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# MFDS leads development of international common guidelines with global leadership

- Taking part in the GHWP TC Leaders meeting
- MFDS, chair of GHWP WG1, leads development of international common guidelines and global regulations
- MFDS, actively supports excellent Korean medical devices to enter global market

The Ministry of Food and Drug Safety (Minister Oh Yu-Kyoung) exercised Korea's leadership in global regulations and sought ways to help Korean medical devices to be exported at the GHWP TC Leaders meeting, which was held in Shenzhen, China on 14th and 15th June.

* GHWP(**G**lobal **H**armonization **W**orking **P**arty) : Launched in 1996 to promote global regulatory harmonization for medical devices, the Global Harmonization Working Party(GHWP) is currently joined by 33 members including the US, Japan, China, and Singapore. It consists of a Technical Committee and eight Working Groups. South Korea served as a chair from 2015 to 2017.

Since 2018, the MFDS has served as the chair of GHWP WG1 and stepped up a cooperation framework with medical device regulators around the world. Given the recognition of its excellent review·approval regulatory competence, the Ministry was reelected as the chair this February. It will lead establishment and revision of international common guidelines on prior approval of medical devices for three years to come.

At this meeting, the MFDS presented plans to revise the international common guidelines, such as ❶'Requirements for Electronic Instructions for Use(e-IFU)'. The Ministry introduced Korea's innovative

medical device system to ❷government and industry representatives of GHWP member countries and displayed Korea's advanced regulatory science and rapid market entry of innovative medical devices to the outside world widely.

The MFDS also discussed future work plans with eight GHWP Working Groups actively while exchanging opinions on forming a joint working group among members of the GHWP-IMDRF for diverse cooperation among international medical device organizations.

**[MFDS-led establishment·revision plans for international common guidelines]**

- **In 2023, revision of the Principles of Regulatory Requirements for Electronic Instruction for Use(eIFU)**
- **In 2023, revision of the Categorisation of Changes to a Registered Medical Device**
- **In 2025, establishment of guidelines for definitions of AI(artificial intelligence)-based medical devices, white papers, and regulatory considerations**
- **In 2025, establishment of guidelines for review and approval of AI(artificial intelligence)-based tissue pathology in-vitro diagnostic medical devices**

Based on its high regulatory capacity, the MFDS will enhance its global leadership in the field of regulations by leading international cooperation. With such a strong global network for regulatory cooperation, the Ministry will make utmost efforts to support for Korean medical devices to be exported to the global market more easily and quickly.


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## Attachment 1 GHWP international common guidelines led by MFDS

### □ List of GHWP international common guidelines led by MFDS (6 in total)

| No. | Title of Guidelines | | Adoption |
|---|---|---|---|
| | MFDS(Korean) | AHWP(English) | |
| 1 | 경미한 변경 보고 가이드라인 | Guidance for Minor Change Reporting | November 2016 |
| 2 | 환자맞춤형 3D프린터 허가 가이드라인 | Guidance for Review and Approval on Customized Medical Devices Manufactured by 3D Printers | November 2017 |
| 3 | 동반진단기기 적합성평가를 위한 고려사항 가이드라인 | Guidance for Approval and Review of In Vitro Companion Diagnostic Devices | November 2017 |
| 4 | 전자사용설명서(e-IFU)의 규제 적용 | Requirements for Electronic Instructions for Use | November 2019 |
| 5 | 의료기기의 중대한 변경 시 고려사항 | Categorisation of Changes to a Registered Medical Device | November 2019 / Revised in February 2023 |
| 6 | 체외진단분석기 동일제품군의 변경허가 가이드라인 | Guidance for Approval of Replacement Reagent and Instrument Family | November 2021 |

| Attachment 2 | GHWP Technical Committee Leaders Meeting and Presentation |
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**< GHWP TC Leaders Meeting >**



**< Presentation on preemptive Korean regulations for such as innovative medical devices >**