Update on China-Denmark Food and Drug Regulatory Cooperation Centre

Stakeholder meeting, 28 February 2019

Jakob Cold, Deputy Director General, Danish Medicines Agency

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State of Play

- Final activities of Inception Project to Strategic Sector Cooperation on Health in China (SSC Health China)
  - Observed GMP inspection in Denmark in November 2018
  - Clinical trials workshop in Beijing in November 2018
- Additional activities in the margin of the Clinical trials workshop in November 2018
- Project document signed in Bejing in January 2019
- Application for SSC Health China submitted last week
- Preparation of first activities of the SSC Health China

Observed GMP inspection in Denmark, Nov 2018

- CFDI observed GMP inspection in DK, week 47
  - Follow up to Inspection Exchange Forum in November 2017
  - 2 CFDI inspectors
- 5 days' visit
  - Intro at DKMA
  - 3½ days at manufacturing site
  - Follow up meeting with DKMA lead inspector and co-inspector
- Focus on sterile manufacturing and biological products

Clinical trials workshop in Beijing, Nov 2018

- 2 days workshop on clinical trials
  - Authorisation procedures, safety, preclinical assessment with focus on FIH, ATMPs, complex clinical trials and case study
- 4 DKMA experts
- 60 CDE participants
  - Small group of senior assessors, many junior assessors

Clinical trials workshop, Nov 2018

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Clinical trials workshop, Nov 2018

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Other activities of Beijing visit, Nov 2018

- High-level meeting at NMPA with Vice-Commissioner Xu
  - Lecture on ”Precision Medicine and Convergence of Technologies: Opportunities & Challenges”
- Visit to CMDE
  - Meet and greet
- Explorative meeting with CDE at technical level
  - Adjustments to work plan
- Round table with DK stakeholder companies
  - Valuable input on positive experience and challenges

Lecture at NMPA

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Visit at CMDE

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Project document signed, 29 Jan 2019

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Application for SSC on Health in China submitted

- Application submitted last week
- DKMA contributed with draft work plan
  - Further discussions with Chinese authorities
  - Budget input
  - Review of application documents
- Awaits approval
- Main responsible: MoH and Sector Counsellor

Ambitious workplan

25 activities in 2019-2021 within the areas of:

- Information exchange and *best practice sharing* on the development and implementation of drug regulatory frameworks and standards.
- Licensing and authorization procedures for drugs and medical devices.
- Market surveillance, inspections, safety reporting and product recalling
- Guidelines, laboratory testing, control procedures, accreditations
- Exchange on quality management and personnel training

Modes of cooperation:

- Exchange of information on policies, laws and regulations
- Joint seminars, workshops, virtual meetings and technical training
- Exchange visits

Preparation of SSC activities

- Workshop on Quality Documentation in Clinical Trials, Beijing, next week
  - 2 days, 2 DKMA experts, up to 100 CDE staff
  - Chemical and biological products
- Workshop on Medical Devices frameworks in DK and CN, April 2019
  - 3 DKMA experts
  - CMDE and NIFDC (tbc)
  - Explorative, technical meeting
- PTS on radiopharmaceuticals
  - To start development of protocol for PTS
  - Plan visit by NIFDC to see preparation for PTS, June 2019

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