

Update on the establishment of the China-Denmark Food and Drug Regulatory Cooperation Centre

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State of play

- Awaits signature of the MoU on the Centre
- CFDA visit at DKMA 13 March 2017
- Development of the Joint Working Programme on-going
 - First exchange of proposals in January and February
- Common satisfaction with the DK government decision on a growth consellor on health at the Royal Danish Embassy in Beijing
- Recommendations of the DK Growth Team to underpin the cooperation between DK and China

CFDA visit at DKMA 13 March 2017

- High level representation
 - CFDA: Director General Yuan Lin, Director Zhang Gaotong
 - DKMA: Director General Thomas Senderovitz, Deputy Director General Jakob Cold, relevant Directors of Division etc.
- Tour of the DKMA
- Constructive and frank exchanges



Content

Presentations to outline

- the strategic priorities of the DKMA until 2021,
- the reform of the Chinese Drug law and challenges faced,
- a model for governance of the Centre in relation to medicines and medical devices,
- possible areas for cooperation within the key areas identified in the draft MoU on the Centre and
- proposals for activities to be included in the first joint working programme on medicines and medical devices.

Discussions

Some possible topics of cooperation

- Evaluation of medicines
 - Capacity building: External medical assessors
- Scientific Advice
- Inspections
 - Risk based approach to inspections, training of inspectors, inspectors' powers
- Laboratory control of radiopharmaceuticals
- Exchange of experience on new technologies in relation to medical devices

Outcome of the CFDA visit

- Continued relation building
- Agreement on high ambitions for the Centre was confirmed
- Identification of further topics and activities for cooperation
- First Joint Working Programme should be established before signature of MoU
- Further elaboration on the governance for the Centre
- DKMA proposal for Joint Working Programme drafted

Next steps

- Chinese feedback on DKMA proposal for Joint Working Programme
- Virtual meeting to further develop the Joint Working Programme
- DKMA visit to CFDA/subordinate agencies before the summer



