Update on China-Denmark Food and Drug Regulatory Cooperation Centre

Stakeholder meeting, 7 December 2017

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State of Play

- China-Denmark Drug Administrative Law Exchange Forum
  - ➢ Visit from CFDA/CFDI on 9-10 October 2017
- Course in Chinese cultural understanding
- China-Denmark Inspection Exchange Forum 22-23 November 2017
- Exchange on Joint Working Programme
- Development of Inception Project to Strategic Sector Cooperation on Health in China

China-Denmark Drug Administrative Law Exchange Forum

- High-level CFDA/CFDI delegation visit at DKMA 9 October 2019
- Agenda
  - Status of revision of Drug Administrative Law
  - Authorisation of medicines
  - MAH concept
  - Danish regulation of manufacturing and distribution of medicines
  - Medicines inspection
  - Accountability
  - Compensation for medicinal injury (Patient Compensation Association)
  - Regulation of herbal medicines in EU

Key messages on Chinese DAL reform (1)

Context:

From generics-oriented to the combination of innovative drugs and generics and from a big pharmaceutical country to a strong pharmaceutical country

- Drug Manufacturers: 4176
- Drug Distributors: 465618
- Total output of healthcare industry: 3.1676 trillion Chinese Yuan
- Total sales of healthcare products: 839.3 billion Chinese Yuan
- Import of healthcare industry: 55.1 billion Chinese Yuan
- Export of healthcare industry: 48 billion Chinese Yuan

Key messages on Chinese DAL reform (2)

Overall prevention and control of risks

Overall fulfillment of responsibilities

Overall promotion of systems

Overall improvement of capabilities

Mission of regulators: Protect and promote the health of the public

Biggest risk to public health: No therapy for the disease

Key messages on Chinese DAL reform (3)

Basic principles

- Drug administration shall be patient-centered, based on risk-benefit evaluation and adopt life scientific and strict life-cycle management
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Innovation:

- Systems go from passive to proactive
- Regulation go from traditional to modern
- Foster a self-discipline industry without too much regulation

Key messages on Chinese DAL reform (4)

Issues to be discussed about MAH:

- The division of responsibilities between MAH and CMO
- The division of responsibilities between the local regulator and the regulator where the MAH is located when the CMO is not at the same location with the MAH
- The relationship between MAH and retailers

Clinical trial:

- Change the approval system into filing system for CT sites
- Change from approval system into acquienscence system for CT programmes

Manufacturing:

- From certification to inspection, from standards to system

Key messages on Chinese DAL reform (5)

Conclusions:

- Company takes primary responsibility
- Government regulatory system
- Co-governance with society

- To be scientific-based, risk-based regulation
- To be society-based, social co-governance
- To be politially-based, shared responsibility

Radical change of regulatory system?

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Visits 10 October 2017

- Sønderbro pharmacy
  - Pharmacy regulation
  - Pharmaceutical price system
  - Regulation of prices
  - Substitution
- Tjellesen Max Jenne
  - Pharmaceutical distribution in Denmark
  - Safety and quality in the supply of pharmaceuticals
  - Interaction with DKMA

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China-Denmark Inspection Exchange Forum

- 3 DKMA inspectors in Beijing for Exchange Forum 22-23 November 2017
- 100 participants from CFDI and provincial inspectorates
  - ➢ 80 GMP inspectors and 20 GCP inspectors
- Agenda
  - ➢ General intro to management of inspectorate
  - ➢ General intro to GMP, GCP and data integrity inspections
  - ➢ Workshops on GMP inspections and GCP inspections with data integrity incorporated
- Well-received, good interactions, many questions

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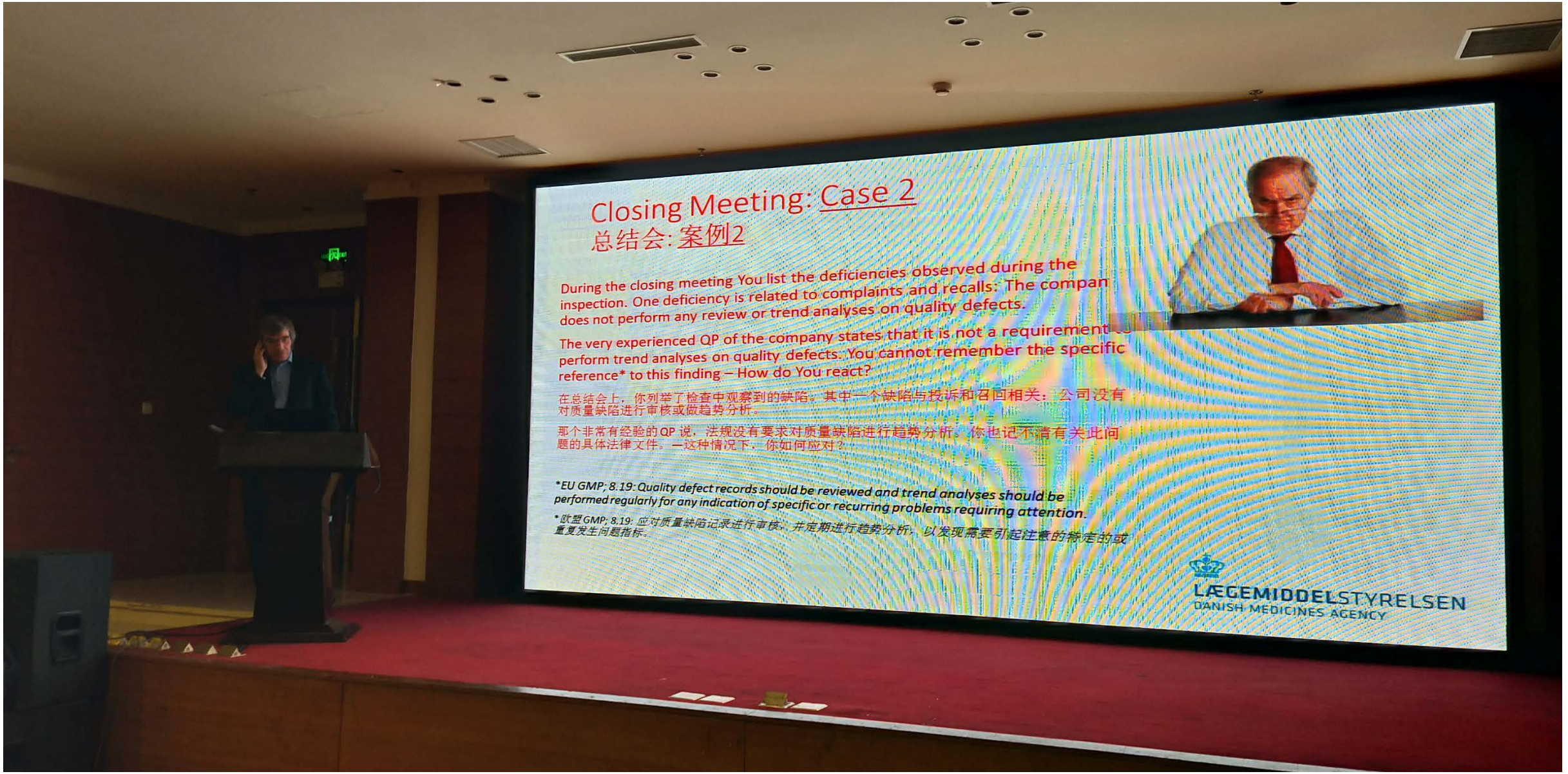
Closing Meeting: Case 2
总结会: 案例2
During the closing meeting You list the deficiencies observed during the inspection. One deficiency is related to complaints and recalls: The compan does not perform any review or trend analyses on quality defects.
The very experienced QP of the company states that it is not a requirement perform trend analyses on quality defects. You cannot remember the specific reference* to this finding – How do You react?
在总结会上，你列举了检查中观察到的缺陷。其中一个缺陷与投诉和召回相关：公司没有对质量缺陷进行审核或做趋势分析。
那个非常有经验的QP 说，法规没有要求对质量缺陷进行趋势分析。你也记不清有关此问题的具体法律文件。—这种情况下，你如何应对？
*EU GMP; 8.19: Quality defect records should be reviewed and trend analyses should be performed regularly for any indication of specific or recurring problems requiring attention.
*欧盟GMP; 8.19: 应对质量缺陷记录进行审核，并定期进行趋势分析，以发现需要引起注意的特定的或重复发生问题指标。
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Exchange on Joint Working Programme (1)

- Aim to sign Joint Working Programme 2018-2020 before end of year
- Feedback from CFDA and subordinate agencies early November
  - ➢ Generally acceptable, but include medicines assessment training, GCP inspections and microbiological testing
- Revised draft Joint working Programme sent late November to CFDA
  - ➢ Not include microbiological testing due to lack of DKMA expertise

Exchange on Joint Working Programme (2)

2018 activities, e.g.

- Pilot projects medicines evaluation exchange
- Testing of radiopharmaceuticals
- Workshops on Innovative Medicines:
  - ➢ Clinical assessment
  - ➢ Biological and biosimilar medicines
- Workshop on assessment of clinical trials, including scientific advice
- Visit to DKMA for inspectors with observed GMP inspection

Cooperation from stakeholders needed

- Use (old) dossiers for pilot projects on medicines evaluation exchange
  - ➢ Accept from MAHs to use dossiers
  - ➢ Assistance in selecting relevant dossiers
- Observed GMP inspection Q1 2018
  - ➢ 2 Chinese observers
  - ➢ Extra ressources required from inspected company
- Contact persons?

Next steps

- Signature of Joint Working Programme 2018-2020
- Scheduling activities of 2018
- Implementation of Inception Projects and other activities
- Workshop on Chinese regulation of medical devices

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