

Update on China-Denmark Food and Drug Regulatory Cooperation Centre

Stakeholder meeting, 26 October 2018

Jakob Cold, Deputy Director General, Danish Medicines Agency



State of Play

- Activities of Inception Project to Strategic Sector Cooperation on Health in China
 - Visit to NIFDC on radiopharmaceuticals in May
 - Pilot project on Clinical Trials and Medicines Assessment in September
 - Planned activities on inspections and clinical trials in November
- Workshop on Chinese medical device system in June
- Workshop on Innovative Medicines – Clinical Assessment in Beijing, 12 September
- Preparation for application for Strategic Sector Cooperation on Health in China (SSC Health China)

Visit to NIFDC on radiopharmaceuticals

- Visit 22-24 May by DKMA to NIFDC to explore feasibility for a Proficiency Testing Study (PTS) on radiopharmaceuticals
 - 3 DKMA scientific staff + 1 coordinator
 - Presentations and discussions
- Outcome: 2 PTS in draft work programme
- Also discussions with NIFDC, CDE and CFDI on draft work programme for SSC Health China

Visit to NIFDC on radiopharmaceuticals



Visit to NIFDC on radiopharmaceuticals



Pilot project on clinical trials and medicines evaluation

- 6 CDE staff at DKMA 24-27 September for training session/workshops
 - ½ day intro, outro and assessment
 - 1½ days on clinical trials authorisation
 - 1½ days on medicines evaluation
 - General discussion on training and quality management
- 8 DKMA experts involved
- Real cases used in the pilot project on both clinical trials and medicines evaluation
- Lessons learnt: scientific level equivalent, focus on process optimisation, Chinese context different
- DKMA evaluation on-going

Pilot project on clinical trials and medicines evaluation



Pilot project on clinical trials and medicines evaluation



Next Inception Project activities

- CFDI observed GMP inspection in DK, week 47
 - Follow up to Inspection Exchange Forum in November 2017
 - 2 CFDI inspectors
- Clinical Trials Exchange Forum in Beijing with CDE, week 48
 - 4 DKMA experts
 - Expect 50 CDE staff

Relation building

- Informal meeting between DKMA Director General and Vice-Commissioner XU Jinghe, NMPA, on 11 September in Washington DC
- DKMA Director General also visits Chinese authorities in week 48
 - NMPA, CDE and CMDE
 - Round table with DK stakeholder companies (tbc)

Workshop on Chinese medical device system

- Workshop kindly arranged by Med Tech stakeholders on 1 June
- Purpose:
 - Better understanding of Chinese system
 - Inform our cooperation with regards to medical devices
- CMDE new actor in the SSC

Workshop on Innovative Medicines – Clinical Assessment

- 1 day workshop took place 12 September at CDE
- 2 DKMA experts
- 35 CDE assessors
- The workshop covered
 - EMA regulatory procedures and processes
 - Clinical assessment of innovative medicines

Workshop on Innovative Medicines – Clinical Assessment



Application for SSC on Health in China

- DKMA contributes with draft work plan
 - Further discussions with Chinese authorities
 - Budget input
- Review of application documents
- Main responsible: MoH and Sector Counsellor

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