities, Including Capacity Development	2.318.601
Consultancies (max. 30% of grand total)	400.000
Unallocated funds (max 20% of grand total	750.354
Total DKK	**9,971,558**

MFA File No:
2015-25181

Project Document for Strategic Sector Co-operation in Health

between

Denmark and Brazil

General information	MFA File no. 2015-25181
Project Title	Strategic Sector Cooperation between Brazil and Denmark on supporting efficient healthcare management in Brazil – Phase 2
Partner Country	Brazil
Project duration	March 2020 – March 2023
Total budget (DKK)	9.971.558 DKK
Thematic focus	The SSC focus is two-folded: A Diagnostic Related Groups (DRG) System and Digital Transformation Regulation of pharmaceuticals and medical devices
Partner Public Authority **Contact person and contact details**	**Brazilian Ministry of Health (BMoH)** Tatianna Meireles de Alencar, Head of International Affairs Office (AISA) E-mail: aai@saude.gov.br / Phone: +55 61 3315-2813 or 2053 **Brazilian Health Surveillance Agency (ANVISA)** Laila Sofia Mouawad, Coordinator for Internacional Cooperation E-mail: Laila.Mouawad@anvisa.gov.br / Phone: +55 61 3462-5404
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Danish Embassy **Head of Representation** **Sector Counsellor**	**The Royal Danish Embassy in Brasilia** Nicolai Prytz, Danish Ambassador to Brazil Brit Borum Madsen, Health Counsellor, E-mail: brimad@um.dk / Phone: +55 (61) 99667-8275
Summary of background analysis and key strategic choices **(max 2 pages)**	***Main development challenges in the Brazilian healthcare sector*** As is the case for many healthcare systems all over the world, Brazil faces challenges due to a rapidly aging population and a transition in terms of disease burden from predominantly infectious diseases to non-communicable diseases (NCDs). Additionally, Brazil is also confronted with increasing treatment costs in combination with public budget constraints. This puts pressure on the public health sector (the Unified Health System, SUS) and its constitutional obligation to provide free and equal access to healthcare. A large, complex and decentralized healthcare

system needs structur to counter all of these challenges at the same time. Despite impressive results in the reform of the Brazilian healthcare system, challenges still remain, not least in relation to the coordination of care, coverage of primary care, accessing specialist and high-complexity care at secondary and tertiary level and medicine.

Hence, Brazil faces a persistent challenge to guarantee timely and good healthcare on an equal basis to everyone who needs to use the system. According to a 2018 research, 69.7% of the population depend exclusively on SUS, while the remaining 30.3% are covered by supplementary private health assistance. According to WHO, in 2017 government expenditure accounted for 41.9% of the total Health Expenditure in Brazil, while the private expenditure accounted for 58.1%. Additionally, out-of-pocket payments is still very high (27.5% in 2017), an indicator of the difficulties of citizens in gaining access to timely quality healthcare. More efficient healthcare management can contribute to better, faster and universal access to healthcare services and products in the public sector (SUS) with the same available resources.

Overall Strategic SSC Approach and Partner Intuitions

Denmark and Brazil share a similar strategic emphasis on improving healthcare management in order to achieve better quality healthcare and increased patient safety with the same resources.

Phase 2 of the Strategic Sector Cooperation (SSC) between Denmark and Brazil aims at ensuring better, faster and universal access to quality and coherent healthcare services and products by supporting the development of more efficient healthcare management in Brazil.

The SSC Phase 2 continues to encompass a two-fold approach to support more health for the same resources and is divided into two pillars;

PILLAR I is a cooperation between the Brazilian Ministry of Health (BMoH) and the Danish Health Data Authority (DHDA) and focuses on better use of health data to improve access to quality healthcare. Thematically, PILLAR I is divided into a continued cooperation on Diagnostic Related Group system[1] (DRG) – between BMoH and DHDA (work area A); and a new cooperation on Digital Transformation in Healthcare – between the IT Department of the Healthcare System under BMoH (DATASUS) and DHDA (work area B).

PILLAR II is a continued cooperation between the Brazilian Health Surveillance Agency (ANVISA) and the Danish Medicines Agency (DKMA) aiming at supporting more efficient, faster and transparent approval processes of pharmaceuticals and – as something new - medical devices.

Hence, the Brazilian partners of Phase 2 continues to be the Brazilian Ministry of Health (BMoH) and ANVISA; and the Danish Ministry of

[1] A DRG-system is a financial and administrative management tool based upon a grouping of patient in Diagnosis Related Groups (DRG-groups) and a calculation of the cost of treatment of patients in the DRG-groups. The DRG-system can be adjusted to create incentive structures to award health units for proper planning of e.g. patient pathways.

Health continues to be partner authority on the Danish side. Due to the new focus on Digital Transformation in healthcare relevant experts and external professional competencies, e.g. from MedCom and sundhed.dk, will also be involved in Phase 2.

MedCom is a publicly funded, non-profit association. MedCom's role is to contribute to the development, testing, dissemination and quality assurance of electronic communication and information in the healthcare sector in order to support continuity of care. MedCom is developing standards and profiles for the exchange of health data throughout the entire Danish health care sector.

Sundhed.dk is the Danish portal for the public healthcare services and enables citizens and health professionals to find information and communicate with the Danish healthcare service. The portal provides patient-centred digital services that enable access to the citizens' own data, general information about health and provides access – where relevant - to the Danish healthcare service. Danish Regions, KL - Local government Denmark (organisation representing the 98 Danish municipalities) and DMoH, finance sundhed.dk.

The expansion of SSC organizationally and in terms of volume and objectives, both within existing and new areas of cohesion, is an expression of close relationships and a successful first phase of mutual benefits.

In short,

- Phase 2 under PILLAR I will support BMoH in reviewing and developing a new Digital Health Strategy, including the development of a number of huge investments projects in a digital transformation of the healthcare sector in Brazil alongside the establishment of a Brazilian DRG system.

- Phase 2 under PILLAR II will support ANVISA in the implementation of a new strategic plan running from 2020-2023 (to be completed) with a special focus on improved and more agile case handling.

Please see the section below for more information about the link between SSC Phases 1 and 2.

Strategic cooperation areas to encounter main development challenges

PILLAR I: Improving healthcare by better use of data

Systematic and better use of health data, across all levels of governance, for planning, benchmarking, monitoring and financing purposes etc. is essential in order to achieve better access to quality healthcare services. More specifically, it supports coherent patient pathways, patient safety, efficient daily operations, and optimal long-term design of the different healthcare activities and processes.

However, the decentralized nature of SUS is reflected in and reproduced by a variety of different health information systems in Brazil. Thus a large number of non-interoperable health information systems exist, which do not support a national and common health data platform for

collecting and sharing data. On the contrary, the health data provided is 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.

Furthermore, SUS has a heterogeneous financing system based on the following payment methods: fee-for-service, bundled (package), bed days or historical budget. BMoH lacks data on the cost structure or production in SUS and while the three former payment methods rely on a historical cost table not reflecting current value, the latter is assigned a historical value reference. In short, BMoH lacks reliable information on healthcare production and the cost hereof.

To overcome these challenges, BMoH is seeking to develop and implement a Brazilian DRG system and to redefine the National Policy for Information and Informatics on Health (PNIIS) from 2015. Based on the positive results from SSC Phase 1, BMoH is seeking inspiration and support from Denmark in reviewing PNISS and developing a new National Digital Health Strategy **(work area B, outcome A and output A.2).**

Furthermore, based on a request from BMoH, DHDA will contribute to the nationwide digital transformation process through involvement in a number of major investments projects in Brazil which are all linked to the new Digital Health Strategy;

- A huge and ambitious national investment project establishing a national health data network across all three levels of healthcare (federal, state and municipal level) including all the health units hereof, that is both hospitals and primary care units **(Work area B, output A1 and A.3)**.
  - A pilot project in the state of Alagoas called "Conecte SUS" (in English "Connect SUS"). With this pilot project, BMoH seeks to computerize and digitize all health units with the objective of creating a unified health data network where managers and health professionals in all health care units will have access to patient data and records in order to improve the quality of services. Patients will also be provided access to own health data. The pilot project will provide the basis for a national implementation of the above-mentioned national health data network **(Work area B, output A.3)**.
  - A restructuring and strengthening of the national health data area. This includes the promotion of interoperability of the large number of health information systems throughout Brazil **(Phase 1 and work area B, output A.4)**. Moreover, it includes an improved data production by simplified and qualified health data through e.g. the introduction of a Brazilian Minimum Data Set **(Phase 1 and work area A, output A.1)**.This radical restructuring of health data is necessary and supportive of the development of the national health data network and accordingly for the Conecte SUS pilot project in Alagoas.

	This SSC Phase 2 between BMoH, DATASUS and DHDA builds upon the work and results of Phase 1. Firstly, SSC Phase 1 provided the political basis for decision. Through examples it proved the possibility of developing a Brazilian DRG system for nationwide implementation by making e.g. a DRG prototype within the speciality of cardiology, including the grouping logic, a cost database and tariffs calculation for DRG patient groups. Moreover, this development work on a DRG prototype showed the needed data basis, the possible use and potential benefits of a Brazilian DRG system. Secondly, SSC Phase 1 constituted comprehensive work on data infrastructure and processes focusing on the implementation, maintenance and operation of standards and terminologies in the Danish healthcare sector. Furthermore, SSC Phase 1 provided profound insight into the Brazilian and Danish data reporting systems and registries, identifying further steps needed in Brazil to support nationwide interoperability supportive both of the: - development of a Brazilian DRG system **(work area A);** and - new focus area of a digital transformation of the public unified health system in Brazil (SUS) emphasising the development of a national health data network etc. **(work area B).** In sum, the SSC collaboration between BMoH and DHDA during Phase 2 is a continuation of SSC Phase 1. **PILLAR II: Improving healthcare by more efficient and transparent administrative processes on new pharmaceuticals** Medicine is provided free of charge by SUS. Although access to medicine in Brazil is relatively high, challenges related to the availability of medicine and socioeconomic inequalities exist. Despite the fact that lower income families receive more medicine free of charge from government-funded sources than the wealthier families, 26 pct. of the medicines obtained by the bottom income quintile of the population are paid for from their own budget. Moreover, as SUS experiences lack of material and human resources, the medicines and treatments available are often based on older generation drugs with little access to new medicines. ANVISA has limited capacity to respond to an increased demand for pharmaceuticals. This has given rise to a substantial backlog on handling applications for authorisation of pharmaceuticals, posing long waiting times for approval of medicines and hence barriers for better and faster access to new and innovative pharmaceuticals for the population. On December 29, 2016, a law (Law 13.411/2016) allowed ANVISA to restructure its staff in order to speed up the analysis of registration process. At the same time, the law also established a deadline of 365 days to register new medicines. Since December 2016, the backlog has decreased immensely and the average time for approval of medicines in Brazil has been greatly improved. In numbers, ANVISA e.g. reduced the backlog of requests for new products awaiting approval in 2019 from 589 in December 2018 to 233

	in December 2019 and increased in the number of pharmaceutical products authorized; from 187 in 2017 to 375 in 2019 – a 100% increase in just three years. The SSC cooperation between ANVISA and the Danish Medicines Agency entered into force on December 21, 2016 and has supported ANVISA's efforts to enhance and accelerate management processes in line with abovementioned law. Hence, the SSC collaboration between ANVISA and the Danish Medicines Agency has been supportive of the positive improvements experienced by ANVISA. As there is a call for more efficient case handling in order to secure even better and faster access to new and innovative pharmaceuticals for the population, the cooperation activities during Phase 2 will build upon the abovementioned positive transition achieved during Phase 1 and focus on further improving approval processes around pharmaceuticals, pharmacovigilance and – as something new – also medical devises. ***Selected topics for SSC cooperation Phase 2*** **PILLAR I: Improving healthcare by better use of data** The Brazilian Ministry of Health (BMoH) and the Danish Ministry of Health (DMoH) have agreed that PILLAR I should aim at improving healthcare management through better use of health data. Within this framework, Danish support for two complementary areas of work have been identified. These are **work areas:** A. **A Brazilian DRG system**[2], including a focus on - use and operation of a minimum data set - health system registries for the running of a DRG system as well as wider use. B. **Digital transformation,** including support on development and/or implementation of - the Digital Health strategy for Brazil covering ➢ a Brazilian National Health Data Network ➢ national electronic prescriptions ➢ governance mechanism for interoperability standards ➢ a Brazilian Health Data Portal ➢ data analysis and data-driven management. Progress in the abovementioned areas has the potential to support equitable and universal access to quality healthcare and increase the sustainability of the health systems. Work area A and B are closely interlinked and the respective activities will continually be coordinated, as e.g. a platform serving a national health data network will also facilitate an introduction of a Brazilian DRG system etc.

[2] A DRG-system is a financial and administrative management tool based upon a grouping of patient in Diagnosis Related Groups (DRG-groups) and a calculation of the cost of treatment of patients in the DRG-groups. The DRG-system can be adjusted to create incentive structures to award health units for proper planning of e.g. patient pathways.

	PILLAR II: Improving healthcare by more efficient and transparent approval processes for pharmaceuticals and medical devises ANVISA and DMoH have agreed that PILLAR II should aim at improving healthcare management by facilitating more efficient and transparent approval processes considering the overall licensing principles of pharmaceuticals: quality, safety and efficacy. Innovative, efficient and transparent work processes and regulatory frameworks on pharmaceuticals and medical devices are essential for faster and uniform case handling of high quality to ensure faster and better access to innovative and essential pharmaceuticals and medical devices for the Brazilian population. Access to innovative and essential pharmaceuticals and medical devices improves treatment in general and can, more specifically, help alleviate a range of externalities associated with the increase in chronic health issues in Brazil. Within this framework, 8 main cooperation areas have been jointly identified by ANVISA and DKMA. These are: A. Agile case handling of clinical trials and handling of complex clinical trials; B. Pharmacovigilance reporting and monitoring; C. Handling of biosimilar medicine, in particular with a view to their traceability and monitoring post-marketing; D. Handling of medical devices in a regulatory setting and to exchange experiences on e.g. artificial intelligence and deep learning mechanisms; E. Various topics within Good Manufacturing Practice (GMP) to foster further inspiration in terms of their handling; F. Tools to combat illegal activities related to medicines; G. Lean manufacturing and QMS (Quality management systems); H. Laboratory control for post-marketing surveillance. Hence, Phase 2 will contribute to increased capacity building for more agile and more transparent approval processes and for some of the activities emphasis will also be dedicated to a risk-based approach in order to make best use of available resources. The joint objective is to inspire improved regulation and agile case handling, supporting e.g. revision of administrative procedures, guidelines, policies and cross-disciplinary thinking.
Linkages to UN Sustainable Development Goals	The SSC project contributes to the fulfilment of the following UN Sustainable Development Goals (SDG´s): SDG no. 3: Ensure healthy lives and promote well-being for all at all ages Specific targets: 3.8: Achieving universal health coverage, including financial risk protection, access to quality health essential health-care services to safe, effective, quality and affordable essential medicines and vaccines for all.

	3.B: Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.
Project Logic (Theory of Change) ½-1 page	Denmark and Brazil share the same general principle of public healthcare, which includes free and equal access for all citizens. The two countries also share a broad base of common values and interests in addressing current challenges. One common strategic goal shared by Brazil and Denmark is to promote health and wellbeing by providing access to timely and coherent quality care, including safe and effective pharmaceuticals and medical devises. In the margin of the SSC project, an additional instrument will be involved. This includes applying for scholarships under the Danida Fellowship Centre programme allowing representatives of the SSC partner institutions to participate in relevant short-term training courses in Denmark. **PILLAR I: Improving healthcare by better use of data** Better and systematic use of data for planning, benchmarking, monitoring and financing purposes etc. is key in improving access to quality healthcare as it contributes to cost efficiency and supports governance. More specifically, it supports coherent patient pathways across sectors and health providers, patient safety, efficient daily operations, and optimal long-term design of the different healthcare activities and processes. In short, advancing appropriate and better use of health data increase the sustainability of health systems and the accessibility, quality, efficiency and effectiveness of healthcare. DHDA has in-depth knowledge and expertise in collecting, sharing and using health data, leading to more effective, flexible and coordinated ways of organising healthcare and it is expected that cooperation on strategical digital health initiatives will be mutually beneficial. In both countries, there is a substantial unexploited potential for systematic use of the large amount of available health data to improve quality and productivity in healthcare. *Work area A: DRG* Moreover, based on Phase 1, BMoH has decided to initiate another major lighthouse project, namely an implementation of a Brazilian DRG system. Hence, the cooperation in this work area is supporting a national implementation project running in parallel with the SSC cooperation on DRG. More specifically, the objective of Phase II is to support the development and deployment of such a DRG system in Brazil in order to:

	➢ Improve health analysis (benchmarking, performance evaluation and productivity analysis) regarding health services carried out in the national territory: public, supplementary and private. ➢ Improve the financing model on specialized care and enable the introduction of a new payment logic to SUS providers based on DRG activities. In Denmark, DRG has contributed to a focus at state, regional and municipal level on - a high degree of cost control - a high cost-effectiveness - a high level of performance in relation to prioritized areas in health - a high quality of treatment - increase in activity and decrease in waiting times. Hence, the Danish DRG system has been used to increase the activity at the hospitals in order to reduce the waiting lists and to support the implementation of the patient rights of guaranteed short time for diagnostics and treatment. The increase in productivity countrywide has on average been 2,4 pct. annually for the entire period since the introduction of the Danish DRG system in 2002 As Brazil faces challenges by a biased billing system (contributing to a biased supply of healthcare services), poor cost control and little information about production and productivity, a DRG systems shows great potential in providing, among other things, activity increase and more effective use of resources. This, in turn, provides an increase in healthcare services and an improved access to healthcare. Based on the findings during Phase 1, it is BMoH's vision to implement a Brazilian DRG system to achieve transparency on cost and productivity and possible, to improve the financing and payment system of SUS. The specific outcomes and outputs of PILLAR I, work area A are listed below and further detailed in the corresponding work plan (annex 4.1A). *Work area B: Digital transformation* In the second half of 2019, BMoH has announced plans of releasing a new Digital Health strategy regarding a digital transformation of the health sector. In continuation hereof, BMoH has asked for guidance from DHDA regarding the development of a new strategy with a special focus on governance, handling of stakeholders etc. Included in this new Digital Health strategy is a lighthouse project within for the current Brazilian Government, namely the development of a National Health Data Network (a shared data platform) merging patient data (vaccines, care services performed, exams, hospitalizations, prescribed medicine etc.) across all levels of healthcare throughout Brazil; hospital care, primary care etc. and across municipal, state and federal level. Hence, connecting all public health units in the country, the Health Data Network promotes a Single Patient Record through timely exchange of information between all relevant healthcare professionals, allowing continuity of quality care, ensuring greater efficiency in the clinical care of citizens and reducing costs in health management.

The National Health Data Network will also contribute to better logistics, organized supply of healthcare services and improved healthcare management, as the patient data will be pushed back to clinical and administrative management at federal, state and municipal level. The huge investment by BMoH in this ambitious National Health Data Network will be led by a pilot project in the state of Alagoas. The model implemented in Alagoas will subsequently be launched throughout Brazil to the benefit of SUS and the citizens of Brazil.

The Danish experience on the "Digital Health Strategy 2018-2022: 'One secure and coherent health network for all' drawn up and endorsed by the government, KL and the Danish Regions will be shared with BMoH. Focus will be on the joint, cross-sectorial making of an operational strategy with the overall objective to strengthen digital collaboration on health for every citizen.

Furthermore, Denmark initiated the work on a National Service Platform (NSP) in 2008 and have since been working on the implementation, operation and further development of NSP. The platform has been a gradual development project where the platform is continuously developed with more and more services offered via the platform.

One of the services added to NSP is a Shared Medication Record, where every provider of healthcare dealing with the patients' medication has access to the same data regarding medication across the entire healthcare services. This has not only promoted efficiency, it has also enhanced quality and patient safety as many medication errors occur due to a lack of overview of the patients' total medication, especially when the patient moves across sectors.

The Danish pathway for setting up the NSP and lessons learned on how medication data can be shared in an efficient and secure way across the whole healthcare service, from hospital to primary care etc. as well as to the citizen himself, will be shared with BMoH/DATASUS. Furthermore, DHDA has been invited by the Brazilian Minister of Health to contribute to the pilot project in Alagoas.

Standards play a crucial role when IT solutions are developed and implemented. Denmark has a long tradition of working with standards in eHealth. The standards can be national but often international standards are adapted and put into play for nationwide use in Denmark. These experiences could prove beneficial in a Brazilian context and DHDA has been requested to provide guidance and share knowledge regarding how to work with standards in order to make them implementable as well as the sharing of knowledge regarding how such work can be governed.

The specific outcomes and outputs of PILLAR I, work area B are listed below and further detailed in the corresponding work plan (annex 4.1B).

PILLAR II: Improving healthcare by more efficient and transparent approval processes for pharmaceuticals and medical devices

The overall goal of PILLAR II is to continue to promote and further expand exchanges and cooperation in the field of pharmaceuticals and to include exchange of knowledge, challenges and lessons learned in the field of medical devises.

Based on Phase 1 and two high-level visits - one in Brasilia in February 2019 and one in Copenhagen in September 2019 – the above-mentioned 8 key areas (**cooperation area A to H**) were identified for cooperation during Phase 2. Within these focus areas, essential regulatory challenges will be addressed.

By sharing knowledge on medicines and medical devise regulation, ANVISA will further strengthen their regulatory capacity and deepen the knowledge of relevant Danish/European regulation and procedures.

DKMA has expertise in regulation of pharmaceuticals and efficient administrative processes that seek to optimize timely access for the patients to safe pharmaceuticals of high quality. DKMA has thorough experience with international cooperation and cooperates with authorities in several countries, both inside the European Union and outside.

The SSC project will assist and inspire ANVISA in optimising its process handling in various fields while also addressing mechanisms of a technical nature. To accommodate the request from ANVISA, PILLAR II will focus on supporting training and introducing suggestions of optimized processes related to complex regulatory areas in order for ANVISA to further strengthen the handling of pharmaceuticals and medical devices.

It is important to stress that the collaboration between ANVISA and DKMA is of mutual inspiration for regulatory handling of pharmaceuticals and medical devices. Both knowledge sharing and capacity building will contribute to ensuring timely access to innovative as well as affordable medicines and thereby contribute to improving public health.

The specific outcomes and outputs of PILLAR II are listed below and further detailed in the corresponding work plan (annex 4.2). For each output, except output A.1, a catalogue of key findings will be developed (output indicator). The catalogue will consist of concrete and reasoned ideas presented and developed in the various workshops for possible implementation to support a continued positive development. The ideas may take various forms depending on needs, conditions and objectives. For instance, each catalogue could consist of a suggestion to provide for a change to:
- an existing procedure/ implementation of a new procedure;
- new or altered legislation/guideline/approach;
- altered cross-disciplinary approaches;
- education of staff; or
- other initiatives that may support a positive change that strives for optimization of a given area.

	Methodology The strength of this government-to-government partnership is that the cooperation 1) is based on a direct dialogue between the relevant technical staff and health experts in both countries; and 2) enables sharing knowledge and experiences to build up capacity in public health authorities and develop solutions for the Brazilian context. Supporting changes in health planning and management in Brazil is not about applying Danish solutions directly in a Brazilian context but to: 1. Create room/space for mutual inspiration and dialogue; 2. To share new approaches to common challenges; and 3. Co-produce solutions applicable in the local context. The methodology of the SSC is multifaceted and consists of expert inputs to workshops and study tours, capacity building, development of guidelines, review of legal frameworks etc. In between face-to-face activities such as workshops, technical and strategical visits, training seminars etc. experts will work together via videoconference, e-mail etc. The methodology will be based on mutual respect and dialogue between Danish and Brazilian partner authorities and experts. This method ensures that the partnership creates valuable learnings and knowledge to the benefit of Brazil and Denmark. As DMoH, DHDA, DKMA and other involved Danish experts are not qualified to advise on initiatives in a Brazilian context (and vice versa), the role of the Danish partners is to identify and make available best practice in areas, where Denmark has knowledge and experiences that can be of inspiration to the Brazilian partners.
Main objective of SSC project	The SSC between Brazil and Denmark will aim to support the improvement of healthcare management in Brazil. This improvement is an essential element for ensuring better, faster and universal access to quality healthcare services and products. In this context BMoH and DMoH/DHDA have agreed to focus on improving healthcare management by better use of data (PILLAR I), while ANVISA and DMoH/DMA have agreed to focus on improving healthcare management by collaborating on more efficient and transparent approval processes of pharmaceuticals and medical devises (PILLAR II). **PILLAR I** The main objective of the SSC Phase 2 is to support: ➢ BMoH in making a Brazilian DRG system for nationwide implementation; and ➢ DATASUS in releasing a new Digital Health strategy regarding a digital transformation of the public healthcare sector. Focus will be on the joint, cross-sectorial making of an operational strategy supporting digital solutions, not least a shared health data network.

	PILLAR II The main objective of the SSC Phase 2 is to support ANVISA in the implementation of the new strategic plan running from 2020-2023 with a special focus on improved and more agile case handling. The new strategic plan is being completed at the time of writing, but the SSC activities have been aligned with the upcoming plan and its main objectives. Hence specific topics relevant to the new strategic plan has been selected and included in the cooperation as well as a more generic approach focusing on LEAN, good manufacturing practices and inspection hereof. The scope of the two components of the SSC is described in more detail below.
Outcome and output PILLAR I	
Work area A – see annex 4.1A	
Outcome A – PILLAR I **(work area A)**	To support BMoH in the development of a Brazilian DRG system which can be used by politicians, clinicians and administrators across all levels of governance (federal, state and municipal level to get more health out of the same money spent on health care
Output A.1	To contribute to the design of a strategical pathway, including a dialogue on related preparatory activities, for the development of a Brazilian DRG system
Outcome B – PILLAR I **(work area A)**	To improve governance and cross-sectorial stakeholder communication and involvement
Output B.1	To strengthen governance and implementation by focus on the dialogue with and education and involvement of external stakeholders (DRG ambassadors), such as selected project hospitals and the medical societies in Brazil
Outcome C – PILLAR I **(work area A)**	Capacity building regarding the development of a DRG toolbox; a grouping logic and a cost database
Output C.1	To develop and validate two prototypes of the Brazilian DRG-system within selected specialties. This includes the: - development and validation of two grouping logics and the validation hereof; - establishment of two corresponding cost databases using the available information from the selection of sample hospitals.
Work area B – see annex 4.1B	
Outcome A –PILLAR I **(work area B)**	To support BMoH in reviewing and developing its Digital Health Strategy, with a more pragmatic approach focused on the health issues to be addressed by technology, which will guide strategic decision making at all levels of government (federal, state and municipal)

Output A.1	Knowledge sharing focusing on technical details of Conecte SUS and the National Health Data Network
Output A.2	To contribute to the development of the Digital Health Strategy for Brazil
Output A.3	Support for implementation of national electronic prescription
Output A.4	Support for implementation of the governance mechanism for interoperability standards
Output A.5	Improve users' experience with the Brazilian Health Data Portal
PILLAR II - see annex 4.2	
Outcome A – PILLAR II	To contribute to the continuous development of agile, high-quality case-handling of complex clinical trials to support improved patient safety
Output A.1	Capacity building regarding agile case handling of clinical trials
Output A.2	To strengthen the handling of complex clinical trials (e.g. umbrella, basket and platform trials) and procedures for co-development of in-vitro diagnostics as these trials are increasingly difficult to deal with from a regulator's perspective
Outcome B – PILLAR II	To strengthen pharmacovigilance reporting in Brazil and the monitoring and analysis thereof
Output B.1	To contribute to increased pharmacovigilance reporting, including timely and agile analysis of the data
Outcome C – PILLAR II	To contribute to enhanced knowledge on the handling of biosimilar medicine in Brazil, in particular with a view to their traceability and monitoring post-marketing
Output C.1	To identify possible ways to handle biosimilar medicine in Brazil, in particular with a view to their traceability and monitoring post-marketing
Outcome D – PILLAR II	To contribute to mutual inspiration and development on the handling of medical devices in a regulatory setting and to exchange experiences with and views on future challenges in terms of the vastly growing and increasingly complex technology linked to medical devices such as artificial intelligence and deep learning mechanisms faced by regulators
Output D.1	Knowledge and experience exchange regarding the handling of medical devices, including how to master the challenges caused by the vastly growing and increasingly complex technology linked to medical devices such as artificial intelligence and deep learning mechanisms
Outcome E – PILLAR II	To contribute to the continuous development of coordination and planning of GMP related activities, in particular GMP inspections of manufacturing sites of medicines and training of GMP-inspectors
Output E.1	To Strengthen procedures on GMP inspections and related activities, including capacity building regarding various GMP topics in order to foster further inspiration in terms of their handling
Outcome F – PILLAR II	To contribute to the continued development of mechanisms that may inspire to further development of relevant tools to combat illegal activities related to medicines in Brazil

Output F.1	To propose mechanisms that may further develop relevant tools to combat illegal activities related to medicines in Brazil
Outcome G – PILLAR II	To provide insight into the concept and use of Lean and QMS (Quality management systems)
Output G.1	Capacity building regarding the potential of QMS and LEAN, the mechanisms and the added value it creates for the organisation and management
Outcome H – PILLAR II	To strengthen laboratory control for post-marketing surveillance
Output H.1	To support continued development of risk-based selection of medicinal products for post-marketing surveillance testing
Assumptions and risks	The specific outputs and activities outlined in the SSC project are subject to a number of risks and dependencies, which could result in a re-scoping of the project. Generally for all outputs, the results depend on the cooperation between Brazilian and Danish stakeholders, political will, access to information and the availability of the relevant experts and trainers for training in the Brazilian and Danish partner institutions and, where relevant, external institutions, consultancies, medical societies etc. Based on the Danish experiences, the success of the development and implementation of a DRG-system will to some extent depend on the involvement and ownership of health administrators, clinicians and other health professionals. It is therefore highly relevant that the medical society in Brazil or renowned and respected doctors related to the selected clinical specialties, will be included to ensure that the DRG grouping reflects the Brazilian clinical practice. In this context, it is equally important that one or two of the Danish clinicians who participated in the development and maintenance for the grouping system in Denmark contribute to grouping in close collaboration with the Brazilian colleagues. Furthermore, the deliverables and activities for the key building blocks of the development of a Brazilian DRG system for implementation also depends on: - A decision on which procedure-coding system Brazil wants to use, so one of the key building block for the DRG grouping logic is in place. - The implementation of a Brazilian Minimum Health Care Data Set (CMD) in 2020, when data will be needed on healthcare provided in Brazil in order to start the development of the clinical grouping logic. Specifically to the cooperation on digital transformation (PILLAR I, work area B), the cooperation outputs are to some extend depending on a number of political, administrative and technical decisions, practical possibilities and solutions which will, inherently, show along the development and implementation of the major investments project which PILLAR I, work area B is linked to. Hence, in order to secure continuous relevance of the SSC activities and the subsequent outputs for the major Brazilian investment projects, re-scoping of the SSC project

	and/or content changes might appear needed and will be managed accordingly to the needs arriving. In regards to pillar II, the key assumption is that knowledge exchanged can be used to develop concrete and current solutions where relevant in a Brazilian and Danish context, and therefore it is of importance that the SSC cooperation is maintained anchored at high-level in both Brazil and Denmark and continuously aligned with the upcoming new ANVISA strategy running from 2020 – 2023. If the abovementioned elements and assumptions are not met, the foundation of the collaboration is changed and the aim and direction of the project will have to be revised. In such case, challenges will be met by: • Taking up the specific challenges in a steering committee meeting in order to conclude on a way forward; • Initiate a critical dialogue on ways to overcome challenges and ensure that the relevance of the SSC-project to national health authorities in Brazil is maintained. If necessary, this can include a revision of the project.
Management set-up	Steering Committee Two parallel steering committees will be established: - A PILLAR I Steering Committee (SC PI) with participation from BMoH, DATASUS, DMoH, DHDA and the Danish Embassy. The SC PI covers both PILLAR I work area A and B. - A PILLAR II Steering Committee (SC PII) with participation from ANVISA, DMoH and DKMA and the Danish Embassy. Danish and Brazilian partner authorities appoints members of both steering committees at sufficient high level to enable mutually binding decisions. Terms of Reference (ToR) for respectively SC I and II will be outlined and approved at the first Steering Committee meetings. The two steering committees are independent committees, responsible for the progress and decisions on the PILLAR I and II projects. Both Steering Committees will meet annually (or according to needs) to decide on needed adjustments and changes to the work plans, provide policy guidance and share experience, knowledge and lessons learned. Two Chairmen (one from the Brazilian side and one from the Danish side) will be appointed at the first meeting in both SC I and II. These two Chairmen for each SC will take turns in chairing meetings in the steering committees. The meetings are primarily expected to be conducted via video conference, but whenever possible, the meetings will be coordinated during visits by DMoH/DHDA to Brazil or BMoH/DATASUS to Denmark

	(PILLAR I) or by DMoH/DKMA to Brazil or ANVISA to Denmark (PILLAR II). The SC PI secretariat tasks will be the shared responsibility of the DMoH project leader and the Sector Counsellor in collaboration with the DHDA project coordinator. The SC PII secretariat tasks will be the shared responsibility of the DMoH project leader and the Sector Counsellor in collaboration with the DKMA project coordinator.
Contributions from Danish Public Authority	Partner institution (Danish Ministry of Health) • Secure high-level commitment to a long-term partnership with the Brazilian partner institutions and other relevant authorities; • Build relationships with Brazilian partner authorities and other relevant stakeholders; • Appoint a project manager and ensure continuity in project management; • Ensure that the SSC project is in line with the overall strategic priorities of the Danish authorities and ensure high-level institutional commitment; • Provide overall management of the project progress, economy and human resources; • Financial management and settlement of accounts with the Ministry of Foreign Affairs of Denmark; • Participate in steering committee meetings. Co-organize steering committee meetings; • Monitor and evaluate the SSC project progress (i.e. in yearly progress reports provided by the DKMA and DHDA in cooperation with the Sector Counsellor); • Contribute to the practical arrangements and logistics for activities conducted in Denmark. Implementing partners (DHDA and DKMA) • Planning and coordination of and participation in SSC activities and responsible of continued dialogue, coordination and information sharing with Brazilian partner authorities in between SSC activities to ensure project progress; • Build relationship with partner authorities and other relevant stakeholders; • Appoint a project responsible who will coordinate activities on behalf of the implementing partner;

	• Prepare experts for their participation in the specific activities; • Identify relevant experts, services and institutions to participate in the described activities; • Prepare practical arrangements and logistics for activities; • Practical preparation of the experts (e.g. travel information); • Develop and readjust work plans and contribute to budget plans, including descriptions of targets/milestones and technical input as well as budget for planned activities; • Be part of the relevant steering committee, co-organize and participate in its meetings; • Contribute to the practical arrangements and logistics for activities conducted in Denmark. Other partners (The Danish Embassy to Brazil) • Host the Sector Counsellor; • Support the implementation of the SSC through the sector Counsellor by providing managerial and administrative support as needed to facilitate the process; • Participate in steering committee meetings; • Prepare practical arrangements and logistics for activities held in Brazil; • Host workshops, high-level dinners etc. Other partners (Sector Counsellor) • Facilitate and support the Danish public authority in the identification, development and implementation of the SSC project PILLAR I and II; • Contribute to the development and possible readjustment of the work plans to be agreed between the Brazilian and Danish partner institutions; • Facilitate and support project implementation through regular dialogue and coordination with Brazilian and Danish public authorities; • Participate in steering committee meetings. Co-organize steering committee meetings; • Act as the main contact point for the Brazilian partners supporting the implementation of the SSC-project; • Build up broad network and facilitate contacts;

	• Contribute to identification of scholarship opportunities in coordination with the Danish public authorities and the Danida Fellowship Centre (DFC).
Contributions from partner authority	• Ensure that the SSC project is in line with the overall strategic priorities of the Brazilian authorities; • Secure high-level commitment to a long-term partnership with the Danish partner institutions and other relevant authorities; • Participate in the steering committee meetings; • Appoint a coordinator for PILLAR I and II activities and other relevant bilateral dialogue; • Appoint project managers for PILLAR I work area A and B respectively as well as for the 8 different topics within PILLAR II who is available for professional dialogue on a regular basis; • Monitor the SSC project progress and related activities in a Brazilian context supportive of the aimed objective of the cooperation; • Identify relevant experts, services and institutions to participate in the described activities; • Prepare practical arrangements and logistics for activities conducted in Brazil.
Budget	9.971.558 DKK

This Project Document for Strategic Sector Cooperation in Health is issued and signed in two original copies in Portuguese and English, equally authentic. Authorised Signatures:

Signed on behalf of the Ministry of Health of the Federative Republic of Brazil

Signature:.....

Name: Eduardo Pazuello

Position: Ministro da Saúde

Date: 29/06/2020

Signed on behalf of the Danish Ministry of Health

Signature:.....

Name: Magnus Heunicke

Position: Minister for Health and Senior Citizens

Date: 4/8/2020

Signed on behalf of the Brazilian Health Surveillance Agency

Signature:.....

Name: ANTONIO BARRA TORRES

Position: PRESIDENT - DIRECTOR

Date: May, 13th, 2020

Antonio BARRA Torres
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Name: Magnus Heunicke

Position: Minister for Health and Senior Citizens

Date: 4/8/2020