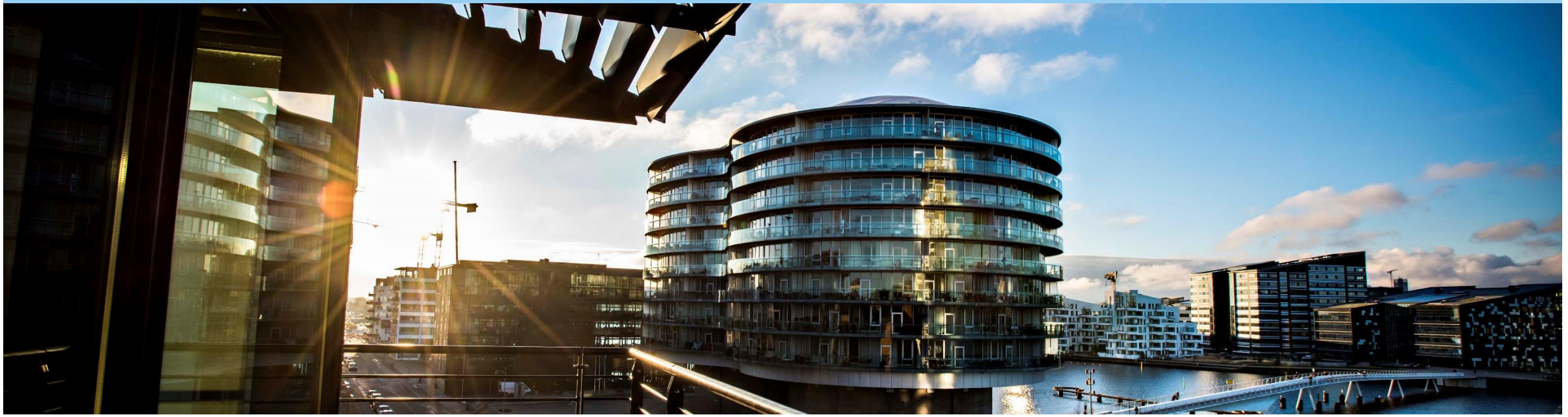
Update on China-Denmark Food and Drug Regulatory Cooperation Centre

Stakeholder meeting January 17, 2017

Jakob Cold, Deputy Director General



LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

Status on MoU

- Awaits signature of MoU
- State Visit December 2016 cancelled
- Works towards signature before end Q2 2017
- Cooperation can be initated under existing MoU between CFDA and DKMA

Expressed Chinese Motives

- Develop regulatory competences
- Build up case handling capacity – reducing massive backlogs (+ 1.000 assessors)
- Review historical approved medicines after more historical criteria
- Qualify procedures for clinical trials and stimulate innovation
- Using Denmark as platform for insight in European (and US-American) procedures
- Share approaches to new or even disruptive technologies (3D print, big data, precision medicine etc.)

DK as such without geopolitical agenda in the East

Context from a Danish regulatory point of view

- Chinese ambition to climb higher in the global value chain
- Efficient providing of health services as fundamental deal between state and people
- Fierce willingness to fight incompetence, fraud and impartiality
- Wish for higher transparency
- Some uncertainty (also to be observed in other complex countries) regarding to
  - Who is the authoritative competent agency?
  - Which procedure should be followed?
  - What are the exact criteria?
  - How to have a dialogue between competent authority and a private company?

Strategic areas of cooperation

- Information exchange and best practice sharing on the development and implementation of drug regulation and standards
- Licensing and authorisation procedures for drug (including medical devices etc)
- Market surveillance, inspections, safety reporting and drug recalling
- Guidelines, laboratory testing, control procedures, accreditations
- Quality management and personnel training

Other scientific and technical exchange related to regulatory science and other activities of mutual interest

Modes of cooperation

- Exchange of information on policies, laws and regulations
- Joint seminars, workshops, virtual meetings and technical training
- Exchange visits at both regulatory and technical levels
- Longer internships
- Other cooperation modes to be agreed by the parties

On-going activities

- Development of working programme
  - Contacts between the parties
  - Ambitious proposal from CFDA
  - DKMA visit to China in Q1 or early Q2
- Development of governance structure
  - Discussions to be initiated