

# Update on China-Denmark Food and Drug Regulatory Cooperation Centre Stakeholder meeting, 9 April 2018

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# 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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