HEALTH SECTOR COOPERATION BETWEEN BRAZIL & DENMARK,
Annual report for 2019

Danish Authorities in International Cooperation

Project description
In 2019, the health sector cooperation between Denmark and Brazil focused on preparing the extension of the Strategic Sector Cooperation (SSC) into its second phase. The two pillars of the second phase (2020-2023) aim at ensuring better, faster and universal access to quality healthcare services and products by supporting the development of more efficient healthcare management in Brazil.

**PILLAR I** is a cooperation between the Danish Health Data Authority (DHDA) and the Brazilian Ministry of Health (BMoH) and focuses on better use of health data to improve efficiency, access to quality healthcare, patient safety and coherent patient pathways etc. More specifically, DHDA will contribute to an ambitious nationwide digital health transformation through involvement in a number of significant investment projects, including the implementation of a Brazilian National Health Data Network and a Health Data Portal, including national electronic prescriptions etc.

**PILLAR II** constitutes a cooperation between the Danish Medicines Agency (DKMA) and Brazilian Health Surveillance Agency (ANVISA) and aims at supporting more efficient, faster and transparent processes around pharmaceuticals and medical devices.

The cooperation between DKMA and ANVISA will be scaled up to enable an expansion of the cooperation on pharmaceuticals, but also the inclusion of medical devices. Focus will be on agile case handling of high quality in various areas of the product lifecycle as well as on LEAN and Quality management systems (QMS). The cooperation will thereby inspire to both improved work processes and regulatory frameworks.

In sum, the Danish partners positively influence strategic decisions, reform initiatives and major change processes in BMoH and ANVISA thereby supporting improved framework conditions for pharmaceuticals as well as eHealth solutions on the Brazilian market.

**Key activities in year 2019**
- Continued capacity building on more efficient, faster and transparent processes around pharmaceuticals.
- Four high-level visits in 2019 (two in Brazil and two in Denmark) to design the second phase of the SSC and align it with new political and strategic priorities.
- The University of Copenhagen received a development research grant in December from the Danida Fellowship Centre (DFC) to run a shared Danish–Brazilian research project, “One Health - Strengthening Health Care Management”.

**Main achievements and lessons learned in 2019**
DKMA has throughout the first phase (2016-2020) supported ANVISA in faster and more agile case handling through capacity building related to revision of administrative and work procedures, guidelines, policies and regulations. Since the establishment of the SSC cooperation, ANVISA has e.g.
- reduced the backlog of requests for new products awaiting approval in 2019 from 589 in December 2018 to 233 in December 2019,
- doubled the number of pharmaceutical products authorized from 187 in 2017 to 375 in 2019,
- reduced the analysis period for e.g. approval of new medicines from 407 days from before the SSC collaboration was established in December 2016 to 226 days in 2018.

Three Danish companies have been included on a contractual basis in a shared Danish – Brazilian research project,”Optimizing Brazilian Health Care with Telemedicine”. This bilateral research project is based on a development research grant from the DFC (2018 call) and is run by the University of Copenhagen.

**Status:** Strategic Sector Cooperation between Denmark and Brazil on supporting efficient healthcare management in Brazil under implementation. Signed in December 2016.

**Project period:** December/2016 to March/2020

**Partners:** Ministry of Health in Brazil (BMoH), Brazilian Health Surveillance Agency (ANVISA) and The Danish Ministry of Health (DMoH). Co-partners are the Danish Health Data Authority (DHDA) and the Danish Medicines Agency (DKMA)

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