Update on China-Denmark Food and Drug Regulatory Cooperation Centre

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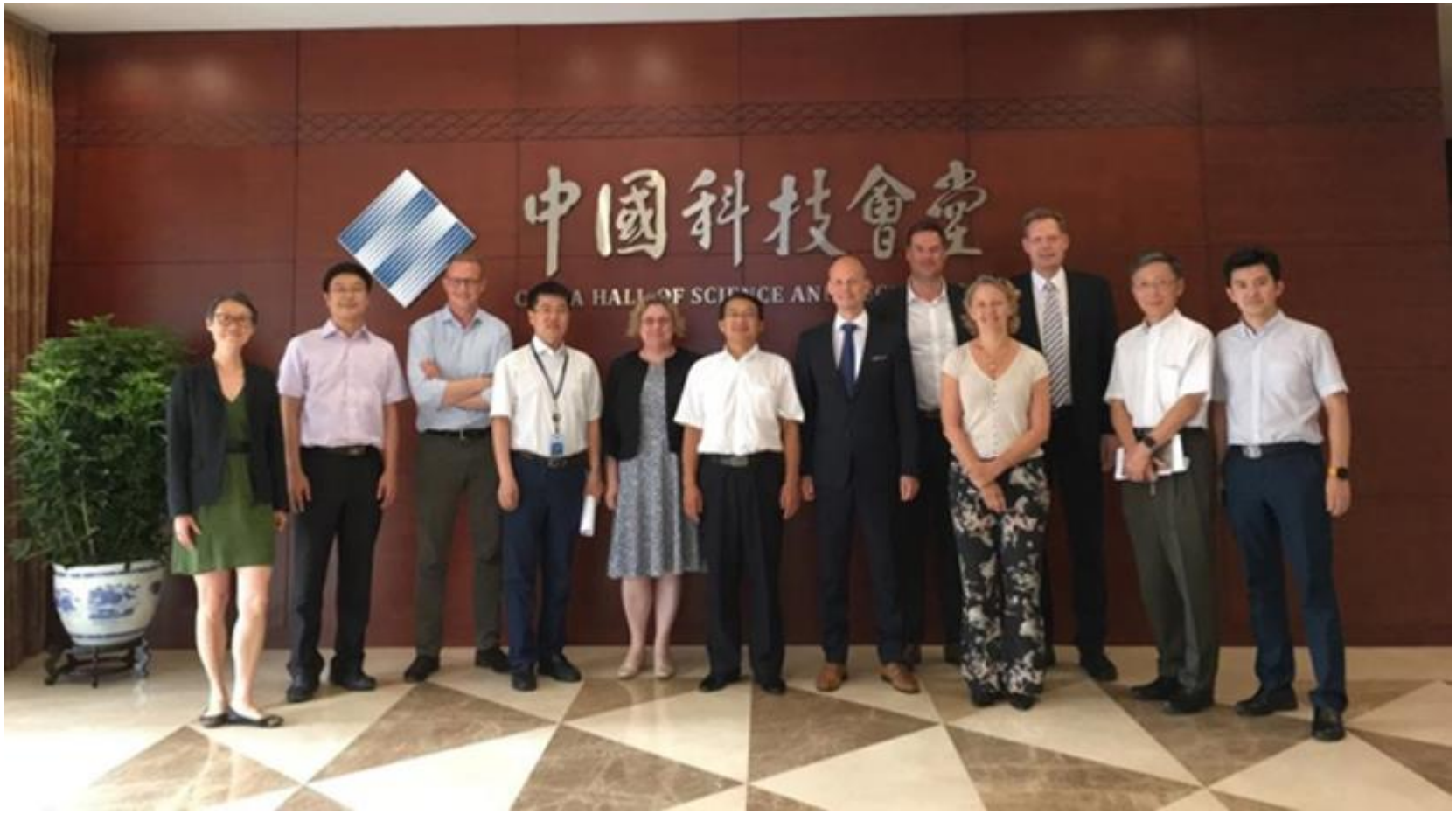
State of play

- China-Denmark Exchange Forum on evaluation of medicines, 20 June 2017, Beijing
- Meeting 21 June 2017 with CFDA, CDE, CFDI and NIFDC to discuss Joint Working Programme
- Meeting 21 June 2017 between CFDA (DG Yuan Lin) and DKMA
- Chinese Regulatory System for Development and Approval of Drugs, 1 September 2017, Novo Nordisk China
  - ➢ Introduction to Chinese regulatory landscape

China-Denmark Exchange Forum on medicines (1)

- Seminar for CDE staff, approx. 120 people attended
- Topics:
  - Organisation of assessment of applications for authorisation of medicines
  - Organisation of medical resources
  - The ‘good clinical assessment’
  - Assessment of the quality documentation of the medicine – chemical medicines
- Well-received presentations and good interaction with CDE staff

China-Denmark Exchange Forum on medicines (2)



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Development of Joint Working Programme

- Working on a 3 year Joint Working Programme
- Exchanges are still on-going
- Expect a seminar on management of inspectorate to take place in Beijing in November
- Hope a seminar on authorisation of clinical trials and scientific advice to take place in Bejing also in November
- Chinese high priority:
  - ➢ Exchange of staff – Chinese medicines assessors at DKMA for extended periods
- Confidentiality to be clarified

Chinese Regulatory System for Development and Approval of Drugs, 1 September 2017

- Regulatory workshop for DKMA staff - hosted by MoFA, content and presentations by Novo Nordisk
  - ➢ Background and general introduction
  - ➢ CFDA's reform and profile of China Drug Regulatory Approval
- Insights
  - ➢ Inspections in relation to all applications for clinical trials or marketing authorisation => huge workload =>need for risk-based approach
  - ➢ Scope of authority QC testing and test of all imported batches => focus on collaboration on laboratory testing
  - ➢ Changes in CDE's role and focus on innovative medicines => need for many new assessors
- MD regulatory workshop in 2018?

Next steps

- China-Denmark Drug Administrative Law Exchange Forum, 9 October 2017, DKMA
  - ➢ High level CFDA/CFDI delegation
  - ➢ Input into revision of Drug Administrative Law
  - ➢ Agenda under development: authorisation of medicines, MAH concept, medicines inspection, accountability, compensation for medicinal injury
- CFDA/CFDI visits to retail pharmacy and wholesale distributor, 10 October 2017
- Seminar on Chinese culture, 6 November 2017

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