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2020 APEC Harmonization Center Annual Report Published by MFDS

- ☐ The Ministry of Food and Drug Safety (MFDS, Minister Kim Ganglip) published on June 15 the “2020 APEC* Harmonization Center (AHC) Annual Report” both in Korean and English to share AHC’s activities in medical products regulatory convergence.

* APEC (Asia-Pacific Economic Cooperation): An international organization established in November 1989 to accelerate regional economic integration and to leverage growing independence of the Asia-Pacific

- As a permanent center officially endorsed by APEC, the AHC was established in June 2009 under the National Institute of Food and Drug Safety Evaluation, MFDS, to facilitate regulatory harmonization among APEC Member Economies based on close cooperation with regulatory authorities (RAs), international organizations, industry and other stakeholders.

- The annual report aims to help regulators, industry and academia in the APEC region to better understand the goal and mission of AHC, and encourage their active participation in AHC’s activities.

- ☐ The published Annual Report outlines AHC’s key activities in 2020, including ▲ APEC’s Response to COVID-19, ▲ AHC’s Regulatory Convergence Activities for Medical Products (e.g. training, research, international cooperation) and ▲ Centers of Excellence (CoE) Activities.

- In 2020, AHC organized an APEC Virtual Workshop on Facilitated Regulatory Pathways (FRPs) to share APEC RAs’ regulatory approach to COVID-19 and application of expedited pathways. Moreover, AHC’s training on total life cycle of medical devices allowed participants to exchange best practices and experiences related to real-time PCR manufacturing and regulatory approval.

- In addition, AHC conducted a survey on Key Performance Indicators (KPIs) to measure APEC’s progress on regulatory convergence over the past decade and to set forth the future strategic direction. AHC also took part in an APEC Senior Officials’ Meeting to discuss ongoing activities for regulatory convergence and areas for further collaboration.

- MFDS participated in ICH and IPRP virtual meetings as an APEC representative to update on APEC’s current issues and its ongoing regulatory convergence activities and share the outcomes with APEC Member Economies.

- Furthermore, to provide in-depth training on regulatory convergence and foster regulatory experts, Center of Excellence (CoE) training was organized in the areas of Pharmacovigilance, Medical Device Vigilance and MRCT-GCP.

- ☐ As the Ministry in charge of overseeing AHC, MFDS will continue to commit itself to promoting regulatory convergence in enhancing public health and well-being in the APEC region and to helping the domestic pharmaceutical industry take a leap forward.

- The 2020 APEC Harmonization Center Annual Report is available on the MFDS website at www.mfds.go.kr or on the AHC website at www.apec-ahc.org.