대한민국 대전환 한국판뉴딜

Ministry of Food and Drug Safety

Press Release

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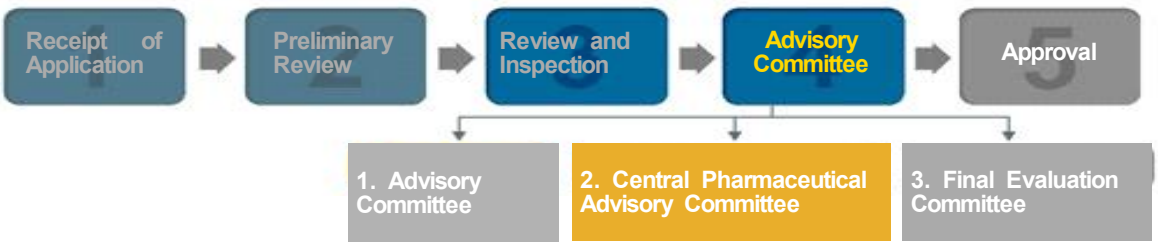
Divisions	· 바이오생약국 바이오의약품정책과 · 첨단제품허가담당관 · 코로나위기대응지원본부 백신심사반 총괄검토팀 · 백신심사반 임상심사팀 · 백신심사반 품질심사팀 · 백신심사반 비임상심사팀
Directors	· 김춘래 (☎043-719-3302) · 정현철 (☎043-719-5351) · 김희성 (☎043-719-5061) · 강주혜 (☎043-719-4151) · 김재옥 (☎043-719-3461) · 김세은 (☎043-719-3531)
Deputy Directors & Researchers	· 김지연 (☎043-719-3311) · 남주선 (☎043-719-5354) · 김지현 (☎043-719-5062) · 왕소영 (☎043-719-3077) · 김연희 (☎043-719-3463) · 송 현 (☎043-719-3538)

Central Pharmaceutical Advisory Meeting Outcomes on Janssen COVID-19 Vaccine

1 Current Review Status for Marketing Authorization



□ On April 1, the Ministry of Food and Drug Safety (MFDS, Minister Kim Ganglip) held a Central Pharmaceutical Advisory Committee (CPAC) meeting at its headquarters in Osong to seek advice on the safety and efficacy of the Janssen COVID-19 vaccine of Janssen Korea Ltd.

○ The meeting was attended by seventeen external experts including thirteen standing members of the Subcommittee of Biological Products, which is a subcommittee for deliberation, three from the Advisory Committee, and one recommended by the Korea Medical Association, as well as eight internal

experts from the Overall Evaluation Team, Clinical Review Team and Quality Review Team of the Vaccine Review Division in the COVID-19 Emergency Response Support Headquarters under the Ministry.

○ The MFDS seeks established multidisciplinary expert advice to secure expertise and objectivity throughout COVID-19 vaccine review and approval processes.

- The CPAC aims to provide advice on the safety and efficacy of new medicines in accordance with Article 18 of the Pharmaceutical Affairs Act.

- Given the gravity of the current pandemic, all COVID-19 vaccines and treatments must go through a three-tiered advisory process involving the CPAC as well as the COVID-19 Vaccine Safety and Clinical Efficacy Advisory Committee and the Final Evaluation Committee.

2 Purpose of the Meeting

□ The CPAC meeting was held to determine whether the Janssen COVID-19 vaccine may be recognized as safe and efficacious and whether to grant a marketing authorization based on the submitted documents such as clinical data.

○ Specifically, the advice sought at the meeting included overall advice on the vaccine's efficacy and safety as well as plans for post-authorization safety.

3 Outcomes of the Meeting

□ Based on the documents filed by Janssen Korea Ltd. for marketing authorization, the CPAC came to the following conclusions after discussing whether to consider the Janssen COVID-19 vaccine to be safe and efficacious.

○ The Committee recognized that the vaccine is necessary for preventive purposes against COVID-19, advising that the vaccine may be granted a

marketing authorization when taking into account the meeting outcomes of the Advisory Committee.

○ (**Overall Opinions on Efficacy**) In terms of the preventive effect of the vaccine according to the submitted data, the vaccine showed its efficacy at 14 and 28 days in people aged 18 and over after one dose of vaccination, which led to the conclusion that the vaccine has demonstrated sufficient preventive effect to be granted a marketing authorization along with a recommendation for monitoring and follow-up of data on long-term efficacy.

* efficacy at 14 days after vaccination: approx. 66.9% (116 confirmed cases in the vaccinated group and 348 in the control group)

* efficacy at 28 days after vaccination: approx. 66.1% (66 confirmed cases in the vaccinated group and 193 in the control group)

○ **(Safety)** Safety profile with reported adverse events from clinical trials was deemed to be within the acceptable level.

○ **(Plans for Post-authorization Safety)** The Committee concluded that the safety plans for the Janssen vaccine were appropriate, and recommended a post-authorization Risk Management Plan (RMP) to monitor and follow up on adverse events that have been reported during clinical trials.

○ With these conclusions, the Committee agreed that the Janssen COVID-19 vaccine of Janssen Korea Ltd. may be granted a marketing authorization.

4 Future Plans for Review and Approval

□ The MFDS will take into account all the information gathered from the Advisory Committee and the CPAC, including expert advice and recommendations as well as conclusions on the vaccine's efficacy, effectiveness and dosage regimen.

○ The Ministry will make a final decision on whether to grant a marketing authorization to the Janssen COVID-19 vaccine after examining necessary documents such as quality data in a final review by the Final Evaluation Committee.

☐ The MFDS will continue to do its utmost to ensure rigorous review and approval processes for COVID-19 vaccines and treatments while at the same time guaranteeing objectivity and transparency across all approval and review processes by taking into account multidisciplinary expert advice.