IRISH MEDICINES BOARD
ADVISORY NOTICE

ADVISORY NOTICE

Medicine Feeders

(incl. spoons, droppers, syringes, and pacifiers/soothers)

IMB Safety Notice: SN2011(16)
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MANUFACTURER/SUPPLIER
Various

TARGET GROUPS
General public
Pharmacies
Hospital personnel
Retailers

ISSUE
Medicine feeders (incl. spoons, droppers, syringes, and pacifiers/soothers) are classified as medical devices. Such devices can be categorised as (1) Medicine feeders with volumetric markings or specifications and (2) Medicine feeders without volumetric markings or specifications. **Medicine feeders without volumetric markings or specifications are not intended to provide a measuring function or to accurately measure medicine doses.**

BACKGROUND
For companies wishing to place medicine feeders on the Irish market, they must be in compliance with Medical Devices Directive 93/42/EEC and S.I. No. 252 of 1994, as amended. As such, these devices and their labelling are required to bear a CE mark. There are two categories of medicine feeders:

1. **Medicine feeders provided with volumetric markings/specifications**
   Medicine feeders with volumetric markings or specifications are classified as class I medical devices with a measuring function. Notified body intervention is required for the aspects of manufacture concerned with the conformity of the metrological requirements as outlined in the Medical Devices Directive 93/42/EEC and S.I. No. 252 of 1994, as amended. These devices are required to bear a four digit notified body number under the CE mark on the device and its packaging.

2. **Medicine feeders provided without volumetric markings/specifications**
   Medicine feeders without volumetric markings or specifications are classified as class I medical devices. These devices are not intended to provide a measuring function or to accurately measure medicine doses. These devices are also required to bear a CE mark on both the device and its packaging. However, according to Medical Devices Directive 93/42/EEC and S.I. No. 252 of 1994, as amended, there is no requirement for a Notified Body to review any aspect of these devices and as such they will not bear a four digit notified body number.

ADVISORY NOTICE

The IMB has become aware of a number of non-compliant medicine feeders (incl. spoons, droppers, syringes, and pacifiers/soothers) that have been provided to pharmacy outlets, retail outlets and hospitals in Ireland. The non-conformances noted have varied from inadequacies in the labelling, to products that have not been assessed by a notified body. A number of customer communications regarding these non-conforming devices have already been issued by individual manufacturers/suppliers. These are included in the appendix below for your reference.

ACTION OR RECOMMENDATIONS

Advice for Pharmacists / Hospital personnel / Retailers

-Ensure that your staff is made aware of this advisory notice. Be aware of the differences between the above products and consider the intended purpose/accuracy of these products prior to use.

-In instances where a device is not supplied to the consumer with its original packaging/labelling, ensure that the use, accuracy, cleaning, etc of the device is clearly outlined to the customer.

Advice for Consumers

-Before using a medicine, particularly an oral liquid, ensure that you have confirmed with the pharmacist how it should be administered (i.e. by spoon, dropper, syringes or pacifier/soother).

-Ensure that you understand the dosage required and how best to measure the dose.

-Consumers with any concerns or questions should consult with their pharmacist or general practitioner.

ENQUIRIES

Should you note any further non compliant products please contact the medical device vigilance and compliance team at:

Human Products Monitoring
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

Appendix – Customer Communications