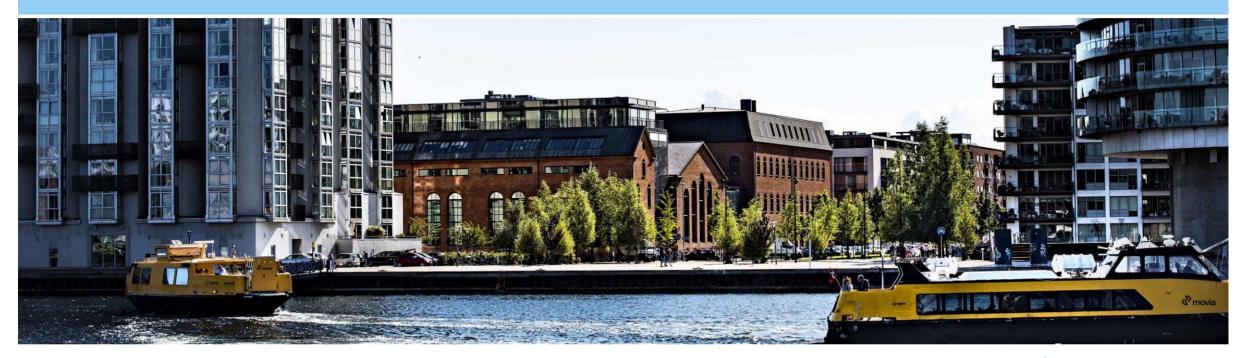
Update on China-Denmark Food and Drug Regulatory Cooperation Centre

Stakeholder meeting, 9 April 2018

Tina Engraff, Senior Adviser





State of Play

- Agreement on Joint Working Programme, in principle
- Activities of Inception Project to Strategic Sector Cooperation on Health in China
- Workshop on Chinese medical device system in pipeline
- Preparation for application for Strategic Sector Cooperation on Health in China (SSC Health China)



Agreement on Joint Working Programme

- Agreement, in principle
 - Still not signed
 - Activities progress in line with Joint working Programme
- Excerpt of 2018 activities:
 - Pilot project medicines evaluation exchange
 - Testing of radiopharmaceuticals
 - Workshop on Innovative Medicines Clinical assessment
 - Workshop on assessment of clinical trials, including scientific advice
 - Visit to DKMA for inspectors with observed GMP inspection



Inception project activities (1)

Confirmed visit in May by DKMA to NIFDC to explore feasibility for a Proficiency Testing Study on radiopharmaceuticals

- 3 DKMA scientific staff + 1 coordinator
- Preparations on-going

Also opportunity to discuss draft work programme for SSC Health China with relevant authorities



Inception project activities (2)

Pilot project on medicines evaluation exchange

- 4 Chinese senior assessors for up to 2 weeks (maybe in June)
- In-house at DKMA for training sessions/workshops
- Exploring how to make use of external expertise, e.g. University of Copenhagen
- Chinese interests:
 - Benefit-risk assessment
 - Risk management
- DKMA in process of identifying relevant dossiers to be included in pilot project
 - Targeted meeting with relevant stakeholders, if necessary



Workshop on Chinese medical device system

- Workshop early June kindly arranged by Med Tech stakeholders
- Purpose:
 - Better understanding of Chinese system
 - Inform our cooperation with regards to medical devices



Next steps

- Scheduling activities of 2018
- Implementation of Inception Projects and other activities
- Workshop on Chinese regulation of medical devices
- Preparations for application of SSC Health China





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