Strategic Sector Cooperation between Denmark and Brazil on supporting efficient healthcare management in Brazil

December 2016

Acronyms and abbreviations

ANVISA	Brazilian Health Surveillance Agency
BMoH	Ministry of Health in Brazil
CONASEMS	National Council of Municipalities' Health Secretariats
CONASS	National Council of States' Health Secretariats
CONITEC	National Committee for Health Technology Incorporation
DKK	Danish Kroner
DHDA	Danish Health Data Authority
DMA	Danish Medicines Agency
DMoH	Danish Ministry of Health
DRG	Diagnosis Related Grouping system
ENAP	National School of Public Administration
GC	Growth Counsellor
HC	Health Counsellor
HDP	Health Data Programme
IBGE	Brazilian Institute of Geography and Statistics
ICT	Information and Communication Technology
IDB	Inter-American Development Bank
INCA	National Cancer Institute of Brazil
INT	International Affairs Unit, Danish Ministry of Health
G. Nova	Laboratory for Digitalisation and Innovation in Brazil
MFA	Ministry of Foreign Affairs of Denmark
MoU	Memorandum of Understanding
NCD	Non-communicable diseases
OECD	Organisation for Eco0nomic Co-operation and Development
PAHO	Pan American Health Organisation (Regional Office of the WHO)
PNIIS	National Policy for Information and Informatics on Health
PILLAR I	Better use of health data
PILLAR II	More efficient and transparent approval processes on pharmaceuticals

SAS	Secretary of Health Care (BMoH department)
SC	Steering Committee
SSC	Strategic sector cooperation
SSC Digital	SSC Digitalisation and Innovation
SOP	Standardized operation procedures
Sub-SCs	Sub Steering Committees
Sub-SC I	Sub Steering Committee in PILLAR I
Sub-SC II	Sub Steering Committee in PILLAR II
SUS	Unified Health System
ToR	Terms of Reference
WG	Working Group
WG-A	Working Group A
WG-B	Working Group B
WG-C	Working Group C

SSC Project – Project Proposal

Thematic focus	Denmark and Brazil share a similar strategic emphasis on improving healthcare management in order to achieve better quality healthcare with the same resources. *The Strategic Sector Cooperation (SSC) between Denmark and Brazil aims at ensuring better, faster and universal access to quality healthcare services and products by supporting the development of more efficient healthcare management in Brazil* . The SSC encompasses a two-fold approach and is divided into two pillars, PILLAR I and PILLAR II. **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, three complementary areas of work have been identified. These are: a. Health data and organisational structure b. DRG-system for selected clinical specialty [1] c. National Centre of Terminology Support within these areas will assist BMoH in the current process of developing an e-health strategy and will support the implementation of the National Policy for Information and Informatics on Health (PNIIS). The policy defines the principles to promote interoperability of health information systems and standardised data in order to enable a common national data repository, hence providing the basis for more efficient healthcare management. In continuation hereof, an improved health data platform will facilitate a possible introduction of a DRG-system. Better use of health data, including standardised terminology, 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. **PILLAR II: Improving healthcare by more efficient and transparent approval processes for pharmaceuticals** The Health Surveillance Agency in Brazil (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. This focus is in line with ANVISA's policy paper, the Strategic Plan 2016-2019, seeking to provide faster and better access to healthcare services and products for the Brazilian population.

[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.

	Innovative, efficient and transparent work processes and regulatory frameworks on pharmaceuticals are essential for faster approval times to ensure access to innovative pharmaceuticals for the Brazilian population. Access to innovative pharmaceuticals improves treatment in general and can, more specifically, help alleviate a range of externalities associated with the increase in chronic health issues in Brazil. This SSC addresses the UN Sustainable Development Goal 3, and in particular target 3.8 on achieving "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".
Summary of the preparation project	The purpose of the preparatory project phase was to identify relevant partners and area(s) of interest for cooperation within health that would benefit both Brazil and Denmark. As is the case for many healthcare systems all over the world, Brazil faces a number of challenges due to a rapidly aging population and a major 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 severe public budget cuts. 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. The large, complex and decentralized healthcare system is not structured to counter these challenges. Despite impressive results in the reform of the Brazilian healthcare system, challenges still remain, not least in relation to the coordination of care, gaps in coverage of primary care, barriers to accessing specialist and high-complexity care at secondary and tertiary level and shortages of medicine. During the last year experts from both Denmark and Brazil have engaged in identifying a relevant area for cooperation with support from the HC. In December 2015 a delegation from DMoH, the Danish Medicines Agency (DMA) and the Danish Health Data Authority (DHDA) visited health authorities at federal, state and municipal levels, health units etc. In February 2016 a study tour to Denmark by representatives from BMoH, the National Cancer Institute of Brazil (INCA), the Municipal Health Secretariat in Sao Paulo and the National Council of Health Secretariats (CONASS) took place, where the Brazilian delegation learned about the Danish healthcare system, expertise and solutions. In June 2016, two technical delegations, one consisting of experts from DMoH and DHDA, and the other with experts from DMA visited Brazil in order to prepare the content of the SSC and continue the dialogue on identifying key areas of cooperation, activities and output indicators for the SSC.
Background	Brazil is the fifth largest country in the world by geographical area counting approx. 200 million inhabitants. Brazil has a three-tier system of governance including a federal district, states (26 states) and municipalities (5.560 municipalities). The health system is structured in a similar way. Brazil faces a persistent challenge to guarantee timely and quality healthcare on an equal basis. Private share (out of pocket payments) of the total health

	expenditure is still very high (25 pct. in 2014), 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 quality healthcare services and products in the public sector (SUS) with the same available resources. Therefore, the SSC has a two-fold approach to the current efforts by BMoH and ANVISA to support more efficient healthcare management. **PILLAR I: Improving healthcare by better use of data** The decentralized nature of SUS is reflected in and reproduced by a variety of different health information systems in Brazil[2]. Thus a large number of non-interoperable health information systems exist that do not support coherent and coordinated patient care. This proliferation of fragmentised health information system reflects a historical absence of a national health data policy to enable a national health data platform for collecting and sharing health data. Despite the immense amount of health data produced by the various health data systems throughout Brazil, the structure and organisation of the systems have caused a number of systemic challenges, the main ones being: 1) poor quality of health data and lack of national standardized terminology serving as common reference within and between disciplines and health information systems, 2) a fragmentised production and high redundancy of heath data and 3) a biased billing system contributing to a biased supply of healthcare services. This indicates that 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. To overcome these challenges, BMoH is seeking to restructure and strengthen the national health data area, hence drawing inspiration from international models, standards and experiences. BMoH has already developed various e-health policies and strategies in cooperation with a number of external actors, the National Policy for Information and Informatics on Health (PNIIS) from 2015 being the main one. The objective of PNIIS is to define principles and guidelines for the public and private health stakeholders under SUS to promote interoperability of health information systems in Brazil and to strengthen the production of simplified and qualified health data in support of better healthcare management and planning at all three levels of governance. Two main objectives of BMoH are the establishment of a national health register and a National Centre for Terminology that will contribute to qualified clinical decision making and administrative management of SUS. The dialogue with BMoH has showed a wide range of possible areas of cooperation, and the scope of the initiatives has been narrowed down in accordance with 1) the requests of BMoH based on the most immediate challenges in the data health area, 2) the Danish competences and lesson

2 Health information systems refer to any system that captures, stores, manages or transmits information related to the health of individuals or the activities of organisations that work within the health sector.

	learned of DMoH and DHDA and 3) budget limits and available resources. Hence, PILLAR I will support BMoH in the implementation of selected areas of PNISS and in the development of a technical basis for a future decision to introduce a DRG-system in Brazil. **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. Among the administrative barriers to fast approval of new pharmaceuticals in Brazil, is worth mentioning the lack of standardised operation procedures for approval processes, unnecessary requirements for the regulated sector, lack of standardised criteria for analysis (risk assessment and clinical trials) and lack of internal communication between ANVISA departments. To address these challenges ANVISA has adopted a policy paper, the Strategic Plan 2016-2019, which has two overall objectives: 1. Increase the population's safe access to products and healthcare services subject to health regulation 2. Improve the regulatory framework for health. The Strategic Plan 2016-2019 contains 13 strategic projects of which the SSC contributes to the implementation of project 1 "Improvement of authorisation procedures of products subject to health regulation based on international best practice". The SSC project will therefore assist ANVISA in optimising its pre-market activities for faster approval times by supporting more innovative and transparent workflows and approval procedures. To accommodate the request from ANVISA, PILLAR II will focus on supporting training and the introduction of standardised processes related to 1) quality and 2) safety and efficacy.
Project description	With the initiation of the SSC, Brazil and Denmark take the bilateral cooperation between the countries an important step further. In 2014, a MoU was signed between ANVISA and DMA, encouraging bilateral cooperation in the field of health products and medicine administration in the form of information exchange. Later in 2014, a Charter of Intent was signed by the Ministers for Health of the two countries, expressing intentions in strengthening health systems in both countries by exploring opportunities for cooperation, including exchange of good practices,

research, Information and Communication Technologies and innovative solutions for sustainability of public health systems.

Scope of the 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, while ANVISA and DMoH/DMA have agreed to focus on improving healthcare management by collaborating on more efficient and transparent approval processes.

The scope of the two components of the SSC is described in more detail below.

PILLAR I: Improving healthcare by better use of data
Systematic use of data is key in improving access to quality healthcare, as it contributes to cost efficiency and supports the planning of coherent patient pathways. In Brazil, as in Denmark, there is an important potential in better use of data on quality, activity and economy at the different levels of the healthcare system.

Three complementary focus areas
To achieve the objective of PILLAR I and to guide and identify relevant activities three complementary areas of work have been identified as essential:

- Health data and organisational structures for health data management;
- DRG for selected clinical speciality (case mix system);
- National Centre of Terminology.

Progress in these areas can support the bridging of different models and levels of health information systems, increase supply and patient safety, and thereby improve coverage and access to coherent healthcare services.
A Health Data Programme (HDP) was established in 2015 in Denmark by DMoH, and within that same year DHDA was established. The main goal of HDP is to strengthen the basis for data-driven management in the Danish healthcare system.

The Danish DRG-system is managed by DHDA and has contributed to a high degree of cost control and cost-effectiveness, a high level of performance in priority areas and a high quality of care. A strategic focus on changing the incentive structures embedded in the DRG system by adding selected clinical quality measurements to the merely activity-based financing system of today has been included in the HDP.

DHDA operates a national centre for terminology which prepares and releases terminologies that serve as a common reference and tool for unambiguous communication within and across different disciplines. National standardized terminology is a fundamental element for interoperability across the healthcare system and based upon the

experiences of DHDA, the authority has initiated a strategy process to the further improve its work of terminology.

Within the framework of the SSC the Danish lessons learned will be made available to BMoH in order to facilitate a possible similar reinforced strategic work on national health data as a base for data-driven management in the Brazil healthcare system, including supporting organisational adjustments in BMoH. Likewise, the cooperation with BMoH will provide valuable input to the implementation of HDP and the strategic work on terminology in Denmark.

Working groups

To accomplish the tasks of the three complementary areas of work, two technical working groups (WG) will be established. The representatives in the WGs will be highly qualified technical experts with practical experience from Denmark and Brazil. The tasks of the two WGs are described in the following section.

Working Group A: Health data and DRG-system

Health data and organisational structures for health data management and the DRG-system (case mix system) are closely connected. Without an efficient way of collecting and handling the data, there will be no efficient and reliable DRG-system.

Building a comprehensive data platform for planning, benchmarking, monitoring and financing purposes etc. will include registration, processing, analysis and dissemination of health data on activity, economy and quality in primary and secondary healthcare sectors. The same information is needed for the development of the best possible DRG-system. To ensure that the different information can be combined in an efficient way for multiple purposes, including administrative and clinical management, DRG and financing etc., it is essential that all data is identically structured and available within the same data model. Hence, the collecting and handling of data for DRG purposes for selected clinical speciality will be used as a case study of how to build a comprehensive and efficient health data platform, and thereby contributing to BMoH´s effort to establish a national health register.

Working Group A (WG-A) will be responsible for outputs 1 and 2 that will involve activities to exchange knowledge on how data is registered locally, validated and compiled nationally, and processed and disseminated in the Brazilian and Danish health systems. Moreover, it will involve grouping activities, data cleaning and testing activities as well as calculation of tariffs for the selected clinical speciality.

Output 1 consists of written material describing the Danish approach to the national HDP and specific proposals on how to achieve the desired institutional set-up and organisational framework for data management, databased-tool for financing purposes and financing models in Brazil etc. Site visits, workshops and a high level meeting are also part of output 1.

Output 2 consists of a written manual of the content of a DRG-system and the development of a proposal for a test cost database including the calculation of DRG-tariffs on the DRG-groups within a selected clinical

	speciality. This will lead to a short report describing the possibilities of introducing a DRG payment system covering all parts of SUS, including the private units delivering contracted healthcare services to SUS. Site visits, workshops, a high level meeting and testing of a database, among others, will be conducted as part of output 2. Besides experts from DMoH, DHDA and BMoH, WG-A also involves other relevant experts and external professional competencies. 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, related to the selected clinical specialty, will be included to ensure that the DRG grouping reflects the Brazilian clinical practice. In this context, one of the Danish clinicians who participated in the development and maintenance for the grouping system in Denmark will contribute to grouping in close collaboration with the Brazilian colleagues. <u>Working Group B: National Centre of Terminology</u> WG-B is responsible for delivering output 3, which will be the development of a proposal for the establishment of a National Centre for Terminology in Brazil. The activities of WG-B involves exchange of knowledge on management of terminology in Brazil and Denmark and knowledge transfer in relation to the governance and management model of clinical and administrative terminologies adopted by Denmark and the benefits hereof to provide BMoH with a solid basis for a decision to implement a possible National Centre for Terminology in Brazil. **PILLAR II: Improving healthcare by more efficient and transparent administrative processes on pharmaceuticals** To achieve the objective of PILLAR II and to identify relevant activities two basic principles of licencing of medicines are essential: 1) quality and 2) safety and efficacy. More specifically, the SSC-project will support collaboration between Danish and Brazilian experts leading to more efficient regulatory processes for the approval of pharmaceuticals. Through the exchange of knowledge and expertise within certain fields of authorisation of medicines and through the elaboration of standardized operation procedures (SOP) more efficient processes can be achieved in the area of for example assessment of API dossiers[3] on the active ingredients and SOP for quality documentation in relation to clinical trials etc. Within the framework of this SSC Danish expertise and experience will be made available by DMA to ANVISA in order to build up in-house capacity on requirements, quality, efficacy and safety assessments and to introduce more efficient, standardized work processes. The aims will be to improve transparency and quality of authorization processes and reduce approval

[3] API dossier is the complete documentation on the active ingredient required for the approval process.

time to facilitate faster access to the market and hence, to provide faster access to innovative pharmaceuticals for the Brazilian population.

As part of the SSC on Digitalisation and Innovation (SSC Digital) between Brazil and Denmark, The Danish MindLab will assist the Brazilian Government and the National School of Public Administration (ENAP) in developing a Laboratory for Digitalisation and Innovation in Brazil (G. Nova). Within the framework of this new laboratory a project named "Speed up Business" will look at digitalisation and more efficient and innovative work processes. ANVISA has requested support from G. Nova in a process leading to a possible redesign of their API assessment flow process.

The collaboration between ANVISA and G. Nova will be conducted outside the scope of the Health SSC-project. However, elements of the Health SSC-project, including a review of the Danish flow process for assessment of API-dossier focusing on improving the quality of assessments and reducing the time used, will provide a technical basis for a possible cooperation between ANVISA and G. Nova with the support of MindLab within the framework of SSC Digital.

Hence facilitation by G. Nova of an ANVISA project on a redesign of the API assessment flow process will be agreed upon by ANVISA and the Steering Committee of SSC Digital. The use of facilitators in G. Nova and any other activities to be carried out between ANVISA and G. Nova, the expected outputs and all related costs will be the responsibility of SSC Digital.

SSC Health and SSC Digital will keep each other informed about possible additional areas of synergy between the two SSC projects.

<u>Working Group C: Pharmaceuticals</u>
WG-C is responsible for outputs 4 – 7. The number of outputs reflects the differences in professional expertise and in requirements of documentation and assessments between different types of medicinal products.

Outputs 4 – 6 mainly involves the developing of drafts lists for ANVISA SOPs and guidelines for:

- Requirements for and assessment of active pharmaceutical ingredients (API-dossiers) (output 4);
- Quality documentation requirements and assessment for radiopharmaceuticals (output 5);
- Quality documentation requirements and assessment for biologicals and biosimilar (output 6).

Output 7 involves the development of a draft list of points for an internal SOP for:

- Quality documentation in clinical trials and efficacy assessment (output 7).

All tasks and responsibilities are described in more detail in the section "Management set-up".

Purpose, results, outputs & indicators	The purpose of the SSC project is to support efficient healthcare management in Brazil. Improving healthcare management in Brazil will be an essential element in ensuring faster and universal access to quality healthcare services and products. Result, output indicators, outputs and activities are elaborated on below.
Objectives	The objective of the SSC project is two-fold and divided into two pillars, PILLAR I and PILLAR II: **PILLAR I** will support BMoH in the implementation of PNIIS and in providing the basis for a possible introduction of a DRG-system in Brazil to contribute to improved access to quality healthcare services by better use of health data. *PILLAR I is pursued through three complementary areas of work: 1) health data and organisational structures for health data management, 2) DRG-system, and 3) national centre of terminology.* **PILLAR II** will contribute to ensuring faster and better access to pharmaceuticals by more efficient and transparent approval processes in line with the ANVISA Strategic Plan 2016-2019. *PILLAR II is pursued by supporting better work processes based on the basic principles of 1) quality and 2) safety and efficacy.* These are all areas where Danish health authorities and other partners have relevant competences and experiences and where there is potential for building a strong, equal and lasting partnership between Brazil and Denmark.
Result indicator	Four overall result indicators are relevant: • Deliverables in the form of a technical document outlining a proposal for a data and organizational framework for data management using the data needed for building a DRG system as a case study, including concrete proposals on how the results can be implemented. • The development of a prototype of a cost database and calculation of DRG-tariffs for selected DRG-groups and a report on a possible introduction of a general DRG-system in Brazil. • The development of a proposal for the establishment of a National Centre for Terminology in Brazil. • Deliverables in the form of: - A draft list of requirements for submission of active pharmaceutical ingredients (API-dossiers); - A draft list of items to be changed in ANVISA SOP on assessment of radiopharmaceutical quality-dossier - A draft list of points for an internal new ANVISA SOP on insulin, filgrastim and extrapolations of indications;

	- A draft list of points for two revised ANVISA guidelines on assessment of quality documentation in relation to clinical trials phase 1-3: ➢ Synthetic and semisynthetic medicinal products ➢ Biological medicinal products; - A draft list of points for internal ANVISA SOP on main requirements in efficacy documentation and assessments in oncology field for early advice for companies. The result indicators under PILLAR II in the form of draft lists will provide the technical basis for ANVISA to make their final versions of new ANVISA SOPs and guidelines. The result indicators under PILLAR I and II will be verified through: • Yearly SSC reports; • Progress reports half yearly before each Sub-SC I and II meetings; • Minutes from the Steering Committee, Sub-SC I and II and the WGs technical meetings; • Booklet, overview and report based on Danish experiences relevant for the organisational and technical restructuring of the health data area linked to data needed for a DRG-system; • Completion of a test cost database and a report on the possible introduction of a DRG-system in Brazil; • 1 draft list of requirements for submission of API-dossiers, 3 drafts lists for ANVISA SOP's and 2 draft lists for external guidelines; • Study tours, training seminars and workshop reports and participant evaluations.
Output 1	**Knowledge and experience exchange regarding a roadmap for developing an organisational platform and tools for better use of health data**
Output 1.1 indicator	Development of a booklet in English describing the Danish approach to the establishment of a national Health Data Program
Output 1.2 indicator	10 days site visit in Brazil to follow the data from registration to data warehouse, processing, analysing and disseminating (coordinated with the DRG activity output 2.2)
Output 1.3 indicator	One week workshop in Denmark for 3 people preparing a high level meeting (coordinated with the DRG activity output 2.5)
Output 1.4 indicator	3 days high-level meeting in Brazil (coordinated with the DRG activity output 2.6)
Output 1.5 indicator	One week workshop in Brazil preparing the implementation of the decisions from the high-level meeting (coordinated with the DRG activity 2.7)
Output 2	**Knowledge and experience exchange on a possible introduction of the DRG-system in Brazil**
Output 2.1 indicator	Develop an overview of the content of a DRG-system
Output 2.2 indicator	10 days site visit in Brazil to follow the data from registration to data warehouse, processing, analysing and dissemination (coordinated with the health data activity output 1.2)

Output 2.3 indicator	Two weeks technical visit in Brazil. Development of a prototype Brazilian DRG-grouper for a selected patient groups within a selected clinical specialty
Output 2.4 indicator	One week technical visit in Brazil. Grouping of patients in selected hospitals within the chosen specialisation in Brazil
Output 2.5 indicator	One week workshop in Denmark for 3 people preparing a high-level meeting (coordinated with the data-activity 1.3)
Output 2.6 indicator	3 days high-level meeting in Brazil (coordinated with the data-activity 1.4)
Output 2.7 indicator	One week technical visit in Brazil as a follow-up from the high-level meeting and for preparation of a test cost database (coordinated with health data activity 1.5)
Output 2.8 indicator	One week technical visit in Brazil. Development of a test cost database
Output 2.9 indicator	Development of a report on a possible introduction for a implementation of a general DRG system in Brazil
Output 2.10 indicator	Three days one site visit to Brazil
Output 3	**Exchange of knowledge on the process of implementing a terminology management model in Brazil**
Output 3.1 indicator	Detailed material developed describing Brazil's strategy for a National Centre for Terminology
Output 3.2 indicator	Detailed material developed describing the governance and management model of clinical and administrative terminologies in Denmark
Output 3.3 indicator	One week technical visit to Denmark for a group of 5 people to monitor the Danish work processes
Output 3.4 indicator	One week technical visit to Brazil to develop an implementation proposal for a National Centre for Terminology in Brazil and prepare a high-level meeting in Brazil
Output 3.5 indicator	3 days high-level meeting in Brazil to present the proposal for the establishment of a National Centre for Terminology in Brazil
Output 3.6 indicator	Development of a status report on the results of the activities proposed for the implementation of a National Centre for Terminology in Brazil
Output 4	**Knowledge and experience exchange regarding requirements for and assessment of Active Pharmaceutical Ingredients dossiers (API-dossiers)**
Output 4.1 indicator	4-day workshop in Brazil to develop a draft list of requirements for submission of API-dossier (legal framework and guidelines)
Output 4.2 indicator	4 hours teleconference
Output 5	**Knowledge and experience exchange regarding quality documentation and assessment for radiopharmaceuticals**
Output 5.1 indicator	3-day workshop in Brazil to develop a draft list of items to be changed in ANVISA SOP on assessment of radiopharmaceutical quality-dossiers
Output 5.2 indicator	4 hours teleconference
Output 5.3 indicator	3 days field visit in Denmark for three persons at radiopharmaceutical laboratory (DMA) and production facility (either hospital or Risø)
Output 5.4 indicator	4 hours teleconference

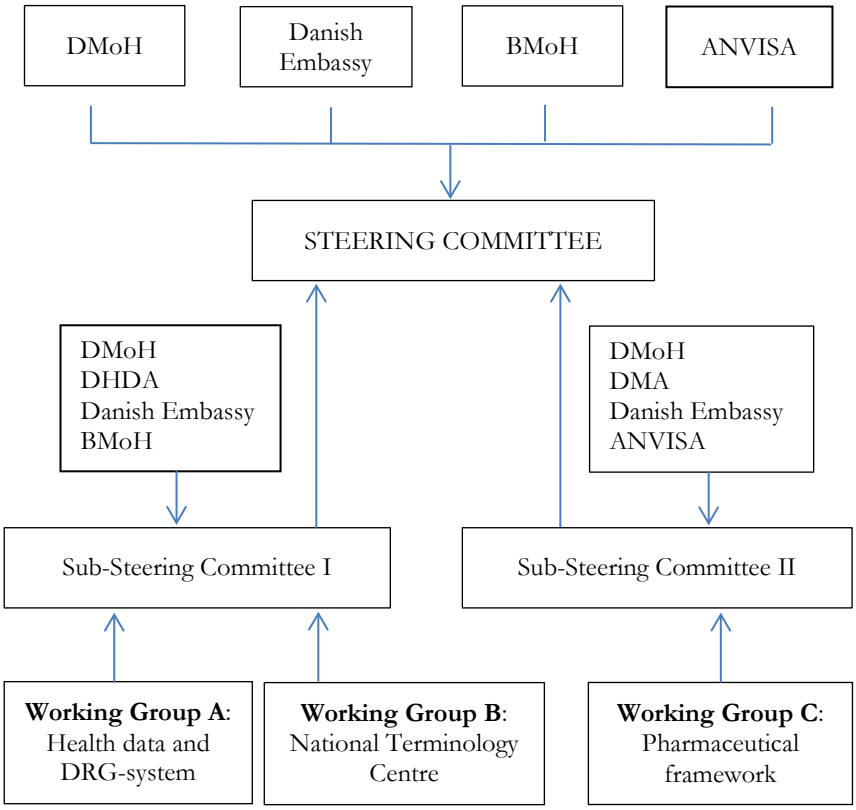
Output 6	**Knowledge and experience exchange regarding documentation, assessment and extrapolation of indications for biological and biosimilar medicinal products + Quality documentation in clinical trials (both biological and chemical medicinal products)**
Output 6.1 A + B indicator	5-day workshop in Brazil to develop: 1. A draft list of points for an internal new SOP on insulin, filgrastim and extrapolations of indications (6.1.A); 2. Two draft lists of points for internal new ANVISA SOPs on assessment of quality documentation in relation to clinical trials phase 1-3 for synthetic and semisynthetic medicinal products as well as biological medicinal products (6.1.B).
Output 6.2 indicator	6 hours teleconference (2 x 3 hours)
Output 7	**Knowledge and experience exchange regarding efficacy documentation and assessment in the oncology field**
Output 7.1 indicator	2 day workshop in Brazil to develop a draft list of points for an internal ANVISA SOP on main requirements in efficacy documentation and assessment in oncology field for early advice for companies.
Output 7.2 indicator	2-day workshop in Brazil
Activities	It might be relevant to adjust the activities for 2017-2019 depending on the progress of the SSC project.
Management set-up	A key element in the SSC is the identification of the relevant partners on both sides who have the necessary mandate, personnel and technical insights within the two components of the SSC. The field of responsibility and the institutional set-up of the civil service in Denmark do not correspond to the Brazilian institutional set-up. In Denmark, DMoH is in charge of the over-all regulatory and financial framework for the healthcare system, including health insurance and pharmaceuticals. In Brazil, these functions are divided between BMoH, ANVISA and other state-owned agencies. Hence, there exists no single counterpart to DMoH corresponding to the development challenges addressed by the SSC as requested by the federal health authorities in Brazil. Whereas BMoH is identified as the relevant counterpart to DMoH in PILLAR I, ANVISA is identified as the relevant counterpart to DMoH in PILLAR II. As PILLAR I and PILLAR II of the SSC are thematically interconnected and contribute to the same overall purpose, one overall Steering Committee (SC) will be established with two Sub Steering Committees (Sub-SCs). *Steering Committee* The Steering Committee (SC) will decide on possible budget reallocations between PILLAR I and PILLAR II based on recommendations from the Sub-SCs (Sub-SC I and Sub-SC II). All other decisions will be assigned to the two Sub-SCs.

The SC, which consists of members from DMoH, the Embassy, BMoH and ANVISA, will meet for a start-up meeting in Q4 2016. Additional meetings can be called upon request by the two sub-SCs.

Terms of Reference (ToR) for the SC will be developed before and approved during the first meeting of the SC. Before each subsequent meeting of the SC, the Sub-SCs will inform about the progress through progress reports made by the WGs.

A secretariat for the SC will be established. It is the responsibility of the secretariat to organise the meetings in SC, prepare the agendas and submit minutes.

The management set-up for the SSC Steering Committee, Sub Steering Committees and related Working Groups is illustrated as follows:



Sub-Steering Committees

Sub-SC I and Sub-SC II are independent committees, responsible for the progress and decisions on the project and activities within PILLAR I and PILLAR II, respectively. Both Sub-SCs will meet biannually to decide on needed adjustments, changes to the annual work plan and budget as well as to approve the progress reports of the WGs.

It is the role of the Sub-SCs to approve annual work plans and budgets and decide on the allocation of personnel, changes in scope and timing, budget reallocation within each pillar, and thereby provide overall project

	management based on ownership. Additionally, it is the task of the Sub-SCs to approve annual and final reporting and to ensure a common understanding of the purpose and approach towards the project. Further areas of work within the allocated budget frame may be added by the Sub-SCs. Sub-SC I will receive progress reports prepared by WG-A and WG-B before each meeting in Sub-SC I, while Sub-SC II receives progress reports prepared by WG-C before each Sub-SC-II meeting takes place. ToR for Sub-SC I and Sub-SC II will be developed before the first Sub-SC meetings take place and approved during the first meetings. ToR for expert input from consultants will be agreed upon during the meetings in the Sub-SCs or in email procedures agreed upon. A secretariat for each of the Sub-SCs will be established. It is the responsibility of the secretariats to draft the progress reports of the WG's and to organise the meetings in Sub-SC I and Sub-SC II, prepare the agendas and submit minutes. A chairman for each of the Sub-SCs will be appointed prior to the first meeting. <u>Sub-Steering Committee I</u> Sub-SC I consists of members from DMoH, DHDA, BMoH and the Danish Embassy. Observers are representatives from WG-A and WG-B. Each WG will prepare and present progress reports to the Sub-SC I and other technical briefings as requested by the Sub-SC I. The meetings are expected to be held via video conference, but whenever possible the meetings will be coordinated during visits by DMoH/DHDA in Brazil and by BMoH in Denmark. The Sub-SC I secretariat will be the responsibility of the embassy. <u>Sub-Steering Committee II</u> Sub-SC II consists of members from DMoH, DMA, ANVISA and the Danish Embassy. Observers are representatives from WG-C. The meetings are expected to be held via video conference, but whenever possible the meetings will be coordinated during visits by DMoH/DMA to Brazil and by ANVISA to Denmark. The preparation of the progress reports to be presented to the Sub-SC II and other technical briefings as requested by the Sub-SC II will be a joint responsibility by the HC, WG-C and DMoH. The products under output 4, respectively a draft list of requirements for submission of API-dossiers (legal and guidelines) and a final SOP on assessment of API-dossiers will be provided for the Steering Committee under SSC Digital. The Sub-SC II secretariat will be the responsibility of the embassy. Members of the SC, Sub-SC I and Sub-SC II include representatives from DMoH, DHDA, DMA, BMoH, ANVISA and the Danish Embassy.

	WG-A, WG-B and WG-C: The members of the technical WG-A and WG-B are observers in Sub-SC I, whereas the members of the technical WG-C function as observers in Sub-SC II. WG-A and WG-B are responsible for delivering outputs 1+2 and output 3 respectively, while WG-C are responsible for delivering output 4 to 7. As the activities and related output under PILLAR I are accumulation over a three year period, WG-A and WG-B will be affiliated to a Danish project manager, who, together with its Brazilian counterpart, will secure professional and management consistently in the activities of PILLAR I. The Danish project manager will be responsible for: - Coordinating activities between the WG members in Denmark and Brazil; - Reporting the status of the activities to Sub-SC I through progress reports, seminar and workshop reports and participant evaluations; - Ongoing contact to DMoH and HC; - Preparing the annual work and budget plans including targets/milestones, major activities and a plan for technical input and budget for the expected activities together with DMoH and HC; - Providing input for the progress reports. Additionally to the Danish project manager, WG-A and WG-B will be affiliated to a Brazilian counterpart. As there is envisaged a substantial synergy between the activities of WG-A and WG-B, strong coordination between the project managers for these two WGs is important. It is therefore considered a possibility to choose one project manager to be in charge of both WGs. Project Managers of the WG-A and WG-B include representatives from BMoH and DHDA.
Justification of proposed methodology, activities and input in relation to expected results (simple theory of change)	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. In relation to PILLAR I, 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. However, 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. Both Denmark and Brasil have developed strategies for better use of health data and it is expected that cooperation on their implementation will be mutually beneficial. Moreover, Denmark is one of the 16 countries in the world employing a DRG-system for measuring productivity, setting tariffs for basic and highly specialised care, activity based financing and daily decision making etc.

In terms of PILLAR II, DMA has expertise in pharmaceutical law and efficient administration processes providing fast access for the patients to safe pharmaceuticals of high quality. DMA has thorough experience with international cooperation and cooperate with several countries, both inside the European Union and outside.

The strength of this government-to-government partnership is that the cooperation 1) is based on a direct dialogue between the relevant technicians and health experts in both countries and 2) is about sharing knowledge and experiences building up capacity in public health authorities for helping enabling solutions for the Brazilian context.

The SSC will address some elements of PNIIS and the Strategic Plan 2016-2019 as requested by the Brazilian partners and is designed to support the implementation of these elements. 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 for inspiration and new ways of approaching common challenges
2. Create forums for dialogue and exchange of knowledge and experiences
3. Co-produce solutions applicable in the local context.

Methodology
The methodology of the SSC consists of expert inputs to workshops and study tours, preparation of cost databases, guidelines, review of legal frameworks etc. In between workshops, technical visits, training seminars and study tours 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 for the benefit of Brazil and Denmark.

As DMoH, DHDA, DMA 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.

Risks and dependencies
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.

Specifically, the deliverables and activities related to output 1 and output 2 are subject to a number of preconditions. Particularly the scope of these

	outputs depends on the possibility of a profound insight on how data is registered locally, validated and assembled nationally and processed and disseminated throughout the Brazilian health information systems. Moreover, the deliverables and activities related to output 2, e.g. the development of a prototype for a cost database and a rapport of the possibilities of introducing a DRG-system in Brazil also depends on the availability of the key expertise in Denmark with in-depth knowledge on the development of the Danish DRG-system and the commitment of the relevant medical societies in Brazil and Denmark.
Environmental, gender and social impacts – and improvements to good governance	The overall observed development challenges that the SSC project is responding to are related to human rights and democracy, improvements to good governance, social impact and general economic development. Good health information systems, improved governmental tools and an economic incentive structure in Brazil benefit citizens, patients and health care professionals: • It leads to more effective and transparent planning, more productivity and better distribution of resources; • It leads to more effective and flexible ways of organising treatment, leading to improved quality and safety in treatment and care; • It enables more individualised treatment by providing historical patient data and coherent patient pathways; • It leads to better management for developing, monitoring and evaluation of public health policies. The outcome of the SSC is expected to affect the management and performance of SUS positively. As free and equal access to SUS and social participation in the planning hereof is a constitutional right for all citizens in Brazil, improved performance and management of SUS will be positively related to human rights and democracy in Brazil. Better and more efficient healthcare services and products are essential to prosperity and human development in Brazil. Hence, the SSC project is believed to have a direct positive social and economic impact on the Brazilian population, increasing access to healthcare services and pharmaceuticals, thereby limiting the need for out-of-pocket payment for pharmaceuticals and decreasing social inequality. The poorest part of the population is the most affected by the gap in coverage of healthcare and lack of access to free pharmaceuticals, where high out-of-pocket payments are a main obstacle for equal access to quality healthcare services. The activities in the project are gender neutral.