FOR IMMEDIATE RELEASE

HEALTH SCIENCES AUTHORITY
PRESS RELEASE

19 September 2011

HSA SUSPENDS ZERIN® (PARACETAMOL) TABLETS 500MG

The Health Sciences Authority (HSA) is alerting members of the public to the suspension of the licence of Zerin® tablets 500mg. Zerin® tablets contain paracetamol, are manufactured by Jayson Pharmaceuticals Ltd and distributed in Singapore by Ziwell Medical (S) Pte Ltd. Zerin® tablets are used for the relief of fever and pain, and are available as an over-the counter (OTC) medicine.

2 Although the health risk to the individual consumer is low, HSA is suspending Zerin® tablets due to product defects recently found with this product. This is to prevent the exposure of members of the public to a product that is not compliant to quality standards. All sales and distribution of Zerin® tablets have been discontinued from the public healthcare institutions, private medical clinics and pharmacies.

3 From HSA's ongoing post marketing surveillance, four reports of product defects were investigated since August 2011 regarding Zerin® tablets, where some tablets from different batches were found to contain small foreign particles.

4 Testing by HSA's laboratories has shown that the foreign particles are inert, non-toxic substances and assessed to pose minimal risk to consumers. Tests also showed that the paracetamol content in Zerin® tablets complies with registered specifications.

HSA's Actions

5 After the initial reports of product defects, and as a precautionary measure, HSA has suspended the sales and distribution of Zerin® tablets since August 2011.

6 HSA is currently working with Ziwell Medical (S) Pte Ltd and Jayson Pharmaceuticals Ltd to ascertain the cause of the product defects in Zerin® tablets. This includes a planned on-site audit of the manufacturer to assess its facilities and processes, including the review of possible root causes for the quality defects, as well as any corrective and preventive actions taken to address the root causes.

7 HSA has also worked with the relevant drug companies and healthcare providers to ensure that there are sufficient supplies of other brands of paracetamol to meet national needs.

8 As an added precaution, HSA had suspended the local licences of all products manufactured by Jayson Pharmaceuticals Ltd. Besides Zerin® tablets, the other

product marketed in Singapore is Histacin® (chlorpheniramine) 4mg tablets, an antihistamine. The suspension of licence will disallow further sales of Histacin®.

Consumer Advisory

9 Consumers who have stocks of Zerin® tablets are advised to stop consuming the product. Consumers who have already taken the affected product should not be unduly alarmed as the product defect has been assessed to pose minimal risk to health.

10 Consumers who require paracetamol are advised to use any of the more than ten alternative brands of paracetamol tablets available in Singapore. Alternatively, they could also seek the advice of their healthcare providers.

11 Consumers may wish to contact Ziwell Medical (S) Pte Ltd at Tel : 9059 2771 / 9059 2775 / 9059 2779, or email : recallserve@gmail.com should they have any enquiries on this product suspension. Consumers may also contact the HSA hotline at Tel: 6866 3400 or email: hsa_info@hsa.gov.sg.

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- **About the Health Sciences Authority (HSA)**

The Health Sciences Authority (HSA) is a multidisciplinary agency that applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services, Applied Sciences, to protect and advance national health and safety. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. It operates the national blood bank, Bloodbank@HSA, securing the nation's blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit www.hsa.gov.sg.

- **About HSA's Health Products Regulation Group**

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

ANNEX A

FREQUENTLY ASKED QUESTIONS

1. Why is the license of Zerin ® tablets suspended?

The sales and distribution of Zerin ® tablets were suspended after HSA received reports of product defects. Some tablets from different batches were found to contain small foreign particles, which signalled a product quality defect. While investigations on the cause of the problem are still ongoing, suspension of Zerin® was initiated as a precautionary measure.

2. Are the foreign particles found on the Zerin® tablets harmful?

From HSA's laboratory testing, these particles are inert, non-toxic substances and assessed to pose minimal risk to consumers. All the batches tested complied with the product's specification for paracetamol content.

3. What should I do if I have already consumed the Zerin® tablets previously?

Those who have already taken the affected product do not need to be unduly alarmed as the particles in the tablets have been assessed to pose minimal risk to health.

Consumers who require paracetamol are advised to use any of the more than ten alternative brands of paracetamol tablets available in Singapore. Alternatively, they could also consult a medical practitioner for advice if they are in doubt.

4. What should I do with my existing Zerin® tablets?

Consumers are advised to stop consuming Zerin ®. Consumers who require paracetamol are advised to use any of the more than ten alternative brands of paracetamol tablets available in Singapore. Alternatively, they could also consult a medical practitioner for advice if they are in doubt.

5. What checks did HSA do before approving Zerin® tablets?

All western medicines such as Zerin ® need to be registered with HSA before they are made available for sale in the market. Companies need to provide the relevant data and studies to demonstrate that their products meet the international standards of safety, efficacy and quality. This information allows detailed assessments regarding the ingredients in the medicine, how effectively the medicine works for the purpose intended, and the severity of side effects.

Approval will be granted only after HSA is satisfied that the potential benefits of the medicine outweigh the likely risks for the intended uses of the medicine.

To ensure ongoing compliance to quality and safety standards for marketed medicines, HSA has in-place a post-market surveillance programme, as follows:-

i. Investigation and surveillance

Routine compliance and quality checks are conducted on marketed products and public feedback on product defects are investigated. .

Products that do not meet stipulated standards or found to pose risks to members of public may be suspended from further sales or recalled from the market.

ii. Adverse Drug Reaction (ADR) Monitoring Programme

HSA's ADR Monitoring Programme draws on the network of local healthcare professionals, who actively report adverse drug reactions to HSA and from the international network of national regulators to detect adverse effects and defects relating to health products.

We review scientific literature, company reports and safety signals detected by other drug regulatory authorities to ensure that the benefit-risk profile of the medicines continues to remain favourable after they are marketed in Singapore. This programme aims to detect significant safety signals that may arise so that appropriate actions can be taken to protect public health and safety.

In the event that the likely risks outweigh the benefits, HSA can initiate various courses of regulatory actions such as instituting label changes to enhance warnings or requesting companies to suspend sales and withdraw the medicine from the market.

ANNEX B

PICTURE OF ZERIN® TABLETS 500MG