



SINGAPORE, 27 JUNE 2017

HSA UPDATES

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HSA UPDATES NO 2/2017

HSA UPDATES ON THE PHASING-OUT OF LYSOZYME-CONTAINING PRODUCTS AS THERAPEUTIC PRODUCTS

The Health Sciences Authority (HSA) has conducted a re-evaluation of the benefit-risk profile of lysozyme and concluded that it has failed to show efficacy. As such, HSA will be phasing out the use of lysozyme in therapeutic products in Singapore. Currently, lysozyme-containing products are approved as an expectorant and mucolytic for chronic sinusitis, as well as treatment for bleeding. The affected products are Neuzym (Eisai), Leftose (Wellchem), Neuflo (Yung Shin) and Lyzyme (Zyfas).

2 The re-evaluation was undertaken following the voluntary cancellation of the product Neuzym by the registrant (Eisai) in March 2016, due to the failure of recent post-marketing studies to show statistical significant differences in the efficacy of lysozyme compared to placebo. HSA concluded likewise that evidence from the post-market clinical studies as well as published literature to date had failed to show efficacy of lysozyme.

3 While lysozyme has a long history of use in Singapore since 1989 with no significant safety concern, the lack of efficacy rendered its use as a therapeutic product unjustifiable. Nonetheless, the lack of efficacy for therapeutic use does not preclude the use of lysozyme in other categories of health products such as health supplements.

4 Therefore, lysozyme-containing products will be de-registered as therapeutic products in Singapore. Considering the long history of use of lysozyme in Singapore and the acceptable safety profile, currently registered lysozyme-containing products will be allowed a grace period until 31 December 2018, before the products are removed from the Register of Therapeutic Products.

**HEALTH SCIENCES AUTHORITY
SINGAPORE
27 JUNE 2017**

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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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