

## Announcement regarding Recall of OTC Eye Drop Product

On April 21, 2011, Santen Pharmaceutical Co., Ltd. (Osaka, Japan / Ticker 4536) announced the recall of one production lot (please see below for details) of its *Sante Xyon* eye drops which were sold only in Japan. Santen identified a possibility that a small number of *Sante Xyon* which did not meet regulation standards may have been distributed to the market.

Please be advised that there is no risk in terms of safety of the recalled product and there is no potential harm to users' health. Santen truly apologizes for the inconvenience caused by the recall, and Santen will confirm to further strengthen its quality control so that a similar incident will not occur again.

- 1) Product Name : *Sante Xyon* Eye Drop
- 2) Subject Production Lot Number : ZN0076
- 3) Number of subject products : 30,600 units
- 4) Reason for the Recall  
Due to a malfunction of the filling machine during the manufacturing process, a small portion of the subject product was diluted by purified water used for pharmaceutical manufacturing. As Santen could not totally rule out the possibility of the affected product being distributed to the market, Santen has decided to recall the subject product.
- 5) Effect on Health Condition  
As the subject product has been diluted by purified water used for pharmaceutical manufacturing, there is no risk to users' health. To date, Santen has received no health complaints.

6) Recall Commencement Date : April 21, 2011

7) Recall Process

If you are in possession of the subject product with the manufacturing serial number ZN0076, please send F.O.D. to the address listed below.

Customer Center

Santen Pharmaceutical Co., Ltd.

3-9-19 Shimoshinjo, Higashiyodogawa-ku, Osaka 533-8651

TEL: 06-6321-8950

8) Contact

For inquiry regarding the product and the recall:

Customer Center

Santen Pharmaceutical Co., Ltd.

TEL: 06-6321-8950

For inquiry regarding this press release:

Corporate Communication Group

Santen Pharmaceutical Co., Ltd.

TEL: 06-6321-7007

<Subject Product>



<Top of the Box>

<Back of the Bottle>



Please see the manufacturing serial number (lot number) in the circled part of the product as per shown in the above pictures.