Activity Title and Number: EU-China Medical Devices Expert Roundtable III(MDER III); A355C2	**Beneficiary:** China Food and Drug Administration (CFDA); European Commission Directorate General for Health and Consumer Policy (DG SANCO);
Location and Date: Beijing, 1-2 September, 2014	**Stakeholders**: China Association for Medical Devices Industry (CAMDI), European Coordination Committee of the Radiological, Electromedical, and Healthcare IT Industry (COCIR)

Brief Activity Report

Relevance and Impact

Following the success of the Medical Devices (MD) Roundtable II in 2012, the CFDA and the DG SANCO agreed to continue strengthening these dialogues through a third medical devices roundtable. The Joint EU-China MD Expert Roundtable III (MDER III) aims to build upon previous meetings by analysing differences between the European and Chinese MD regulatory frameworks to ultimately minimize barriers, encourage stronger cooperation, and increase mutual understanding of industry issues. EUCTPII organised a two-day seminar in Beijing to present the conclusions and recommendations of the EU-China comparative study on the regulatory regime of MD. The report gives a better understanding to both CFDA and DG SANCO, Chinese and European industry on MD regulations and implementation as well as information on market access rules.

Activity Description

In the context of the new Chinese legislation on MD published in 2014 and the latest text of the MDD and IVDD draft text of the EU legislation, the Working Groups consisting of Chinese and European industry experts analysed the differences between the European and Chinese MD legislation and standards. The experts reviewed the Chinese legislation published on July 30, 2014 and effective on October 1, 2014 - Revised Order No. 650 “Regulation for the Supervision and Administration of Medical Devices”, Order No. 5 “Administrative Measures on the Registration of IVD Reagents”, Order No.6 “Medical devices instruction and label management regulations“ and Order No.7 “Provisions for Supervision of Medical Device Manufacture”. The latest text of the European Union IVD Regulation from September 29, 2012 was used for comparative study. Chinese and European regulators were present at the seminar as observers to ensure that issues raised by the experts will be addressed.

Results

- ✓ A better understanding on technical issues related to medical devices as expressed through regulations and practices in both markets.
- ✓ Identification of relevant issues for further discussions between DG SANCO and CFDA as China will be implementing 20 orders based on the framework legislation 350.