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

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MANUFACTURER/SUPPLIER

RSW International Limited, United Kingdom.

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TARGET GROUPS

General public Pharmacies Retailers



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.



BACKGROUND

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.

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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.

NOTICE

ACTION OR RECOMMENDATIONS

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.

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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.

ENQUIRIES

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 Beaumount 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

SAMPLES OF THE 'FIRST STEPS' FEEDER RANGE



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