

Update on China-Denmark Food and Drug Regulatory Cooperation Centre

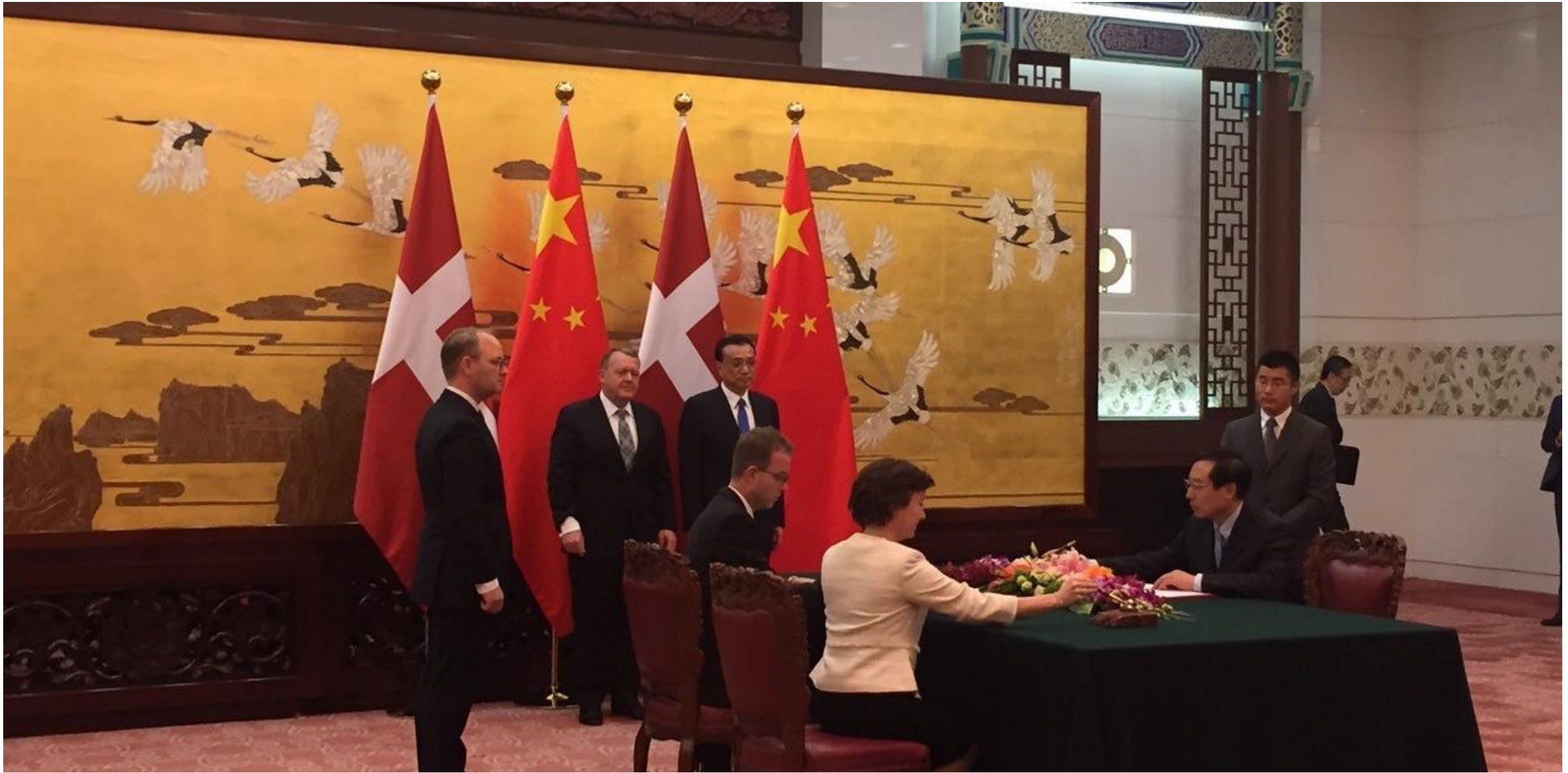
Thomas Senderovitz, MD., Director General



State of play

- MoU on the Centre signed on 3 May 2017
- The Centre was launched on 4 May 2017
- Bilateral meeting with CFDA on 4 May 2017









丹麦卫生部

Ministry of Health of Denmark

中丹食品药品监管合作中心

China-Denmark Food and Drug Regulatory
Cooperation Centre



国家食品药品监督管理总局
China Food and Drug Administration



Ministry of Environment and Food of Denmark
丹麦环境与食品部



Ministry of Health of Denmark
丹麦卫生部



LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY







中丹食品药品监管合作中心
China-Denmark Food and Drug Regulatory
Cooperation Centre
CFDA

世界卫生组织生物制品标准化
和评价合作中心
WHO Collaborating Centre
for Standardisation and Evaluation of Biologicals

世界卫生组织药品质量保证
合作中心
WHO Collaborating Centre for Quality Assurance

国家实验动物质量检测中心
National Quality Control Center
for Monitoring of Laboratory Animals

中国医学细菌保藏管理中心
National Medical Bacteria Control Center

国家病毒性肝炎研究中心
National Viral Hepatitis Research Center

国家抗生素耐药药性监测中心
National Anti-biotic Resistance Monitoring Center

国家麻醉品检定实验室
National Narcotic Control Laboratory

卫生部生物技术产品检定方法
及其标准化重点实验室
Key Laboratory of the Ministry of Health for Research
on Quality and Standardization of Biotech Products

国家啮齿类实验动物种子中心
National Center
for Rodent Laboratory Animal Resources

Bilateral meeting CFDA-DKMA 4 May 2017

- Again a constructive meeting between CFDA and DKMA
 - Affirmation of ambitions for the Centre
- Chinese priorities for joint work programme
 - Medicines inspections
 - Laboratory control of medicines
 - Exchange of knowledge and personnel
 - Biosimilars
- Agreement on phased-in approach to activities
- Appointment of liaison officers
- Open and direct communication

Next steps

- DKMA to visit CFDA 20-21 June
 - 1 day seminar on medicines evaluation
 - 1 day of discussion on joint working programme
- Virtual meeting this week to prepare June visit
- DKMA preparation – understanding of Chinese medicines legislation and relevant guidelines
 - Novo Nordisk in Beijing has offered to assist with translated materials
- Agreement on governance
- Development of Joint Working Programme 2017 and onwards

Development of Joint Working Programme

- Chinese interest to have long-term joint working programme
- Activities for Q3 and Q4 2017 to be further developed:
 - Seminar on management of inspectorate
 - Short term exchange of inspectors – Chinese inspectors at DKMA
 - eCTD
- Activities for 2018 and onwards to be proposed
 - Licensing, inspections
 - Medical devices
 - Biosimilars
 - Control of radiopharmaceuticals
- Confidentiality to be clarified

Thank you for your attention

