

Committee on Oversight of Pharmaceuticals and Medical Devices Safety Regulation (CoPMed)

- Committee on Oversight of Pharmaceuticals and Medical Devices Safety Regulation (CoPMeD) was established in the Ministry of Health, Labour and Welfare (MHLW) in 2020, to monitor and assess administrative safety regulations of pharmaceuticals, etc.

Scope of works

(1) Monitoring and assessment of the implementation status of the administrative

CoPMeD monitors and assesses the implementation status of the administrative measures for ensuring safety of pharmaceuticals, etc. to:

- (a) secure safety and
- (b) prevent occurrence and spread of health and hygiene-related hazards caused by the use of pharmaceuticals, etc.

**final decision of safety assessment for individual pharmaceuticals, etc. will be made by the Pharmaceutical Affairs and Food Sanitation Council as before.*

(2) Opinions and recommendations to the Minister of Health, Labour and Welfare

On the basis of the results of assessment of implementation status of the measures, CoPMeD give the Minister of Health, Labour and Welfare opinions or recommendations on the measures which should be taken to secure safety, if necessary.

**Content of the opinions or recommendations shall be published without delay.*

**The Minister of Health, Labour and Welfare shall report the measures taken on the basis of the opinions or recommendations to the committee.*

Committee on Oversight of Pharmaceuticals and Medical Devices Safety Regulation (CoPMeD) cont.

Management rules of the CoPMeD

- (a) Committee members shall independently exert their authority.
- (b) Committee members shall be 10 or less in number. (Temporary members and expert members can be appointed.)
- (c) CoPMeD can also request the heads of relevant administrative organizations to collect information, submit documents and express opinions.
- (d) Health Science Division serves as the secretariat of the CoPMeD.