
Recommendations on GTIN Allocation on pharmaceutical products in the context of Brexit and the EU Falsified Medicine Directive

Purpose

This paper aims to provide high level **recommendations** for a harmonised approach to GTIN allocation on multi-market packs of pharmaceutical products supplied to the market in the United Kingdom in the context of Brexit and the implementation of the [EU Falsified Medicine Directive \(EU FMD, 2011/62/EU\)](#).

Audience

The main target audience for these recommendations paper are pharmaceutical manufacturers using GS1 standards to identify their products as required by the [EU FMD](#) and taking into account the need to change their practices for supplying the multi-market packs in the EU, in Great Britain and in Northern Ireland as a result of Brexit.

Scope

This paper focuses on regulated multi-market packs of pharmaceutical products being supplied to the markets in the EU, in Great Britain and in Northern Ireland. This document focuses only on the assignment and application of the 'unique identifier' requirement of the [EU Falsified Medicine Directive \(EU FMD, 2011/62/EU\)](#) and [Delegated Regulation \(2016/161\)](#), and not on the connection to the EU verification system.

Introduction

Great Britain became a third country to the EU as of 1 January 2021. In practice, this means that the unique identifier required by the EU FMD will not be relevant for pharmaceuticals supplied in Great Britain and that the relevant packs will no longer be required to be verified and decommissioned. This will in particular impact multi-market packs which were, before Brexit, supplied to UK, Republic of Ireland, Malta and Cyprus.

Under the terms of the [Northern Ireland Protocol](#), the EU FMD will still apply in Northern Ireland (NI), for at least four years (until the NI Protocol is due to be reviewed).

It is very important to note that at the time this paper was drafted, there was as yet no regulatory requirement on how to handle the unique identifier on packs supplied to the Great Britain market, nor on assignment of a new GTIN. In case of future regulations on these topics, any new regulatory requirement will supersede these recommendations.

Issue Statement

In this context, and although it is not a regulatory requirement for the time being, most of the pharmaceutical manufacturers have decided already to split their multi-market packs.

For manufacturers, several criteria have been taken into account to decide whether or not a new GTIN will be assigned to the Great Britain packs when splitting the multi-market packs (*non-exhaustive list*):

- **Internal supply chain management process** - the product volume is significantly high and the packs are not aggregated thus it would be resource-wise challenging to decommission each pack one by one upon export.

- **Potential market specific requirements** - there may be specific market requirements for pharmaceuticals identification in Great Britain in the future.
- **Different Market Authorisation Holders (MAH)** - the MAH regulatory approval for the EU is no longer valid for Great Britain and this implies the need for a specific Great Britain MAH on the packs, hence the need of a new GTIN to be assigned. Meanwhile, this provision has been withdrawn at this time.

The recommendations below are focused on the option where the manufacturer decides to assign a new GTIN to the Great Britain packs and the legacy GTIN remains on Northern Ireland, Cyprus, Malta and Republic of Ireland market packs. However, GS1 also acknowledges that manufacturers can decide to assign a new GTIN to the Northern Ireland, Cyprus, Malta and Republic of Ireland packs and the legacy GTIN remains on Great Britain market packs.

In both cases, the assignment of the GTIN is aligned with the GS1 standards provided that the packs for which a new GTIN is assigned can be distinguished from those already available on the relevant market. According to the GS1 "[GTIN Allocation Rules standards](#)", one unique GTIN needs to be assigned to each product offering (defined product configuration).

Recommendations for harmonised GTIN assignment related to multimarket packs which were, before Brexit, supplied to UK, Republic of Ireland, Malta and Cyprus

- A new GTIN will be assigned to the Great Britain packs resulting from the splitting of multi-market packs;
- The legacy GTIN can remain and used specifically for Northern Ireland, Cyprus, Malta and the Republic of Ireland in case of multimarket packs, since the legacy GTIN is already registered in the EU hub. It is also possible to consider stop using legacy GTIN for new batches and, in addition to the Great Britain GTIN, create a new GTIN for these multimarket packs;
- In some cases, a new specific Northern Ireland GTIN will be required because the range of products supplied on the market in Northern Ireland is different than that previously linked to the UK market and is not available in the Republic of Ireland. As a consequence, it could potentially be necessary to have one GTIN for each target market – one for Great Britain, one for the Republic of Ireland, Malta and Cyprus and a third one for Northern Ireland.