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27<sup>th</sup> July 2021

To:  
All Community Pharmacists

Dear Colleagues,

## **RISK TO PATIENT SAFETY: PARALLEL IMPORTS OF THICKENERS AND THICKENED ORAL NUTRITIONAL SUPPLEMENTS**

### **Background**

Food and drink texture modification (including medications) is widely accepted as a way to support the management of people with eating, drinking and swallowing difficulties (dysphagia).

In 2018, following an NHS improvement Patient Safety Alert [NHS/PSA/RE/2018/004](https://www.npsa.nhs.uk/alerts/nhs-psa-re-2018-004), the Department of Health issued [HSC \(SQSD\) 16 /18 Resources to Support Safer Modification of Food and Drink](#), which mandated the global International Dysphagia Diet Standardisation Initiative (IDDSI) terminology and provided implementation guidance across Health and Social Care settings.

This meant a change in the way in which dysphagia diets were classified, from the old “National Descriptors” to the new IDDSI levels. UK manufacturers of thickeners and thickened oral nutritional supplements changed their labelling and instructions accordingly. Speech and Language Therapists (SLTs) assess patients who need texture modified food and/or thickened drinks, and make recommendations on their required IDDSI level.

There was a transition period in 2018, with full implementation of the new framework in Northern Ireland by April 2019. HSCB previously wrote to

community pharmacies in November 2018 ([HSCB letter](#)) to highlight this change.

Following a review of Serious Adverse Incidents, Learning Circular **SQR-SAI-2021-075-(OPS/MHS/AS)** 'Risk of serious harm or death from choking on foods' was issued which highlighted the risks for people with dysphagia receiving food or drink with the incorrect IDDSI level. It also provided key learning points for all staff involved with supporting the care of adults who present at risk of eating, drinking and swallowing difficulties (reissued to Primary Care 14<sup>th</sup> June 2021).

**In summary, people with dysphagia must receive their recommended fluid and food consistency in order to reduce the risk of complications such as choking and aspiration.**

**Parallel imported nutritional product and risk to patient safety**

While IDDSI is the recognised international descriptor, not every country has adopted this framework. HSCB has received reports from SLTs and dietitians that patients have received parallel imported products dispensed from community pharmacies that could cause confusion and increase patient risk; these include thickening products that are not IDDSI compliant and thickened oral nutritional supplements in packs using older "Stage" terminology rather than the new "level" description. Specific products that the HSCB has been made aware of include Thick & Easy™ powder, Nutilis® powder and Fresenius® thickened oral nutritional supplements but this list may not be exhaustive.

**Example 1: Different Scoop Size**

Parallel import thickening products from countries that are not IDDSI compliant will have different mixing instructions on the labels, and different scoop sizes to the UK product. Incorrect mixing instructions and incorrect scoop size can lead to patients receiving the incorrect thickness of food/drink. This poses a significant risk to patients who need texture modified food and/or thickened drinks. **For example:**

<b>Parallel import from Germany</b>	<b>UK product</b>
Name: Thick & Easy™ powder Scoop size: 4.5g	Name: Thick & Easy™ <u>Original</u> powder Scoop size: 1.5g

In this case, the parallel import from Germany was over-labelled to reflect the IDDSI levels framework, but the scoop supplied was the old 4.5g size. Therefore, a patient assessed as requiring a Level 1 could potentially receive

5 x 4.5g scoops instead of 5 x 1.5g per 200ml of liquid. For patients with dysphagia this presents a significant risk.

### **Example 2: Non-IDDSI Descriptors Clearly Visible on Packaging**

For example :a parallel import pack of four bottles of Fresubin® Thickened was over-labelled with an IDDSI description on the top, but the sides of the pack and individual bottles were not. The parallel import product is similar in appearance to the UK product but includes the pre-IDDSI “Stage” descriptor, increasing the risk of an incorrect IDDSI level product being used, e.g. “Stage 2” is not equivalent to IDDSI “Level 2”.

#### **Actions for community pharmacies:**

- IDDSI implementation was completed in NI in 2019, and whilst HSCB recognises that community pharmacies may order parallel imports, it is strongly recommended that community pharmacies stock the UK version of dysphagia products where possible in the interest of reducing confusion and potential risk to this vulnerable patient group.
- In the event of a shortage of the UK product and a parallel import product is sourced, steps should be taken to ensure the patient/carer is adequately supported to use an equivalent dose.
- HSCB has received anecdotal reports of supply issues with nutrition products and would encourage community pharmacists to report supply issues to Community Pharmacy NI via their shortages reporter: [Medicine Shortage Reporter - Community Pharmacy NI](#). These issues will then be shared by CPNI with HSCB/DH for further investigation and action taken as appropriate. Reporting is important to ensure appropriate advice on safe use of alternative products can be issued in the event of a shortage of the UK product e.g. where only a parallel import product can be sourced.

#### Further guidance relevant to this letter:

Current guidance relevant to this guidance is noted below:

1. International Dysphagia Diet Standardization Initiative IDDSI – International Dysphagia Diet Standardisation Initiative [www.iddsi.org](http://www.iddsi.org).
2. NHS Improvement issued Patient Safety Alert NHS/PSA/RE/2018/004 “Resources to support safer modification of food and drink” detailed at: HSC (SQSD) 16 18.

Thank you for your co-operation.

Yours Sincerely,

**Joe Brogan**



**Assistant Director of Integrated Care**

**Head of Pharmacy and Medicines Management**

**Michelle Tennyson**



**Chair Dysphagia NI**

**Assistant Director, AHPS, PPI and Patient Experience**

Cc:

AAH/Sangers

Alliance

Phoenix

NI Pharma (info@nippharma.co.uk)

Trusts' Dietetic and Speech and Language Therapy (SLT) Heads of Service

Nutrition companies

**Contact  
details for**

**Local**

**Integrated**

**Care Offices:**

	<b>South Eastern</b>	<b>Southern</b>	<b>Northern</b>	<b>Western</b>
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BT2 8BS	Tel: 028 9536	2104	BT42 1QB	Londonderry
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