HEALTH SCIENCES AUTHORITY
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HEALTH SCIENCES AUTHORITY, SINGAPORE, AND MINISTRY OF FOOD AND DRUG SAFETY, REPUBLIC OF KOREA, SIGN MUTUAL RECOGNITION AGREEMENT ON GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS

Singapore's Health Sciences Authority (HSA) and the Ministry of Food and Drug Safety (MFDS) of the Republic of Korea signed a Mutual Recognition Agreement (MRA) today on the establishment of requirements for Good Manufacturing Practice (GMP)[1] for Medicinal Products. The agreement was signed on behalf of the respective governments by the Chief Executive Officer of HSA, Dr Choong May Ling, Mimi, and the Minister of MFDS, Oh Yu-Kyoung, at the Shilla Hotel in Seoul, South Korea.

2 The MRA will enable the mutual recognition of GMP certificates and inspection outcomes of medicine manufacturers sited within the two countries. The key benefit is the reduction of regulatory burden on the pharmaceutical and biologics manufacturers in Singapore and South Korea through reducing duplicative onsite GMP inspections by both regulatory agencies. It improves efficiency by cutting down the resources needed to assess manufacturing sites. This will facilitate trade and access to medicinal products for consumers in both countries.

3 The areas of cooperation between HSA and MFDS will include the following:

- Mutual recognition of each other's GMP certificates for the manufacture of investigational medicinal products, active pharmaceutical ingredients, chemical pharmaceuticals, biopharmaceuticals (including biologicals) or herbal medicinal products.

[1] Good Manufacturing Practice refers to the quality assurance which ensures that medicinal products are consistently produced and controlled during manufacture to the quality standards appropriate to their intended use and as required by the marketing authorisation and product specifications.

- At the request of an importer, exporter, or authority (HSA or MFDS), the other authority is able to assess and certify that a manufacturer:
    - is appropriately authorised to manufacture the specified medicinal products or carry out the specified manufacturing operation;
    - is subject to regular inspections by the authority of the territory; and
    - complies with the Pharmaceutical Inspection Co-operation Scheme (PIC/S)[2] GMP standard.
- Exchange of information on GMP compliance (e.g., inspection reports).
- Either authority may request the right to conduct its own inspections of manufacturing sites located in the territory of the other authority in exceptional circumstances for the purpose of health and safety.

4 The longstanding partnership between the two authorities began with the signing of a Memorandum of Understanding (MoU) in 2010 with the then Korea Food & Drug Administration to establish a strong foundation of cooperation in the areas of health products regulation. This was followed by another MoU for GMP collaboration in 2019. Since then, dedicated collaboration and mutual learning between both regulatory authorities have paved the way for further synergy, leading to this MRA.

5 Says Dr Choong May Ling, Mimi, “HSA has always had close working ties with MFDS and I am pleased that we are able to strengthen the relationship through this cooperation. It is a testament to the shared commitment between the two national regulators as we continue to protect public health and safety in our countries. I trust that this collective dedication will pave the way for greater mutual support and information exchange as we uphold the high manufacturing and quality standards of medicinal products in our jurisdictions.”

6 Minister Oh Yu-Kyoung added, “I find it very meaningful to conclude the GMP MRA here in Seoul with Singapore who became one of WHO-Listed Authorities along with Korea based on the understanding and confidence of regulations of the two

[2] The Pharmaceutical Inspection Co-operation Scheme (PIC/S) was established in 1995 as a non-binding, informal co-operative arrangement between Regulatory Authorities to harmonise inspection procedures worldwide by developing common standards and mutual confidence in the field of GMP.

nations we built over time. Signing the MRA will pave the way for timely supply of safer and more effective medicinal products to the public by bilaterally recognising the results of conformity assessment of the two nations based on mutual trust."

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About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit http://www.hsa.gov.sg/.

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

About HSA's Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA ensures that medicines, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards. It contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.