GS1 Finland

The Global Language of Business

Short guidance to using GTINs

Background

The EU directive on Falsified Medicines aims at prohibiting falsified medicines from entering into the legal supply chains. According to this directive and the defining delegated decrees, prescription medicines have to be labelled with a 2D-datamatrix containing an individual product number, a serial number, the shelf-life and the batch number. The 2D-datamatrix has to be printed on the outer packages from the beginning of 2019 at the latest.

The Nordic Vnr and the NTIN-code based on that, have served as the identifier of the packages in the barcode, but due to new identifying needs also the requirements have changed. The Vnr and NTIN don't always identify the package as precisely as they should. Therefore the transition to using GS1 GTINs instead of NTINs, is recommended as soon as possible and by 2019 at the latest. Changes should preferably be made when other changes are made to the outer packages of medicines.

Actions to be taken by the pharmaceutical company

1

•GET TO KNOW THE GS1-SYSTEM and THE GTIN REGULATIONS

GS1 customer service answers all your questions

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•GETTING A GS1 COMPANY PREFIX, IF YOU ARE STILL LACKING ONE

Company prefixes assigned by the GS1:

- 9-digit company prefix, from which a GTIN-code for 1 000 products can be made
- 7-digit company prefix, from which a GTIN-code for 100 000 products can be made

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•CREATING A GTIN-CODE FOR ALL PRODUCTS AND PACKAGE LEVELS

The holder of the GS1 company prefix creates the GTIN-codes independently and keeps a record of the used GTIN-codes:

- E.g. the 7-digit company prefix + elective 5 digits + check digit = 64YYYYY + AAAAA + T
- The GTIN-code has to be unique. We recommend consecutive numbering e.g. 00001, 00002, 00003 etc.
- The last digit, digit 13 is a check digit, that has to be counted separately for every GTIN-code. The check digit calculator can be found on the GS1 website.

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•ADMINISTRATING GTINs WITHIN THE COMPANY

The possessor of the company prefix is responsible for the GTIN administration. It's the company's responsibility to ensure that the GTINs are unique. Currently Lääketietokeskus assigns the NTIN-codes and answers for their uniqueness.

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•INVESTIGATING THE COMPLIANCE OF THE COMPANY'S INFORMATION SYSTEM AND PROCESSES WITH THE ADMINISTRATION OF GTINs - N.B.

If the company is operating in various facilities or countries, it should be clarified how the administration of the codes should be organised. Is it easier to handle codes on a facility base, where every facility has it's own company prefix? The company prefix doesn't have to be country specific, the same prefix can be used in many countries.

More information: http://wiki.vnr.fi/ and http://www.gs1.fi/

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