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Implementation of traceability of medicinal products for human use

Questions and Answers

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Introduction

In the Official Journal of 16 March 2007, the AFSSAPS published a notice for the holders of marketing authorisation for medicinal products for human use and for head pharmacists working in the pharmaceutical establishments of manufacturers, importers, operators, consignees, wholesalers-dispatchers and wholesale distributors.

This notice covers the review of the coding and labelling system relating to medicinal products for human use in order to support the compulsory information required for tracing medicinal products from the manufacturer to the patient.

Article R5124-58 of the French Public Health code was amended and published in the Official Journal on 24 August 2008 (Order no. 2008-834 of 22 August 2008 – art.2). It specifies that "for each incoming and outgoing transaction, the number and expiry date of all batches must be conserved along with the quantities supplied or received per batch. This shall become compulsory on 31 December 2010".

The outer packaging of medicinal products shall bear the CIP13 code, batch number and expiry date, marked in plain text. ECC 200 Data Matrix marking will be used. This is an international standard and will enable the CIP13 code, batch number and expiry date to be acquired automatically when the label is scanned.

A schedule has been implemented to define the dates of publication of CIP7 and CIP13 switched codes as of 2007, possible implementation of the first Data Matrix system on 1 January 2008, allocation of the first CIP13 codes only on 1 January 2009 and the deadline of 31 December 2010, date on which all medicinal products are to bear the new GS1 -128 coding and ECC 200 Data Matrix marking.

This document follows an initial document published in November 2007, defining the technical characteristics of Data Matrix, a medicinal product traceability support (See "Cahier no. 1" at www.cipclub.org).

Purpose

This document aims to specify the practical methods for implementing traceability of medicinal products for human use, within the framework of the schedule defined by the AFSSAPS (see opinion in the Official Journal of 16 March 2007).

Prior to the deadline on 31 December 2010, various types of marking may coexist during the transition period from January 2009 to December 2010.

This document specifies the various markings that will enable all concerned by the new system to at least read the CIP code; they will appear alongside CIP13 marking, the batch number and expiry date in a Data Matrix that must be implemented as early as possible.

Schedule for the review of codification and implementation of medicinal product marking (exiting the production line) – CIP Recommendations according to the opinion published in the Official Journal on 16 March 2007.

Schedule for MA granted prior to 1 January 2009

				Jan. 2007 to Dec. 2007	Jan. 2008 to Dec. 2008	Jan. 2009 to Dec. 2009	Jan. 2010 to Dec. 2010	Compulsory as of January 2011
		Codification		CIP7/CIP13 Cross-reference table published by the AFSSAPS (1st quarter 2007 and end 2008) published by CIP monthly		CIP7/CIP13 Cross-reference table published by CIP monthly		CIP13
		Dematerialised exchange		CIP7		CIP7 or CIP13	CIP13	CIP13
		Paper exchange		CIP7			CIP13	CIP13
Packaging lines not equipped with the Data Matrix system up to the end of 2010	Reimbursable proprietary medicine and non-reimbursable proprietary medicine	Packaging marking	Plain text	CIP7				CIP13
			In the symbol	CIP7 in barcode 39 format				CIP13 code in Data Matrix (with batch number and expiry date)
		Label marking	Plain text	CIP7				CIP13
			In the symbol	CIP7 in barcode 128 format				To be defined
Packaging lines equipped with the Data Matrix system before the end of 2010	Reimbursable proprietary medicine	Packaging marking	Plain text	CIP7	CIP13			CIP13
			In the symbol	CIP7 in barcode 39 format	CIP13 code in Data Matrix (with batch number and expiry date)			CIP13 code in Data Matrix (with batch number and expiry date)
		Label marking	Plain text	CIP7		CIP13		CIP13
			In the symbol	CIP7 in barcode 128 format				To be defined
	Non-reimbursable proprietary medicine	Packaging marking	Plain text	CIP7	CIP13			CIP13
			In the symbol	CIP7 in barcode 39 format	CIP13 code in Data Matrix (with batch number and expiry date) AND CIP7 in barcode 39 format OR CIP13 in barcode 39 or 128 format (subject to software management)			CIP13 code in Data Matrix (with batch number and expiry date)

Schedule for MA granted after 1 January 2009

				Jan. 2007 to Dec. 2007	Jan. 2008 to Dec. 2008	Jan. 2009 to Dec. 2009	Jan. 2010 to Dec. 2010	Compulsory as of January 2011
		Codification				CIP13 **The AFSSAPS will only allocate CIP 13 codes for recent MA** (CIP13 incorporating a CIP7 code selected from the 3, 49 and 51 to 54 code ranges)		CIP13 (without CIP7)
		Dematerialised exchange				CIP13		CIP13
		Paper exchange				CIP13		CIP13
Packaging lines not equipped with the Data Matrix system up to the end of 2010	Reimbursable proprietary medicine and non-reimbursable proprietary medicine	Packaging marking	Plain text			CIP13		CIP13
			In the symbol			CIP13 in barcode 39 or 128 format		CIP13 code in Data Matrix (with batch number and expiry date)
		Label marking	Plain text			CIP13		CIP13
			In the symbol			CIP7 in barcode 128 format		To be defined
Packaging lines equipped with the Data Matrix system before the end of 2010	Reimbursable proprietary medicine	Packaging marking	Plain text			CIP13		CIP13
			In the symbol			CIP13 code in Data Matrix (with batch number and expiry date)		CIP13 code in Data Matrix (with batch number and expiry date
		Label marking	Plain text			CIP13		CIP13
			In the symbol			CIP7 in barcode 128 format		To be defined
	Non-reimbursable proprietary medicine	Packaging marking	Plain text			CIP13		CIP13
			In the symbol			CIP13 code in Data Matrix (with batch number and expiry date) AND CIP13 in barcode 39 or 128 format		CIP13 code in Data Matrix (with batch number and expiry date

Medicinal product packaging marking during the transition period from January 2009 to December 2010

For MA granted prior to January 2009

Packaging lines not equipped with the Data Matrix system

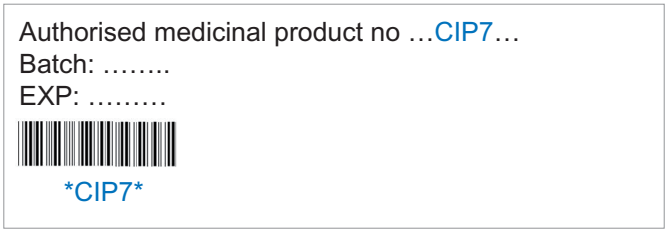
Non reimbursable medicinal product:

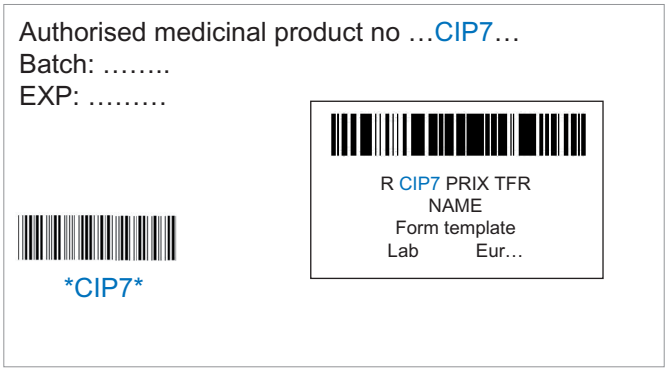
Packaging
- Compulsory marking in plain text notably includes: MA no. (CIP7 code), batch no. and expiry date (see art R5121-138 of the French Public Health Code)
- CIP7 marking in barcode 39 format

Reimbursable medicinal product:

Packaging
- Compulsory marking in plain text notably includes: MA no. (CIP7 code), batch no. and expiry date (see art R5121-138 of the French Public Health Code)
- CIP7 marking in barcode 39 format

Label
- CIP7 marking in barcode 128 format (CIP7 code preceded by a character indicating the reimbursement rate, followed by 6 characters for the price and 2 for the TFR) + CIP7 code in plain text (see order of 21.02.96 and following)





Packaging lines equipped with the Data Matrix system

Non reimbursable medicinal product:

Packaging
- Compulsory marking in plain text notably includes: MA no. (CIP13 code), batch no. and expiry date (see art R5121-138 of the French Public Health Code)
- CIP13 marking, batch no. and expiry date in a Data Matrix [(01)0**CIP13**(17)YYMMDD(10)batch no.]

AND
- CIP7 marking in barcode 39 format

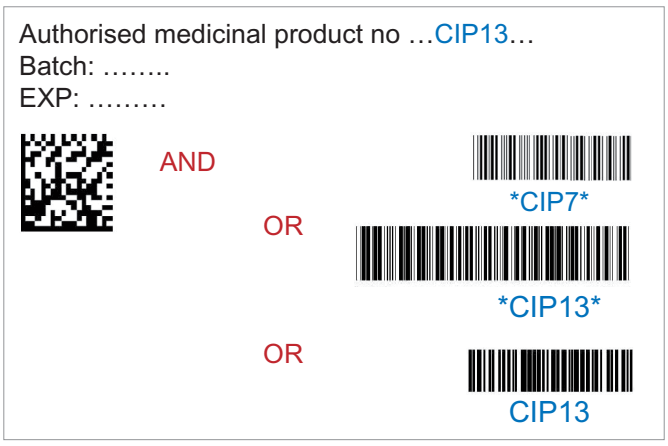
OR
- CIP13 marking in barcode 39 format

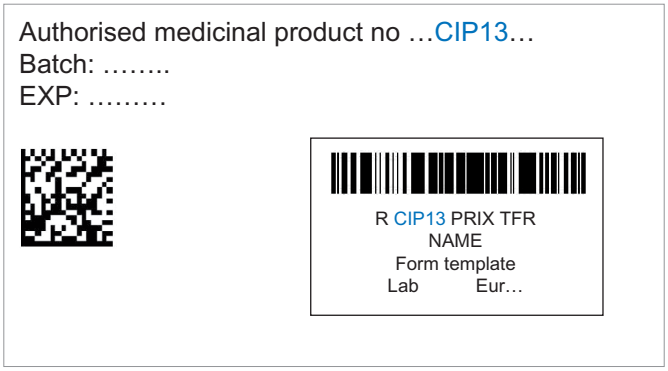
OR
- CIP13 marking in barcode 128 format

Reimbursable medicinal product:

Packaging
- Compulsory marking in plain text notably includes: MA no. (CIP13 code), batch no. and expiry date (see art R5121-138 of the French Public Health Code)
- CIP13 marking, batch no. and expiry date in a Data Matrix [(01)0**CIP13**(17)YYMMDD(10)batch no.]

Label
- CIP7 marking in barcode 128 format (CIP7 code preceded by a character indicating the reimbursement rate, followed by 6 characters for the price and 2 for the TFR) + CIP13 code in plain text (see order of 21.02.96 and following and order of 25 September 2008)





For MA granted after January 2009

Packaging lines not equipped with the Data Matrix system

Non reimbursable medicinal product:

Packaging
- Compulsory marking in plain text notably includes: MA no. (CIP13 code), batch no. and expiry date (see art R5121-138 of the French Public Health Code)
- CIP13 marking in barcode 39 format

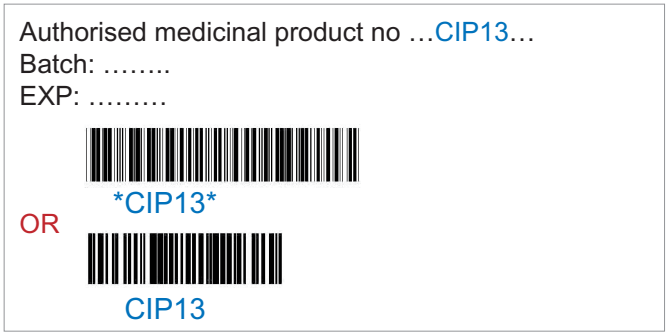
OR
- CIP13 marking in barcode 128 format

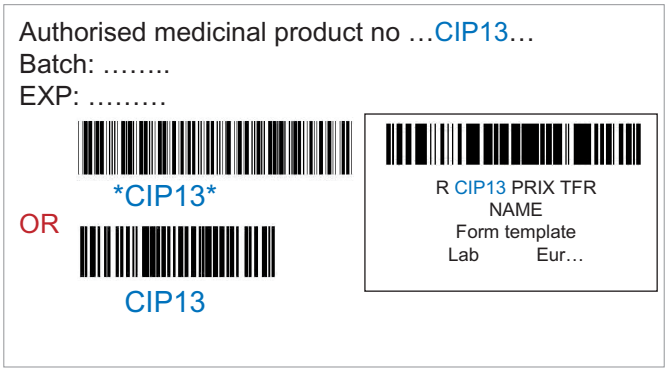
Reimbursable medicinal product:

Packaging
- Compulsory marking in plain text notably includes: MA no. (CIP13 code), batch no. and expiry date (see art R5121-138 of the French Public Health Code)
- CIP13 marking in barcode 39 format

OR
- CIP13 marking in barcode 128 format

Label
- CIP7 marking in barcode 128 format (preceded by a character indicating the reimbursement rate, followed by 6 characters for the price and 2 for the TFR) + CIP13 code in plain text (see order of 21.02.96 and following and order of 25 September 2008)





Packaging lines equipped with the Data Matrix system

Non reimbursable medicinal product:

Packaging
- Compulsory marking in plain text notably includes: MA no. (CIP13 code), batch no. and expiry date (see art R5121-138 of the French Public Health Code)
- CIP13 marking, batch no. and expiry date in a Data Matrix [(01)0**CIP13**(17)YYMMDD(10)batch no.]

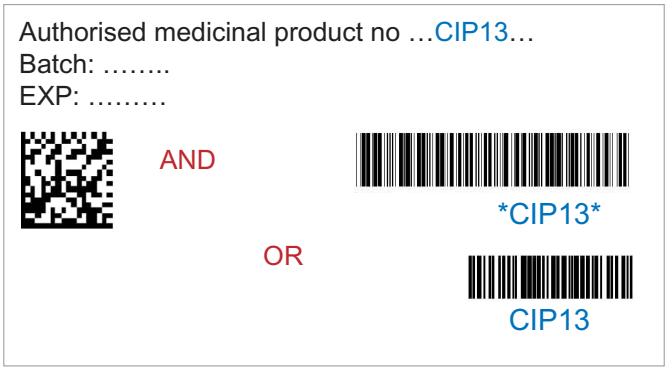
AND
- CIP13 marking in barcode 39 format

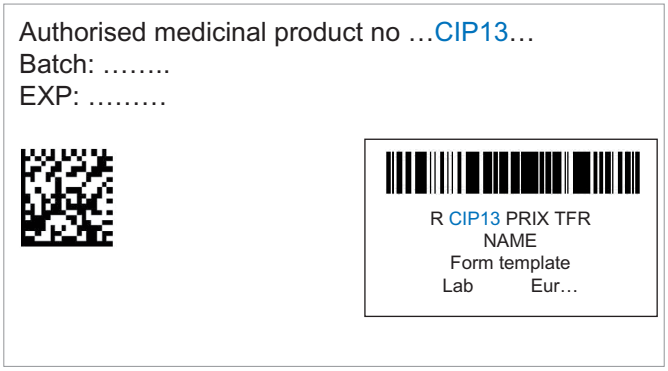
OR
- CIP13 marking in barcode 128 format

Reimbursable medicinal product:

Packaging
- Compulsory marking in plain text notably includes: MA no. (CIP13 code), batch no. and expiry date (see art R5121-138 of the French Public Health Code)
- CIP13 marking, batch no. and expiry date in a Data Matrix [(01)0**CIP13**(17)YYMMDD(10)batch no.]

Label
- CIP7 marking in barcode 128 format (preceded by a character indicating the reimbursement rate, followed by 6 characters for the price and 2 for the TFR) + CIP13 code in plain text (see order of 21.02.96 and following and order of 25 September 2008)





Marking on packaging of all medicinal products as of January 2011

Non reimbursable medicinal product:

Packaging
- Compulsory marking in plain text notably includes: MA no. (CIP13 code), batch no. and expiry date (see art R5121-138 of the French Public Health Code)
- CIP13 marking, batch no. and expiry date in a Data Matrix [(01)0**CIP13**(17)YYMMDD(10)batch no.]

Reimbursable medicinal product:

Packaging
- Compulsory marking in plain text notably includes: MA no. (CIP13 code), batch no. and expiry date (see art R5121-138 of the French Public Health Code)
- CIP13 marking, batch no. and expiry date in a Data Matrix [(01)0**CIP13**(17)YYMMDD(10)batch no.]

Label
- To be defined

Authorised medicinal product no …CIP13…
Batch: ……..
EXP: ……

Authorised medicinal product no …CIP13…
Batch: ……..
EXP: ……

?

Lab

Questions and Answers

Questions and answers relating to marking type and content

How is data structured in the Data Matrix system?

The data present in Data Matrix and used for traceability purposes is the CIP13 code, the expiry date and the batch number.
The data is preceded by a data identifier (ID or Application Identifier AI). This is used to determine the precise nature of the data to follow.
The identifiers used in the context of these recommendations are:
01 followed by the product code,
17 followed by the expiry date,
10 followed by the batch number.
To indicate to the scanner and to the associated software that GS1 -128 syntax is present in Data Matrix, the data must be preceded by «FNC1» of which the value is ASCII 232. This character is used by the 2D scanner but is not transmitted.
The data relating to each data identifier has a specific structure:
01 indicates the product code or GTIN (Global Trade Item Number) which is of fixed length.
This product code must contain 14 characters. A CP13 format product code is used in medicinal products for human use: This is a 13-character code with prefix 3400 followed by a character specifying the category (9 for allopathic proprietary medicine, 8 for UCD) followed by the 7 characters of the current CIP7 code and ending by a key control character. A zero «0» is therefore added before the CIP13 code. The addition of a zero does not modify the CIP13 control key.
17 indicates the expiry date, is of fixed length and must contain 6 characters in YYMMDD format. If the date is not stated it must be replaced by «00» (zero zero). This date format is different from that in plain text taking the MM-YYYY format (see European QRD version 7.2 of October 2006 – appendix 1, chapter 8, Expiry date). This date should be taken to mean the last day of the month stated.
10 indicates the batch number which is of variable length and contains from 1 to 20 characters. It is either numeric or alphanumeric. The first character should be different from zero to avoid any ambiguous interpretation. This batch number must be strictly identical to the number in plain text, with the same dashes, full stops etc.
Punctuation marks should not be used in batch numbers.
As batch numbers vary in length from one medicinal product to another, it is recommended placing it in last position in the data. If this is not the case it is necessary to indicate the end of the batch number by a group separator character such as «GS», of which the value is ASCII 29. This character makes it possible to close data fields of variable length.
Example
FNC1010340093000012017AAMMJJ10A11111
The ID must not be placed in brackets during data coding

in Data Matrix in order to respect the GS1 -128 syntax.
Brackets should only be used if the standardised format is to be printed in plain text to enable easy reading by the human eye.
(01)03400930000120(17)AAMMJJ(10)A11111
Comment: The CIP code, expiry date and batch no. must be written in plain text. Printing of the standardised format is optional.
The information present in the Data Matrix system must be strictly identical to the standardised information written in plain text next to the marking and to the dematerialised information transmitted by EDI.
Other data identifiers exist in the standard and could be added if they are useful for mentioning other data in Data Matrix.

Can the CIP13 code appear alone in the Data Matrix?

No, the Data Matrix must contain the CIP13 code, batch number and expiry date. Data Matrix marking was selected to support a GS1-128 structure containing the necessary information for managing traceability per batch.

Can data other than the CIP13 code, batch number and expiry date be included in the Data Matrix?

Yes, other data can be added. However it must be able to be identified by GS1 by means of a data identifier or standardised AI (i.e. AI 11 indicates the production date, AI 21 the serial number and AI 8005 net retail price etc.).
If certain non-standardised data is for internal use only and is never used in the distribution chain, AI between 91 and 99 should be used. AI 91 to 99 can be used to identify alphanumeric data of variable length with a maximum of 30 characters.

What do EAN-128, GS1-128, barcode GS1-128 and barcode 128 mean?

EAN-128 syntax is the correct term and this has now become GS1-128 syntax.
GS1-128 syntax is a structure containing a variable amount of data that is detected by data identifiers (AI).
Barcode GS1-128 and the Data Matrix are types of marking (or symbols) used to represent structured data in GS1-128 syntax.
All medicinal products for human use must bear Data Matrix marking, supporting GS1-128 syntax and containing the following data by the end of 2010 at the latest: CIP13 code, batch no. and expiry date, identified by (AI) 01, 10 and 17.
Barcode 128 is a linear barcode used to mark a variable amount of data in a sequence without a specific structure or separators (AI) in order to identify the data contained therein. It does not contain GS1-128 syntax.
The same marking is used for the label. (See Notice to manufacturers of proprietary medicine as published in the Official Journal on 7 March 1996). To save space, the C type is recommended for the first 12 characters and the B type for the thirteenth.
It can also be used to mark the CIP13 code for new stock keeping units marketed after January 2009 pending equipping of the packaging lines in Data Matrix by the end of 2010 at the latest.

Can EAN13 marking be used for medicinal products for human use?

EAN13 marking was not selected for marking the CIP13 code on the packaging of medicinal products for human use.
For medicinal products for human use, the GS1-128 coding structure used to encode the CIP13 code, batch number and expiry date was selected along with the Data Matrix marking support.
During the transition phase, new stock keeping units marketed between January 2009 and December 2010 shall bear barcode 39 marking (currently on cases) or barcode 128 marking (currently on the label) containing the CIP13 code. However, the barcode 39 format is 20 to 30% longer than barcode 128 for CIP13 marking.

Questions and answers relating to printing on packaging

Which information should be printed in plain text?

The information that should feature in plain text on the outside packaging is given in article R5121-138 of the French Public Health Code. Must notably be written: Batch number (Batch), expiry date (EXP) and marketing authorisation number (Authorised medicinal product no.…).
The recommended date format in plain text is MM-YYYY format (see European QRD version 7.2 of October 2006 – appendix 1, chapter 8, Expiry date). The expiry date should be taken to mean expiry at the end of the month stated.
This data does not need to be marked immediately next to the Data Matrix marking.

Can traceability data be entered manually?

No, manual data entry cannot be used for traceability.

Should the data contained in the Data Matrix be printed next to it?

The standard requires that the data contained in the Data Matrix must be printed in plain text next to the marking in (01)0CIP13(17)YYMMDD(10)batch no. format.
However, the French Public Health Code already stipulates that the marketing authorisation number (Authorised medicinal product no.…), batch number (Batch) and expiry date (EXP) must be marked in plain text and legible format on the outside packaging, in accordance with article R5121-138. Printing of this data in (01)0CIP13(17)YYMMDD(10)batch no. standardised format next to the Data Matrix is optional.

What is the best place for the marking?

The Data Matrix contains information concerning traceability and must be present on one of the sides of the secondary packaging.
It must be placed preferably on a flat surface.
It should not be placed on the underside of the packaging to make scanning by the robot easier, except if this contradicts the previous recommendation.
If the Data Matrix is placed on a rounded surface, it must be placed so as to minimise the field depth required for correct scanning. Rectangular Data Matrices are recommended in this case.

Label:
To make the pharmacist's work easier, the Data Matrix marking should be placed, where possible, on the same side as the current label, so that the information relating to traceability and reimbursement can be read in just one scan.
Can the Data Matrix be printed on the non-detachable label slip?
In certain cases the batch number and expiry date are marked in plain text on the non-detachable label slip. Data Matrix marking is therefore possible on the condition that it is also present on the outside packaging.

Data in plain text:
Information in plain text and the marking should be printed next to one another and on the same side of the packaging. This is not however compulsory. This will depend on the type of packaging and the space available.

Blue box:
For centralised MA, can the Data Matrix be placed outside the blue box reserved for country-specific information?
The Data Matrix contains both national and international data. As this marking cannot be read by the patient, it can be placed either inside the blue box or outside the blue box. For practical reasons and subject to confirmation by the EMEA, it is recommended that they be placed outside the blue box as space is limited inside the box.
(See Guideline on the packaging information of medicinal products for human use authorised by the community – February 2008 – pages 17 to 20).

Can the Data Matrix be marked on a label on the packaging?

The AFSSAPS does not wish to apply this principle.

How can legibility of the marking be guaranteed?

Observance of the technical printing specifications for all marking and observance of the standard for print quality tests are essential to guarantee the legibility of the marking by users and the automatic capture of traceability data (See cahier no. 1: Data Matrix printing – Print quality, Data Matrix checks).
Checks must be carried out prior to marketing, away from the production line as they require specific lighting and scanning conditions.

In the case of medicinal products restricted for hospital use, should the Data Matrix be placed on the stock keeping unit packaging and/or on the dispensing unit packaging?

The Data Matrix must be placed on all stock keeping unit packaging including that distributed to or reserved for use in hospitals.
The UCD-Common Dispensation Unit packaging, used in hospitals, may bear the same marking but this is not compulsory.

What does "date of exit from the production line" mean?

Exit from the production line is the date following packaging and prior to batch release.
For products requiring quarantine, exit from the production line takes place following quarantine and prior to batch release.
All cases leaving the production line on 1 January 2011 must bear the Data Matrix traceability marking on the outside packaging. This date can be brought forward by the laboratory where required.
Concerning stock remaining at this date and not bearing Data Matrix but barcode marking, the AFSSAPS agrees to this stock being used until expiration. However, traceability of these products must be guaranteed as far as possible.

Questions and answers relating to the particular characteristics of marking during the transition period - January 2009 to December 2010

What type of marking has been selected for the label?

In accordance with the order of 25 September 2008 as published in the Official Journal on 1 October 2008:

- The label on reimbursable stock keeping units marketed prior to January 2009 shall remain unchanged, that is to say it shall continue to bear barcode 128 marking containing the **CIP7** code and other currently encoded information, up to 31 December 2010.
- For recent MA granted between January 2009 and December 2010, the label must bear the CIP7 code and other currently encoded information in barcode 128 marking and the **CIP13 code in plain text**. This solution may also be selected for MA granted prior to January 2009, if the packaging bears the CIP13 code.
- During this period, the AFSSAPS will allocate CIP13 codes, with the possibility of switching with 7-character codes, to any new medicinal product. The 510 000 to 529 999 code range will be used during this period following saturation of the 300 000 range.

The list of CIP7-CIP13 cross-references is available on the AFSSAPS website throughout the transition period (posted on 7 March 2007). This aims to facilitate implementation of codification for industrialists.
Also during the transition period and in order to facilitate reading by the human eye at dispensing chemists of the CIP7 code contained in the plain text CIP13 code, if manual entry is necessary, laboratories must also define other industrial solutions to enable detection of the 7 characters among the 13 (marking in bold, larger type, insertion of spaces, underlining, information concerning the CIP13 code structure etc.).

Is dual barcode and Data Matrix marking possible and desirable for non-reimbursable proprietary medicine receiving MA before 2009?

If packaging lines are equipped with the DataMatrix system, the CIP7 code must be marked in barcode 39 format or the CIP13 code in barcode 39 or 128 format and the CIP13 code, batch number and expiry date in a Data Matrix.
This dual marking will enable users not equipped with Data Matrix readers to continue to automatically scan the product code, on the condition that the CIP13 code can be managed by the chemists' software (scanners are able to read the CIP13 code but not all software may support it).
Dual marking is essential for chemists equipping with Data Matrix readers at a later date (software and scanning equipment upgrade).

Is dual barcode and Data Matrix marking possible and desirable for non-reimbursable proprietary medicine receiving MA after 2009?

If the packaging lines are equipped with the DataMatrix system, the CIP13 code must be marked in barcode 39 format or 128 format and the CIP13 code, batch number and expiry date in a Data Matrix.
This dual marking will enable users not equipped with Data Matrix readers to continue to automatically scan the product code, on the condition that the CIP13 code can be managed by the chemists' software (scanners are able to read the CIP13 code but not all software may support it).
Dual marking is essential for chemists equipping with Data Matrix readers at a later date (software and scanning equipment upgrade).

How should products marketed between January 2009 and December 2010 be marked if packaging lines are not equipped with Data Matrix?

The CIP13 code must be marked in barcode 39 our barcode 128 format.
With respect to CIP13 marking, barcode 39 is 20 to 30% longer than barcode 128. The space available on the packaging is therefore a parameter to be taken into account when selecting this type of marking.

How should products marketed prior to January 2009 be marked if packaging lines are not equipped with Data Matrix?

The CIP7 code must be marked in barcode 39 format.

How should non-reimbursable stock keeping units marketed between January 2009 and December 2010 be marked if packaging lines are equipped with Data Matrix?

The CIP13 code must be marked in barcode 39 or barcode 128 format along with a Data Matrix.

Will packaging for use in hospitals not bearing Data Matrix marking affect hospital management of medicinal products?

Where Data Matrix marking is present alone this will not cause any problems as scanning of marking on packaging is little practiced in hospitals.

If stock keeping unit packaging is marketed bearing Data Matrix marking, can a subsequent batch from a production line not equipped with Data Matrix be marked using barcode 39 or 128 before coming back to the Data Matrix format?

This is tolerated in the case of production carried out on different sites using different equipment for marking and applies during the transition period up to 31 December 2010.

Questions and answers relating to schedules

What IT development schedule should be established within the medicinal product distribution chain?

Distributors and dispensing chemists must equip their premises with scanners able to read DataMatrix marking. They must also upgrade their software in order to be able to interpret the data recorded.
The AFSSAPS is in favour of "the systematic use of computerised transactions between the various operators, as soon as possible and in keeping with the schedule of implementation of the various codification elements on packaging" (see opinion in the Official Journal of 16 March 2007).
The following schedule has been established for dematerialised Distributor-Depositary-Manufacturer exchange:

- Priority 1: **New order format with CIP 13 code**
  By January 2009 at the latest
- Priority 2: **Full shipping notice and standard box labels**
  Immediately and up to June 2009
- Priority 3: **Acknowledgement of receipt of delivery**
  By June 2010 at the latest (subject to implementation of priority 2)

- Priority 4: **New order format with enriched message** After June 2010
- Priority 5: **Acknowledgement of receipt of the order** After June 2010

When will the reimbursable or certified CIP13 codes for the public sector be published in the Official Journal?

The order of 25 September 2008 relating to the characteristics of drug labelling and published in the Official Journal on 1 October 2008 confirms the passage to 13 characters of the registration number on the list of proprietary medicine reimbursable by the social security. As of 1 January 2009, the lists of reimbursable proprietary medicine and the list of proprietary medicine certified for use in the public sector in the Official Journal will mention the CIP13 code.

Summary

The AFSSAPS published a notice in the Official Journal on 16 March 2007 covering the review of the codification and labelling system relating to medicinal products for human use in order to support the compulsory information required for tracing medicinal products from the manufacturer to the patient.
CIP13 coding replaces that of CIP7; the CIP13 code, batch no. and expiry date must be encoded in Data Matrix marking on the outside packaging of medicinal products and traceability must be effective by 1 January 2011 at the latest.
Further to publication of the first document defining the technical characteristics of Data Matrix, a traceability support, the CIP publishes this second document to describe the various markings available. A question and answer section is also included.

Within the framework set out by the AFSSAPS, the second document aims to specify the practical methods of implementing traceability for medicinal products for human use, to guarantee continuity and fluidity of exchange between the partners of the pharmaceutical distribution chain, notably during the transition period from January 2009 to December 2010.

KEY WORDS

Medicinal products for human use – Codification – Traceability – Marking – CIP13 – CIP7 – MA number – Batch – Expiry date – GS1-128 syntax – Printing – Barcode 128 – Data Matrix – Development – Schedule – Transition period

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