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Evolution of healthcare product coding and marking

Collaborators / authors

This document is the result of the work from the partners of the healthcare product distribution chain: suppliers (manufacturers or distributors) of medical devices, dietary products, derma-cosmetic products, veterinary products and other products, agents, wholesalers, professional associations of retail pharmacists, employers associations of hospital pharmacists.

Introduction

The coding evolution from 7 to 13 characters is common to medicinal products as well as healthcare products. There are several goals to this evolution: answer the expectable saturation of the 7-character code, adopt standards that internationally ensure the uniqueness and recognition of the code and be in line with the regulatory framework of traceability requirement for medicinal products and for some of the medical devices.

As regards human-use medicinal products, the AFSSAPS published a Notice in the 'Official Journal' of March 16, 2007, the purpose of which is the implementation of the coding evolution and the Data Matrix marking in order to support the information necessary for the batch traceability requirement in all pharmaceutical establishments (manufacturers, importers operators, agents, wholesalers and wholesalers distributors). By December 31, 2010 at the latest, this public health requirement will have to be based on one hand, on the evolution of coding from CIP7 to CIP13, and on the other hand, on the implementation of the Data Matrix marking which contains the CIP13, the batch number and the expiry date on the outer packaging.

Concerning medical devices, the Decree No. 2006-1497 from November 29, 2006, sets specific rules for medical device vigilance and modifies the Articles R5212-36 to 42 of the Public Health Code. The list of Medical Devices (MD) that are submitted to specific traceability rules provided under the aforesaid Articles as well as by the implementation schedule are established by the Order of January 26, 2007.This list concerns the MDs which include a substance that, if used separately, is likely to be considered as a blood-derived drug, heart valves and other implantable medical devices (including dental implants) with the exception of ligatures, sutures and osteosynthesis devices. Articles R5222-16 and 17 from the Public Health Code specify the traceability of in vitro diagnostic medical devices within the frame of reagent vigilance.

In November 2007, the AFSSAPS published recommendations for the attention of manufacturers of the medical devices concerned by the implementation of the traceability rules specified in the Decree of November 29, 2006, and the Order of January 26, 2007.

The AFSSAPS particularly recommends that: 'the use of bar codes (1 or 2 dimensions) as a coding system be retained and that the code appear on the unit packaging. In order to avoid mistakes in the choice of appropriate barcodes, it is advisable to gather all the necessary pieces of information into a single easily identifiable and understandable barcode'.

In this context, ACL, an interprofessional association which federates partners of the pharmaceutical distribution chain (suppliers, agents, wholesalers, retail and hospital pharmacists) has decided to change the ACL coding and healthcare product marking (MD, foodstuffs for particular nutritional uses, derma-cosmetic, veterinary and other products) in parallel to the evolution implemented in medicinal products. This decision makes it possible to meet the operational requirements requested by the actors and to answer the specific goal of securing the pharmaceutical chain. Within the frame of coding, ACL signed an agreement with GS1 in order to change the ACL coding for healthcare products from 7 to 13 characters according to the international standard.

Goal of the recommendation

Making available a reference document that is shared by all the actors in the pharmaceutical distribution chain; this document will specify the implementation schedule and conditions for the 13-character coding and marking for healthcare products.

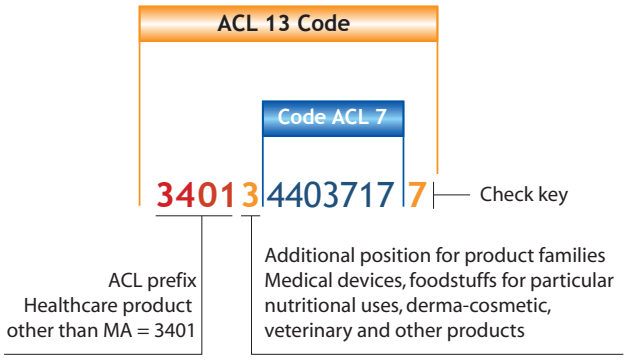
Healthcare product coding

Structure of the 13-character codes

Two 13-character coding types based on the GS1 international standard have been retained: ACL13 and GTIN (Global Trade Item Number). The ACL and GTIN codes can be used both in France and worldwide.

When codifying their healthcare products, every supplier has two options:
- Either continue entrusting ACL with the coding management (ACL13 codes),
- Or decide on a GTIN coding.

• The 13-character ACL code, managed by ACL, has the following structure:



The 13-character ACL code structure is based on the use of:
- a 3401 prefix which identifies the healthcare product outside the drug sector,
- an additional position used to differentiate product families,
- the 7-character ACL code which will gradually disappear,
- a check key.

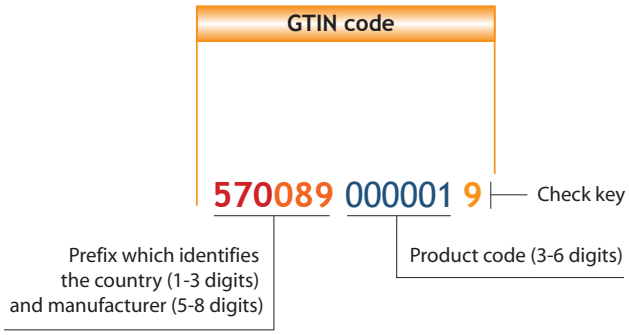
The codes are allocated by ACL according to the rules assumed by the profession (see www.aclclub.org).

The ACL7 code ranges used for coding healthcare products are as follows:

Healthcare products	ACL7 code ranges:
Display packs for items or items put together	250 000 to 269 999
Information media (books, DVD, etc.)	425 000 to 425 999
Items sold in communities or in hospitals	420 000 to 424 999 426 000 to 489 999 600 000 to 669 999 700 000 to 799 999 950 000 to 999 999

The 950,000 to 999,999 range of ACL codes has been used for healthcare product codification since the other ranges were saturated.

• The GTIN code, managed by the manufacturer, according to the following structure:



The manufacturer decides on the 13-character reference code

It is essential that every product has a 13-character reference code and only one.

Therefore, it is crucial that every supplier commits themselves to:
- Using this code and only this one for exchanges (orders, invoices, dispute resolution) with the partners of the pharmaceutical distribution chain;

- Declaring this code and its updates to the ACL association in order for them to ensure the transmission to the actors in the distribution chain: wholesalers, retail and hospital pharmacies.

Cross-referencing the ACL7 codes and the 13-character reference codes

Between January 2009 and December 2010, ACL keeps on allocating ACL7 codes as well as 13-character codes. Upon request from the actors of the pharmaceutical distribution chain, ACL manages a cross-reference table for ACL7/13-character codes (ACL13 or GTIN).
It is essential for any manufacturer who selects the GTIN code as a reference code to inform ACL, so that ACL can manage and distribute the link between the ACL7 and the 13-character reference code.
This cross-reference table is necessary during the transitional scale-up period when both 7-character and 13-character codes coexist. It ensures that all retail pharmacies may order any product, whatever their computer system and whatever the code 13 selected by the supplier. This table also ensures the recognition and uniqueness of the product reference code (whether ACL13 or GTIN) by all the actors in the pharmaceutical distribution chain.

ACL manages a product database, an interprofessional reference that makes it possible to distribute the cross-reference table as well as the regulatory and descriptive structured data.

Implementation schedule for the 13-character code (Figure 1)

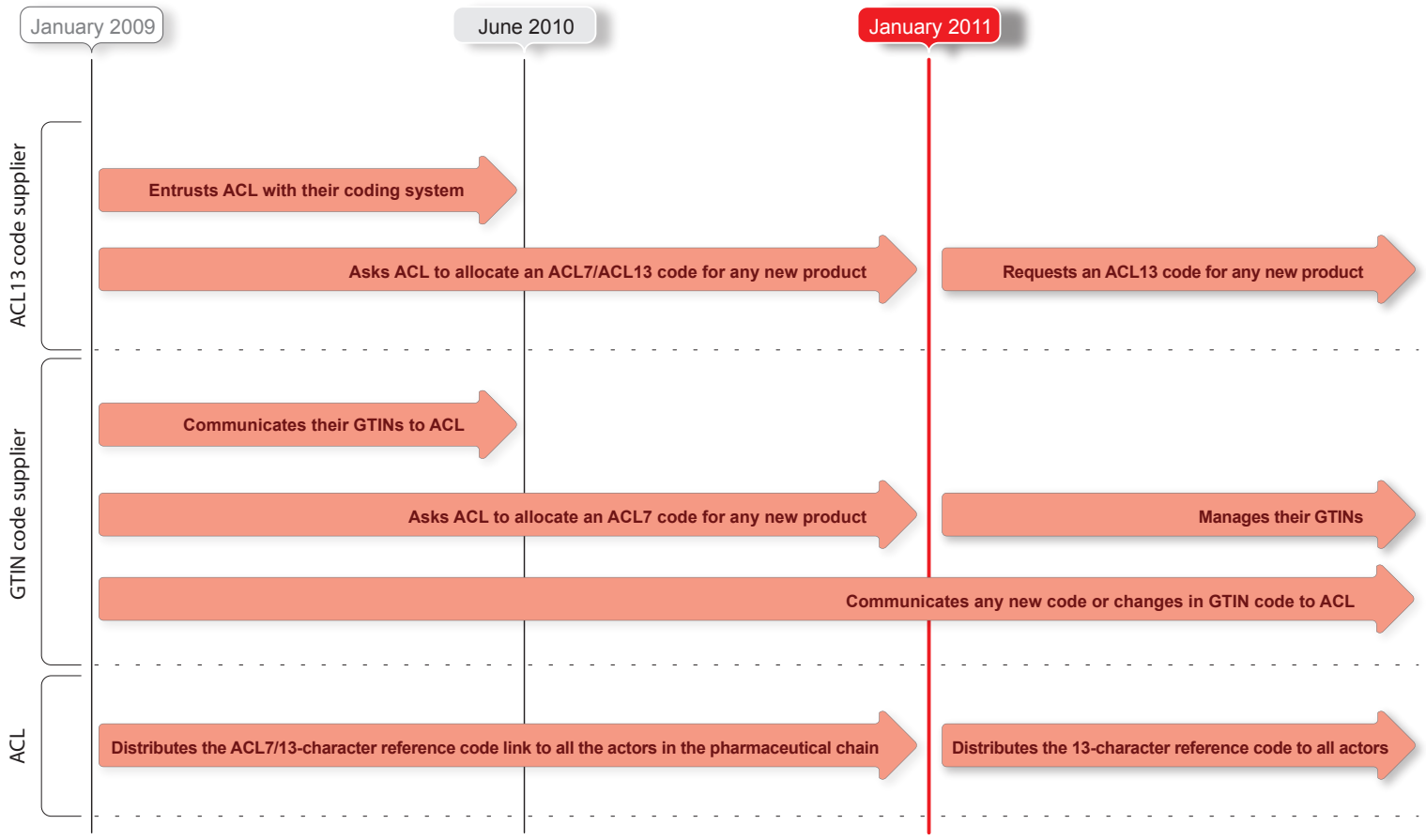
By June 2010 at the latest, the suppliers must identify each of their products with a unique 13-character code (ACL13 or GTIN) which is essential to the pharmaceutical logistics circuit and must communicate this code to ACL.

Suppliers choosing an ACL13 coding

- Up to December 2010:
  For all new products, the supplier asks ACL to allocate an ACL7 code as well as an ACL13 code including the ACL7 code and its check key.
  ACL circulates a cross-reference table for ACL7/13-character reference codes.

- From January 2011 on:
  For all new products, the supplier asks ACL to allocate an ACL13 code, but this code will not be linked to the ACL7 code.

Figure 1: Healthcare product coding – Implementation schedule for the 13-character code



Suppliers choosing a GTIN coding

- Up to December 2010:
  For all new products with a GTIN code, the manufacturer asks ACL to allocate an ACL7 code. Any new GTIN code and any change in GTIN code must be communicated to ACL by the manufacturer. ACL circulates a cross-reference table for ACL7/13-character reference codes.

- From January 2011 on:
  The manufacturer must communicate any new code and any change in GTIN code to ACL. The manufacturer must also report to ACL any change that is made in the descriptive data of its items (name of product range or brand, shape, size, number of units, etc.) as the data are required for the update of the interprofessional database which is distributed to all actors.

Healthcare product marking

Types of marking

The types of marking which were retained for the healthcare products distributed in the pharmaceutical circuit are as follows:

- **EAN-13 linear barcode** to mark the 13-character reference code

- **GS1-128 linear barcode** to mark the 13-character reference code, expiry date and batch number

- **ECC200 two-dimensional Data Matrix marking** to mark the 13-character reference code, expiry date and batch number (see the 'Cahier CIP/ACL' No 1: Technical characteristics of the Data Matrix)

Both the GS1-128 linear barcode (1D) and the ECC200 two-dimensional Data Matrix marking (2D) contain data that are organized according to the GS1-128 syntax.
These markings are helpful if an expiry date and a batch number are associated with the product code.

Each data is preceded with a data identifier (Application Identifier, AI). This is used to be certain of the nature of the data that follows.

The identifiers that are used within the frame of this recommendation are:
01 followed by the product code,
17 followed by the expiry date,
10 followed by the batch number.

It is not recommended to mark the product identifier code only in a linear GS1-128 barcode or in Data Matrix. Other data may be added to the recommended data. However, the data must necessarily be spotted by a data identifier or 'AI' that is standardized by GS1 (for instance, AI 11 defines the manufacturing date, AI 21 the serial number, etc.) If some of this data are not standardized, are for internal use and never used in the distribution chain, the AIs to be used must be within 91 and 99.They can identify some alphanumeric data of variable length with a maximum of 30 characters.

Structure of the data:
In order to indicate to the reader and associated software that it is GS1-128 syntax in a GS1-128 barcode or Data Matrix, the data must be preceded with 'FNC1', for which the value is ASCII 232. This character is operated by the reader but not transmitted.
The information which comes after each data identifier have a specific structure:
01 identifies the product code with a fixed length (13 characters). For healthcare products, the product code is either ACL13 or GTIN. This code must be expressed in 14 characters. Therefore, a zero '0' is added in front of ACL13 or GTIN. The addition of a zero does not change the check key.
17 identifies the expiry date, with a fixed length and expressed on 6 characters according to the YYMMDD format. If the day is not mentioned, it must be replaced by '00' (zero zero) which, as a rule, corresponds to the last day of the month. This format is different from the clear date format expressed by year and month.
10 identifies the batch number, with variable length from 1 to 20 numeric or alphanumeric characters. The first character must preferably be other than zero so that the interpretation is not ambiguous. This batch number must be strictly identical to the number marked in plain text, with the same characters: dashes, dots, etc. It is recommended to avoid punctuation marks in batch numbers. As the batch number varies in size from one item to the other, it is advised to place it in the end-of-data position.

Example
FNC1010340134403717717YYMMDD10A11111
If not the case, it is necessary to indicate the end of the batch number by the 'GS' group separator character which has the value of ASCII 29.
This character enables to close the data fields that have variable length. In order to comply with the GS1-128 syntax, the AIs must not be framed within brackets when encoding the data in the GS1-128 barcode or Data Matrix. Brackets are only used to print the structured form in plain text with the AIs and facilitate reading by the human eye.
(01)03401344037177(17)YYMMDD(10)A11111
Note: printing this structured form is not mandatory if the product code, batch and expiry date data are already printed in plain text on the packaging.

The information included in the GS1-128 barcode or Data Matrix must be strictly identical to the information structured with the AIs, which may be printed in plain text near the marking, and to the dematerialized information transmitted by EDI.

• LPPR Label
As a complement, for refundable healthcare products, the LPPR label bears a 128 barcode marking that includes the 13-character reference code (optional) and the LPPR code, as defined in the Order of June 26, 2003, concerning the coding of the list of refundable products and benefits provided under Article L.165-1 of the Social Security Code and the Notice to manufacturers and distributors of products or benefits listed in the list provided under Article L.165-1 of the Social Security Code, published in the OJ of September 6, 2003.

Marking schedule for outer packaging (Figure 2)

• Up to late 2010:
It is recommended to keep writing the ACL7 code in plain text.
Marking the 13 code is possible as soon as 2009.

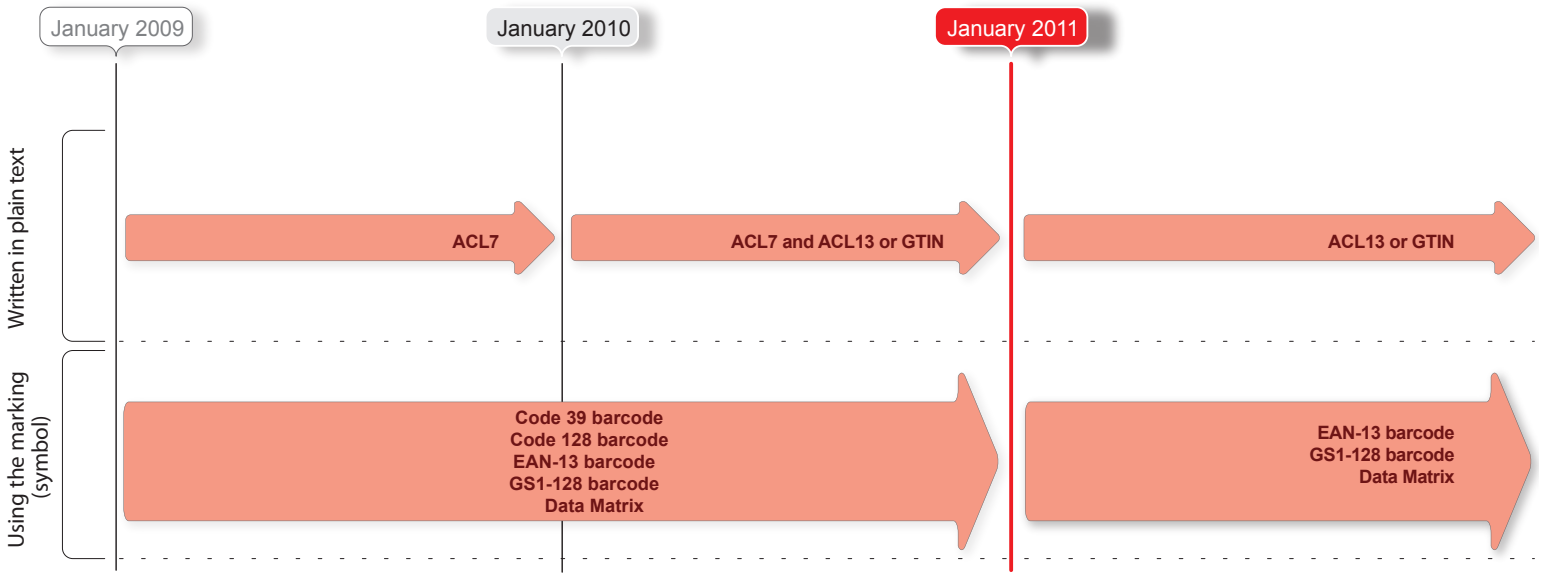
• From January 2010 to December 2010:
It is advised to start marking the 13-character reference code, using preferably one of the following markings:
- EAN-13 barcode for the 13-character reference code (ACL13 or GTIN);
- GS1-128 barcode for the ACL13 or GTIN, batch number and expiry date;
- ECC200 Data Matrix for the ACL13 or GTIN, batch number and expiry date.

Marking the code 13 in code 39 barcode or code 128 barcode is possible during this transitional period but these markings are not recommended beyond 2010.

For manufacturers whose packaging chains are Data Matrix-equipped, the double marking ACL7 in barcode 39 and ACL 13, and expiry date in Data Matrix are recommended. It will enable the users who are not equipped with Data Matrix readers to continue reading the product code automatically.

• From January 2011 on:
It is recommended to write the 13-character reference code both in plain text and in EAN-13 barcode or GS1-128 barcode or Data Matrix marking on the outer packaging of all healthcare products.

Figure 2: Healthcare product marking - Marking schedule for outer packaging



Whenever possible, it is recommended to use only one marking type on a given packaging. Multi-marking impedes the reading and does not allow product management by automatons.

However, during the transitional period, a 7-character code marking and a 13-character code marking may be necessary. This is particularly the case when ensuring that all pharmacists may read at least one marking, even if they don't have Data Matrix readers.

For implantable medical devices and in vitro diagnostic medical devices, the GS1-128 barcode or ECC200 Data Matrix are used to mark the product code, batch number and expiry date, to meet the regulatory requirement of traceability.

Generally speaking, the GS1-128 structured markings (GS1-128 barcode (1D) or Data Matrix (2D) according to the packaging sizes) are preferable for products with expiry dates.

Wholesalers, retail and hospital pharmacies must equip themselves with readers that can read both GS1-128 barcode (1D) and Data Matrix (2D). At the same time, they must develop the software applications so that they can manage 13-character codes and interpret the data acquired via the automated reading of the outer packaging marking.

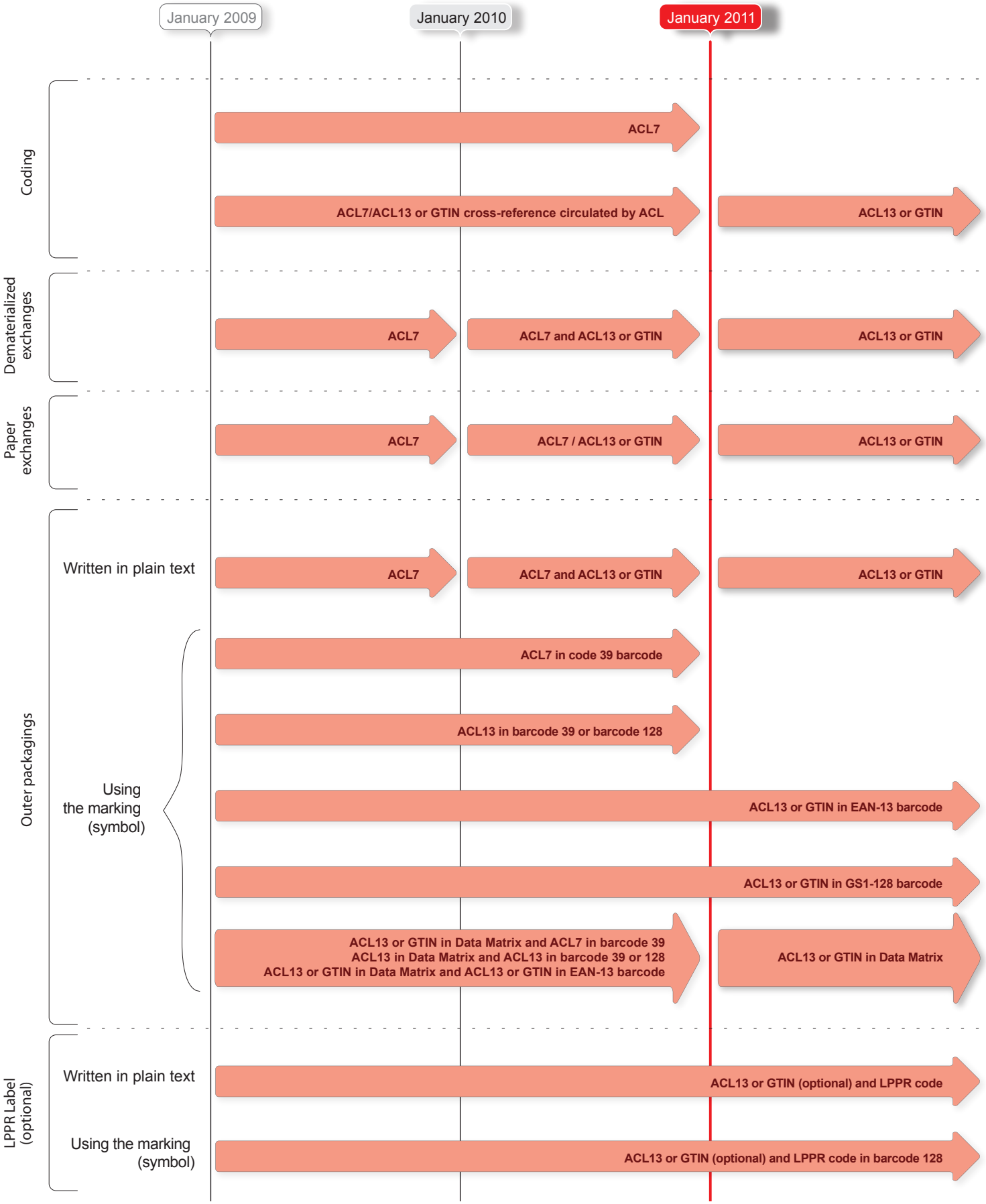
Dematerialized exchanges

For dematerialized exchanges between agents, wholesalers, suppliers, the following schedule is recommended:

- Priority No 1: **New format for the order with 13-character codes**
  Initiation of the test phase in June 2009 at the latest, for a release by all actors in January 2010
- Priority No 2 : **Complete dispatch notice and standard carton labels (DESADV);**
  Straightaway and in June 2009 at the latest
- Priority No 3 : **Acknowledgment of receipt for delivery;**
  At the latest in June 2010 and provided that the dispatch notice has been implemented for most of the flows
- Priority No 4 : **New format for the order with enriched message;**
  After June 2010
- Priority No 5 : **Acknowledgment of receipt for the order;**
  After June 2010.

For these exchanges, it is advised to indicate the ACL7 code as the main code and the 13-character code as a supplementary code up to December 2010. Starting in January 2011, the 13-character code will become the main code.

Evolution schedule of healthcare product coding and marking



Abstract

The coding evolution from 7 to 13 characters is common to medicinal products as well as healthcare products. It is necessary to answer the expectable saturation of the 7-character codes and to go along with the implementation of traceability. For all healthcare products (Medical devices, Foodstuffs for particular nutritional uses, Derma-cosmetic, Veterinary and other products) the partners from the pharmaceutical distribution chain have chosen to retain the international coding standards (ACL13 or GTIN) and marking (EAN-13 barcodes, GS1-128 barcodes or Data Matrix). They have decided to apply these changes on January 1st, 2011, at the latest, in parallel to the changes defined for human drugs (see the Cahiers CIP-ACL No 1 and 2). The purpose of Cahier No 3 is to specify the implementation schedule and conditions for the 13-character coding and marking for healthcare products, as defined by all the actors in the pharmaceutical chain.

The ACL recommendation ensures the consistency on how all the healthcare products distributed in the pharmaceutical circuit are treated, as well as the continuity of interprofessional exchanges, especially during the transitional period to the end of 2010.
During all this period, the cross-correspondence table will be available on the www.aclclub.org website.

KEY WORDS

Healthcare products – Medical devices – MD – Foodstuff for particular nutritional uses – Derma-cosmetics – Veterinary products – Coding – Marking – Traceability – ACL7 – ACL13 – GTIN – Barcode 39 – Barcode 128 – EAN-13 barcode – GS1-128 barcode – Data Matrix – GS1-128 syntax – 13-character reference code – Batch number – Expiry date – Printing – Schedule – Transitional period – Cross-reference table

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