

## [MDREX] 2023 Medical Device Expenditure Report Audit Plans by the MOHW

The MOHW instituted its audit of medical device company expenditure reports starting in 2018 and for 2023 it has publicized its plans to conduct audits on medical device company expenditure reports as follows:

As a background, the MOHW have instituted rules for medical device manufacturers/importers /distributors/sellers on economic benefits these businesses can provide to healthcare professionals and healthcare workers. Therefore, the act of providing samples, supporting healthcare professionals in academic conferences, supporting clinical trials, product presentations etc. would all be subject to the rules instituted by the MOHW. There are caps on these economic benefits detailed in the MOHW rules and such expenditures by medical device companies must be stored and maintained in the form of expenditure reports. If companies violate the maximum permitted economic benefit amount, the MOHW has the authority to criminally refer the company and associated individuals as the criminal statutes stipulates up to 3 years imprisonment or up to KRW 30 million in criminal penalty for such actions. In addition, companies would be subject to up to 3 months business suspension for the associated product if found guilty of providing improper benefits to healthcare professionals.

- ✓ **Target of 2023 MFDS audit:** all medical device manufacturers/importers/distributors/sellers in Korea
- ✓ **Audit:** 2022 expenditure reports retained by medical device companies
- ✓ **Duration:** between June 1 2023 to July 31 2023
- ✓ **Audit method:** Companies will be required to register/upload their 2022 expenditure reports to the government management system KOPS.

In addition, if a company is found to have recorded a fraudulent or false expenditure report, or if a company refuses to submit its expenditure report, it can also be subject to criminal referral for up to 1 year imprisonment or up to KRW 10 million in criminal penalty. Please let us know if you have any questions regarding this MFDS audit on medical device companies in Korea at [\*\*pro@mdrex.co.kr\*\*](mailto:pro@mdrex.co.kr)