



Picture: In September 2019, DKMA inspectors Line Michan and Lisbeth Bregnhøj orchestrated an exchange forum on GCP inspection in Tianjin, China. Inspectors from all Chinese Provinces participated in the successful 2-day event.

Project description

The Strategic Sector Cooperation (SSC) between Denmark and China in the field of health aims at increasing access to care through effective management of health systems in China. The Danish-Chinese government-to-government cooperation consists of two sub-projects, signed in Beijing in January 2019.

Sub-project 1 establishes collaboration on regulatory development and policy exchange in the field of medicines and medical devices. The sub-project focuses on four main areas of cooperation: Authorisation of medicines, Laboratory testing of medicines, Medical devices and Inspections.

Sub-project 2 focuses on quality and capacity development in the primary healthcare sector with attention to integrated care solutions. The sub-project concentrates on three main areas of cooperation: i) Internet-based treatment of common mental health disorders, ii) development and implementation of anti-stigmatization campaigns and iii) policy development in the primary sector.

The methodology of the SSC-project is multifaceted, focusing both on facilitation of workshops, development of new guidelines etc.

Main achievements in 2019

2019 has been a busy year for the SSC project. After the formal signing of the two sub-projects in late January 2019, 13 SSC activities including six workshops and two high level visits have been carried out.

Relations with relevant stakeholders have been further intensified in 2019 resulting in further collaboration in addition to the agreed SSC activities. As an example, the Chinese State Council approved a new Drug Administration Law (DAL). Before approving this important new law, the Chinese National Medical Products Administration (NMPA) hosted a high level seminar where a representative from the Danish Medicines Agency was invited to speak together with representatives from US Food and Drug Administration (FDA) and Japanese FDA. As an additional indication of the close collaboration, the Danish Embassy was asked by NMPA to co-host a seminar for EU representatives and companies on this new DAL after the law was approved.

Key activities in 2020 (Sub-project 1)

Exchange forums on: i) Workshop on ATMPs, ii) Workshop on the requirements for and assessment of API-dossiers, iii) Medicines assessment training in Denmark, iv) Control of radiopharmaceuticals, v) Workshop on Medical Devices and new technologies, vi) Workshop on QM and LEAN, vii) Field visit by Chinese inspectors to DK to observe GCP inspection, viii) Field trip for high-level Chinese delegation to Denmark etc.

A total of 12 activities with involvement of the Danish Medicines Agency and Chinese NMPA sub-agencies are planned in 2020.

Key activities in 2020 (Sub-project 2)

Exchange forums on: i) 2 workshops in Guangdong and Wuxi respectively with the topic of digital solutions and e-mental health in the Danish primary sector, ii) a workshop in Copenhagen to share material from and experience with anti-stigma campaigns in Denmark, iii) High-level visit to Guangdong or Jiangsu, China, in relation to the World Mental Health day, iv) Fact finding mission to Denmark focusing on the role of the General Practitioners (GP) in Denmark, v) Workshop in Denmark focusing on the role of the GP in Denmark including patient pathways in mental health.

A total of 6 activities with involvement of the Danish Medicines Agency and Chinese NMPA sub-agencies are planned. However, due to the impact of the COVID-19 epidemic, all SP1 and SP2 activities planned for Q1 2020 have been postponed. Further rescheduling may be necessary.

Status: Full SSC project under implementation.

SP1 Partners: China National Medical Products Administration (NMPA) and the Danish Medicines Agency (DKMA).

SP2 Partners: National Health Commission (NHC), Chinese Centre for Disease Control and Prevention (CDC), Peking University Sixth Hospital, Guangdong Province and Jiangsu Province. From the Danish side the Ministry of Health (MoH), the Danish Health Authority and the Region of Southern Denmark.

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