



**HEALTH SCIENCES AUTHORITY  
PRESS RELEASE  
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## **HSA COLLABORATES WITH FOUR OVERSEAS REGULATORY AUTHORITIES TO ENABLE FASTER ACCESS TO AN INNOVATIVE TREATMENT FOR TWO SERIOUS EYE DISEASES**

The Health Sciences Authority (HSA) has collaborated with four other international regulatory agencies under the Access Consortium to enable faster access to a new therapeutic product, Vabysmo® (faricimab), for the treatment of two eye diseases that are leading causes of irreversible vision loss. These regulators are Health Canada (HC), the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom, the Swiss Agency for Therapeutic Products (Swissmedic), and Therapeutic Goods Administration (TGA) of Australia.

2 The review involved a five-way product evaluation that was accomplished through the Access Consortium's "New Active Substance Work Sharing Initiative" (NASWSI) for the first time. This multi-agency initiative aims to expedite patients' accessibility to novel medicines and treatment through enhancing efficiency of the regulatory review process and reducing duplication of efforts for both the regulators and the pharmaceutical company. Through the NASWSI, the company submitted the product application to the five agencies at the same time. The review work was divided among the five regulators to assess the safety, quality and efficacy of the therapeutic product, with each assessment further peer-reviewed by the regulators. The company then received a consolidated set of review questions from the Consortium, instead of having to address multiple sets of questions, had it filed separate applications with each regulator in each country.

3 The coordinated approach and communications between the Consortium's regulators and the product applicant also enhanced predictability and transparency. After the coordinated review, each regulator then made an independent decision whether to authorise the therapeutic product for their country. HSA has approved the therapeutic product based on the collaborative assessment that the product was

effective in improving vision or reducing vision loss in patients with neovascular (wet) age-related macular degeneration (nAMD) and diabetic macular oedema (DME) in clinical studies. nAMD and DME are progressive diseases that generally affect people over the age of 50 years or people with diabetes mellitus, and require long-term treatments.

### **About the Access Consortium**

4 The Access Consortium is a coalition of like-minded international health products regulatory authorities. It was renamed from the previous Australia-Canada-Singapore-Switzerland Consortium (ACSS), with the introduction of its newest consortium member, the UK MHRA, in January 2021. The new name reflects the group's key aim of providing patients with timely access to high-quality, safe and effective therapeutic products in the member countries.

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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](http://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.