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DECEMBER 2019 EDITION

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HIGHLIGHTS

13- 14 Nov.

COCIR 60 Year Anniversary

Celebrating **60 years of the benefits** of innovation in medical technology **to society**

The event brought the viewpoints and perspectives of patients, clinicians, academia and industry.

Video available on YouTube here.

COCIR's latest paper "**European Health Data Space: Towards A Better Patient Outcome**" was launched during the event. Download the paper here.

13th November Presentation

President Mr Jan KIMPEN: Celebrating 60 years of the benefits of innovation in medical technology to Society, here

KEYNOTE SPEECHES BY EUROPEAN COMMISSION

- Manuel MATEO GOYET / Member of the Cabinet of Commissioner Gabriel, the Digital Economy and Society portfolio at the European Commission
- Andrzej RYS / Director Health Systems, Medical Products & Innovation at DG Santé, European Commission

HEALTHCARE FUTUROLOGIST: "WHAT DOES THE FUTURE HOLD?"

Koen KAS / Healthcare futurist, entrepreneur, professor of molecular oncology,

and renowned international keynote speaker.

14 November presentations

Secretary General Ms Nicole Denjoy - Welcome, here

Tuula Helander - Keynote speech, here

Session 1:

- Irene NORSTEDT: Horizon Europe, the next EU research and innovation programme (2021-2027), here
- Casper GAROS: COCIR Vision for health research & innovation in Europe, here
- Annemijn ESCHAUZIER: COCIR vision on value in health, here
- Magda CHLEBUS: Stronger together! The power of collaboration, here

Session 2:

- Martin DORAZIL: Digital health and artificial intelligence, here
- Marcus ZIMMERMANN-RITTEREISER: Digital health and artificial intelligence, here
- Henrique MARTINS: Digital Health & Artificial Intelligence - eHealth Network - Progress & Priorities, here

Session 3:

- Holger SCHMIDT: Industry challenges and opportunities for the medical devices sector in Europe, here
- Erik HANSSON: The challenge of regulating medical devices, here
- Hans-Heiner JUNKER: How NB will cope with MDD and MDR, here

Session 4:

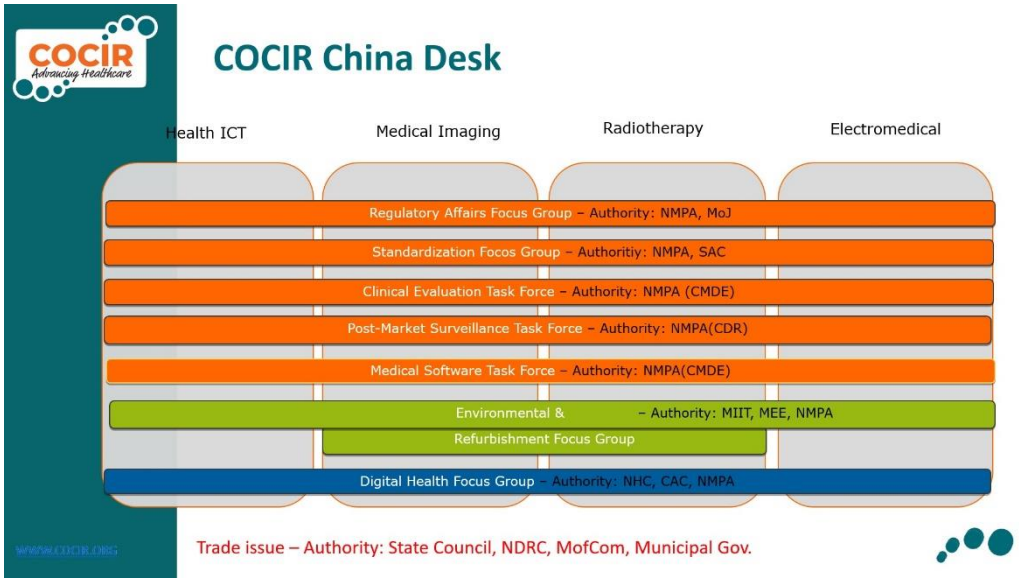
- Jos RUIS: Industry experience and perspectives on circular economy and sustainability, here
- Lorenzo E. DERCHI: ESR views on equipment age and consequences of the economic crisis on radiology, here
- Alessandro CORTESE: ESTRO, European Society for radiotherapy and oncology, here

COCIR China members also expressed congratulations, good wishes, as well as willing to continue their active participating into COCIR China activities, moving forward so that the benefit is also shared with Chinese society.

01 Nov.

Two New Members of COCIR China

A big welcome to these two companies which become members of COCIR China!
Roche now is an Associate Member with Digital Health Focus Group and Medical Software Task Force;
Stryker now is an Associate Member with Regulatory Affairs Focus Group
In summary, this brings COCIR China to a total of 18 members



3 Dec.

A Big Success - Good News on "Buy China" Issue in Guangxi Province

24-26th July, 2019
Guangxi Zhuang Autonomous Region released approvals to local hospitals on the allocation of Type-B large medical equipment, 57 hospitals are included. It clearly requires hospitals to purchase domestic brand equipment, as highlighted in the picture, it clearly marks on the certificate – e.g. 1.5T MR (domestic brand).

03 December, got formal response letter from Guangxi Commerce Bureau, click here, and translation here, saying that:

In the allocation license of Guangxi Health Commission, **"domestic brand"** refers to **products invested and produced by foreign investors or Sino**

foreign joint ventures within the territory of China and the products produced by domestic wholly-owned enterprises are equally qualified to participate in the competition, and no discrimination policy is implemented.

Summary of actions taken -
To Chinese Authorities:
P - mid of November, in the comments that EUCCC sent to **Ministry of Justice** on Regulation on the Implementation for Foreign Investment Law (Draft for Comments), the recommendation on procurement is one of the key ones.
P – 15 October, COCIR China Desk submitted a letter to **MoF** and **MofCom**
P – KR4 of **EUCCC annual Position Paper** 2019/2020, launched at end of Sept.2019
P – 20 Sept., advocacy letter was submitted to **SAMR**
M – 20 September, highlighted the issue during seminar with **CCPIT** and SAMR
P – 21 August, lobby letter was submitted to the **Administration for Market Regulation of Guangxi**
P – 19 August, advocacy letter was submitted to Supervisory Office, **General Office of State Council**
S – 31 July, during Seminar organized by **NDRC**, on the Regulation of Optimizing Business Environment, the issue was highlighted by EUCCC

Supports we asked for supports from EU Gov.:
M – 15 November, in Brussels, met with Policy Officer from **DG Trade**
M – 23 October, COCIR Brussels office presented "Buy China" issue to **DG Trade and DG GROW** during the meeting of Market Access WG Medical Devices
P – mid October, **DG Trade** sent a letter **to MofCom**
M - end of September, during a visit of a delegation of MofCom to Brussels, this issued was mentioned about by **DG Trade to MofCom**
M – 10 Oct., raised the issue during **EU Delegation** meeting with health counsellors from MS' Embassies
M – 4 Sept., SG of COCIR met with **DG TRADE** in Brussels on procurement issue of medical equipment
M – 2 Sept., update the issue to the **EU Delegation** in China
M – 13 June, meeting with **EU negotiators on** EU-China Comprehensive Agreement on Investment (**CAI**) during their trip to China, emphasizing the "Buy China" issue

COCIR China has Informed the EU Delegation in Beijing, and we will continue to monitor the implementation.

COCIR Speech with NMPA on MDR-QMS

08 Nov.

On 8th November, NMPA organized a workshop on Quality Management System of Medical Devices, and asked Jessica Yuan, COCIR China Representative to give a presentation on QMS requirements In the EU linked to MDR. The meeting was well attended by NMPA Department of Supervision, regional MPA, companies, besides Jessica introduced that in the EU, another invited speaker to introduce QMS requirements in US, is an official from US FDA China Office.

With supports from COCIR Brussels colleagues, and members/experts from Europe, Jessica Yuan gave a presentation on the Quality Management System Requirements in the European Union, including the Article 10 of the European Union Medical Devices and In Vitro Diagnostics Regulations, its requirements for Quality Management System, and the Medical Device Single Audit Program Work Group of International Medical Device Regulators Forum, click here for the PPT.

COCIR Wins Award during 10th CIMDR

24 – 27 Sept.

During 24th to 27th September, the China International Medical Device Regulatory (CIMDR) Forum took place in Suzhou. COCIR, which promotes the development of harmonised international standards and regulatory control of medical devices and healthcare IT systems—supported the CIMDR Forum for the 10th year. As a result, COCIR acquired the 10-Year Cooperation Award.

The three-day conference attracted around 2,000 participants. It is one of the medical device industry's most significant conferences, not only for Chinese companies but also for international enterprises.

The deputy commissioner of the National Medical Products Administration, Shifen Chen, attended the conference, as well as several officials from multiple regulatory-related government departments. In addition to the plenary meetings, 17 sub-fora were held, focusing on key regulatory issues including clinical trials, post-market supervision, risk management, and cybersecurity.
Many members presented at CIMDR, which is an essential platform to meet with various stakeholders in the industry. CIMDR provides the industry with a channel to call for market access, equal competition, and a further increase in the efficiency of China's regulatory system.

18 Sept.

DITTA met with Deputy Commissioner of NMPA during IMDRF-16

Using the opportunity of IMDRF 16th Management Committee meeting, which took place in in Ekaterinburg in Russia, on 18th September, DITTA has a bilateral meeting with NMPA delegation.
NMPA Delegation:
XU Jinghe, Deputy Commissioner, NMPA
WANG Lanming, Director-General, NMPA Dept. of Medical Device Registration
GAO Guobiao, Director-General, NMPA Center for Medical Device Evaluation
ZHU Ning, Director, NMPA Dept. of Medical Device Supervision
HE Ye, Policy Officer, NMPA Dept. of International Cooperation
DITTA delegation:
Peter Linders, on behalf of DITTA Chair, Philips
Kiyoshi Inaba, JIRA
Naoki Morooka, Shimadzu
Philippe Lartigue, GE Healthcare
Annika Eberstein, COCIR

The deputy Commissioner provided an overview of current changes in the medical device regulatory system in China, including the amendment to Order 680. The meeting then focused on Artificial Intelligence and standardization.

Artificial Intelligence: China established a digital working group that is also responsible for standards management. CMDE has set up a specific working group on Artificial Intelligence and an online platform to support companies developing AI solutions. They also published a guidance for AI-based medical devices. Participants from NMPA seemed interested in the possibility of a work item on Artificial Intelligence on Artificial Intelligence. It was also mentioned that the next meeting of IEC / TC 62 will include an agenda item on AI / ML and the hope that a Chinese delegation will contribute to the discussion.

Standards: China is proud to co-chair the IMDRF Working Group on standards and was very interested by the outcomes of the survey on the approaches to recognition of standards in the different jurisdictions. They understand the importance of aligning with international standards. China mentioned that they would soon accept Ed 3.1 of IEC 60601-1. NMPA is planning to launch a reform of the system for medical device standardization. They would like to receive input from industry in this process. One of the possibilities they are considering is to make a difference between safety (basic, fundamental) part of standards that must remain

voluntary and other parts (quality) that could be voluntary. Industry welcomed the opportunity to provide input and suggested the organization of a meeting or workshop in China to further discuss standardization.

COCIR China Desk will follow-up with NMPA to see how the industry can contribute to actions taken in China on AI and Standards.

29 Nov.

COCIR China ENVI & Refurbishment FG Annual Meeting in Beijing

Using the opportunity having the Chair of COCIR ENVI Group in Beijing, on 29 November, COCIR China ENVI & Refurbishment FG organized a seminar on EHS topics with experts from China Electronics Standardization Institute. The agenda was as follows -

Summary of activities/achievement in 2019	Weiqing Wang (Chair); Jessica Yuan (COCIR China Representative)	See PPT here
Energy consumption measurement methods for medical electrical equipment standard	Weiqing Wang	
China RoHS conformity assessment rules	Dr. GUAN Qi, China Electronics Standardization Institute	See PPT here
EU Updates: - Circular Economy - EU RoHS - EU REACH - COCIR Self-Regulatory Initiatives (SRI) - Basel	Christian Reckziegel, from Siemens Healthineers	See PPT here

INSTITUTIONAL UPDATES

UDI Enforcement in China

Below Rules on UDI has been announced during CIMDR in September

1. Rules on Medical Device UDI System *click here*

Authority: National Medical Products Administration.

Publish Date: 27th August 2019; Effective Date: 1st October 2019

The Rules, which contain 18 articles, specify the purpose, object of application, construction principles, duties of all parties and related requirements for the construction of the unique marking system for medical devices.

2. Notice on First Batch of Implementation of UDI

Authority: National Medical Products Administration

Publish Date: 15th October 2019

The Notice specifies that from 1st October, 2020, the medical device produced shall have the unique identification of the medical device; medical devices manufactured before 1st October, 2020 may not have a unique identification of medical devices, and the date of manufacture is based on the medical device label.

COCIR China will liaise with COCIR Office in Brussels in order to ensure consistency and convergence on UDI system in China and IMDRF and other jurisdictions.

Public Consultation - *Regulation on the Implementation for Foreign Investment Law (Draft for Comments)*

Authority: Ministry of Justice

Publish Date: 1st November 2019; Close Date for comments: 1st December 2019

The draft Regulation includes 45 articles and 5 chapters, providing a clearer implementation guideline for the Foreign Investment Law (FIL). The European Chamber put together total 70 pages comments from different industry sectors including ours and submitted those to the authority. Below issues of standards and procurement are of the interest of our members.

1) Standard Issue

Article 15 and 16 of the draft Regulation further elaborates Article 15 of the FIL, foreign-funded enterprises are guaranteed by the state to participate in the development work of national, industrial, local and group standards without being restricted by any unit or person.

Both articles demonstrate the commitment to open the standardisation for foreign business. However, Article 15 says that foreign companies can take relevant work according to relevant regulations. Then foreign companies can only take relevant standardisation work if the relevant regulations allow them.

We would suggest designing certain kind of mechanism to provide remedies for FIEs if there is any violation of rights. Moreover, we also suggest strengthening the review of relevant

regulatory documentation and see if there is any provision is not consistent with the Regulation.

2) Government procurement

Article 17 which echoes Article 16 of FIL, no unit or individual may hamper or limit the foreign-invested enterprises from freely entering the government purchase market in the region and the industry in any way. Discrimination or different treatments shall not be created by setting restrictions or unreasonable conditions of information release, qualification review, standard review, organization of company, ownership, share structure, and equity. Also, Article 18 states that government procurement departments shall provide equal instruction and service for domestic-invested enterprises and FIEs.

These articles emphasize the principle of equal treatment in government procurement activities. However, according to the *China Government Procurement Law*, China can still prioritize domestic products, which includes products manufactured by foreign companies in China. Despite the Ministry of Finance has published the Notice Caiku [2019] No 38, which underline the equal treatment principle, in the healthcare equipment sector, some provinces still issue procurement notice, which discriminate foreign brand products.

Given this, the government is suggested to strengthen the fair competition review of related documentation after the FIL coming into force.

The European Chamber and COCIR China are close monitoring the development and will keep members informed.

ACTIVITIES ON Y2019 PRIORITIES

Meeting – **"M"**;
Seminar – **"S"** incl. workshop;
Paper – **"P"** incl. letter;

COCIR China Desk is working with the leadership to establish the priorities of each group for Y2020. Here are some updates on clinical evaluation, standards for 2019. On topics of AE reporting and foreign test reports acceptance, the updates have been shared with members in the previous newsletters.

- Clinical Evaluation and Trial

Updates	Actions achieved
IMDRF CE Extension Working Item - Post Market Clinical Follow-up (PMCF) got approved by Management Committee during IMDRF 16th Meeting in Russia	**"M"** - COCIR nominated some experts from member companies to be in the Advisory Committee of

	CMDE. This AC had a kick-off meeting on 6th Dec.
The Center for Medical Device Evaluation (CMDE) initiated public consultations on the *Catalog of Medical Devices Exempt from Clinical Studies*, https://www.cmde.org.cn/CL0004/19523.html	**"C"** – 30 August, COCIR-EUCCC will collect and consolidate members' comments and submit to CMDE
-	**"M"** – 9-11 July, DITTA Clinical Evaluation (CE) WG representatives, and Jessica Yuan, attended the IMDRF CE WG meeting in Chengdu
Public Consultation by IMDRF CE WG/CMDE of China NMPA, 5th April to 5th June 2019	**"C"** - 3 June, EUCCC/COCIR submitted members' comments to IMDRF CE WG

- Mandatory medical device standards

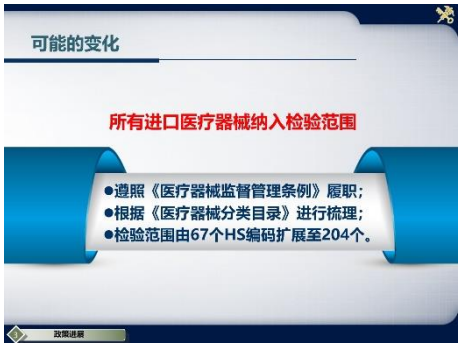
Updates	Actions achieved
-	**"M"** - The European Telecommunications Standards Institute (ETSI) delegation had a trip to China. On 16 Oct., they met with representatives from IT and medical device industries, a member of COCIR was present.
The future *Amend of Order 680* will indicate that *"Article 6 Medical devices shall meet the mandatory national standard or mandatory industry standard when there are no relevant mandatory national standard available. "*	**"P"** – 26 April, a report was developed and contributed to CMDE, with the key recommendation to streamline mandatory standards **"S"** – 16 July, during seminar on Order 680 organized by MoJ, emphasized the issue **"P"** – 23 July, the report above mentioned is being supplemented, due to concerns from competent authorities e.g. CMDSA, insisting medical device standards should be mandatory. **"P"** – KR3 of EUCCC annual Position Paper 2019/2020, to be launched at end of Sept. 2019
The Measures for the Administration of Mandatory National Standards (in WTO-TBT Notification)	**"P"** – 10 April, a lobby letter was submitted to SAMR **"S"** – 13 June, recommended by the Chamber, two member companies attended a seminar with SAMR, Dept. of Legislation, and Dept. of Standards and Technology **"C"** – 27 June, EUCCC Standards WG is collecting members' comments to be submitted to SAMR

OTHER ISSUES / EFFORTS UPDATES

Meeting – **"M"**;
Seminar – **"S"** incl. workshop;
Paper – **"P"** incl. letter;

Shanghai Customs Clearance Issue

"S" - 31 October, invited policy officer from SH Customs to give training to members, and had fruitful questions and answers.



Below future changes will have bigger impacts to members' business in China:
- **All imported medical devices will be in the scope of inspection** (the range is expanded from 67 HS codes to 204)
- Will diversify management to products in different classes
  - Class III - Strictly
  - Class II - Appropriately
  - Class I - Regularly
- Adjust the mode of conformity assessment appropriately and stress the function of Customs

What does this mean, is to be monitored and communicated with SH Customs, as well as the General Administration of Customs at national level.

"P" – 26 July, submit recommendations on medical device customs clearance inspection to Shanghai Customs, specifically emphasized the issues of labeling and legal inspection management.

"M" – 17 July, with the Dept. of Commodity Inspection of SH Customs

UPCOMING EVENTS

18 December 2019, in Beijing, European Chamber 1st Medical Device Forum, co-hosted by COCIR China

Refining the healthcare system has always been a priority for China during the country's reform process. As medical devices play a crucial role in the prevention, diagnosis, and treatment of diseases, this makes the products key to the goal of improving the overall health of the population, laid down in the government's strategic plan Healthy China 2030.

Therefore, the European Chamber and COCIR China will co-host the First Medical Device Forum, at the Hilton Hotel in Beijing, on 18th December 2019. The theme is 'Enhancing Healthy China: Medical Device Supervision and Innovation and Development of the Industry'.

See Agenda here, RSVP here by 16 December 2019.