



SINGAPORE, 13 SEPTEMBER 2022

HSA UPDATES

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HSA UPDATES NO 3/2022

HSA COLLABORATES WITH FOUR OVERSEAS REGULATORY AUTHORITIES TO ENABLE FASTER ACCESS TO TREATMENT FOR CHRONIC MYELOID LEUKAEMIA

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, Scemblix® (asciminib). 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 HSA has carefully considered the data on Scemblix® and assessed that the benefits outweighed the risks for use. HSA’s approval of Scemblix® was based on the Access Consortium’s collaborative assessment that the product is effective in treating adult patients with Philadelphia chromosome-positive chronic myeloid leukaemia (Ph+ CML) in chronic phase previously treated with two or more tyrosine kinase inhibitors (TKIs). The existing therapeutic options are limited for those patients who experience treatment failure or are intolerant to previous TKI therapy, in spite of the availability of TKIs that have improved treatment outcomes. These patients are at higher risk of progressive disease and have worse prognosis. HSA’s approval of Scemblix® aims to provide these patients access to an alternative treatment option.

Access Consortium’s work sharing initiative

3 The product was reviewed through a five-way product evaluation that was accomplished through the Access Consortium’s “New Active Substance Work Sharing Initiative” (NASWSI). 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, and further peer-reviewed by the regulators.

4 The company 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. This coordinated approach and communications between the Consortium's regulators and the product applicant has enhanced predictability and transparency in the review process. After the coordinated review, each regulator then made an independent decision whether to authorise the therapeutic product for their country.

5 To-date, HSA has approved 10 therapeutic products under the Access Consortium's work sharing initiative.

About the Access Consortium

6 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/>.

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