

**Notice Information: - Recall
18 June 2009**

Part 1. Product Information

- a) Title: 'First Steps' Medicine Feeder
- b) Product Name/Type: 'First Steps' Medicine Feeder
- c) Reference: IMB Safety Notice: SN2009(05)
- d) Manufacturer/Supplier: RSW International Limited, United Kingdom.

Part 2. Target Audience

- a) Target Audience: General public
Pharmacies
Retailers

Part 3. Problem/Issue

- a) Problem/Issue: Non-compliant 'First Steps' medicine feeders have been provided to retail outlets in Ireland by RSW International Limited. These medicine feeders are not appropriately CE marked.

Part 4. Background Information

a) Background Information:

The IMB is advising that non-compliant 'First Steps' medicine feeders have been provided to retail outlets in Ireland, including a number of discount retail outlets. These medical devices may also be available for sale on the internet.

These medicine feeders are marketed for the administration of liquid medicines to babies and young children. As they are not CE marked, it cannot be guaranteed that these products have been manufactured to the appropriate standards.

To date, there have been no incidents reported to the IMB in relation to the use of this device within Ireland. As a precautionary measure, as there is a potential for administration of incorrect dosage, the IMB advises all consumers to stop using 'First Steps' medicine feeders.

Part 5. Action to be taken

a) Action to be taken:

Advice for Pharmacies, Retailers and Wholesalers

Pharmacies, retailers and wholesalers should examine their stock to determine if they have any medical devices from the 'First Steps' medicine feeder range.

If you find that you have these products, cease sale of these products immediately and quarantine all stock. Contact the IMB immediately to obtain further instruction and guidance.

Also, should you discover any other similar brands of medicine feeders that do not carry the CE mark, please advise the IMB.

Advice for Consumers

Consumers should check their medicine feeders to determine if their device is branded 'First Steps' medicine feeder range.

If you find that you have one of these devices, discontinue use immediately and seek an alternative. Consumers with health concerns should consult with their general practitioner.

Part 6. Enquiries

a) All enquiries should be made to:

All adverse incidents relating to a medical device should be reported to the:

Human Products Safety Monitoring Department

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Telephone: +353-1-6764971

Fax: +353-1-6344033

E-mail: vigilance@imb.ie

Website: www.imb.ie

Enquiries to the manufacturer should be addressed to:

Mr. David Beaumont

RSW International Limited,

Unit 4 Cowm Top Business Park

Cowm Top Lane

Rochdale OL11 2PU

United Kingdom

Telephone: +44-845-226-8311

Fax. +44-845-226-8322

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SAMPLES OF

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SAMPLES OF THE 'FIRST STEPS' FEEDER RANGE

Part 7. Keywords

a) Keywords:

'First Steps' Medicine Feeder IMB Safety Notice: SN2009(05)