

NOTICES AND COMMUNICATIONS

MISCELLANEOUS NOTICES

MINISTRY OF HEALTH AND SOLIDARITY

Notice to human-use medicinal product marketing authorization holders and head pharmacists of the pharmaceutical establishments cited in article R. 51242 of the French Public Health Code (CSP)

NOR: SANM0720920V

1. Context

Each presentation of a proprietary medicinal product is currently identified by a presentation identification code known as the CIP code. The seven-digit code is cited in the marketing authorization ruling (ruling and appendices) for each proprietary medicinal product.

Review of the code syntax was made necessary by the projected saturation of the seven-digit CIP nomenclature on January 1, 2009 and the coming regulatory change relating to batch number traceability and the inclusion of the expiration date and batch number in the packaging marking.

2. Publication of the new Marketing Authorization presentation codes

In liaison with the representatives of the pharmaceutical industry, the French Agency for the Safety of Health Products (AFSSAPS) has selected the principle of switching CIP code, from 7 characters to 13 characters, and from barcode 39 to EAN 128 (combined with ECC.200 Data Matrix marking) as per the EAN.UCC system.

The new marketing authorization presentation codes will be published and implemented as per the following schedule:

- First quarter 2007: Allocation, by AFSSAPS, of the 13-character CIP code, derived from the CIP 7 code, for all proprietary medicinal products with publication of the table cross-referencing the two codes, CIP 7 and CIP 13, on the AFSSAPS website and in the *Bulletin Officiel* of the Ministry of Health;
- In 2007 and 2008: pursuit of allocation of a CIP 7 code accompanied by the corresponding CIP 13 code for all new presentations or substitution and publication of a cross-reference table at the end of the year under the same conditions as those for the first quarter, 2007;
- From January 2009: allocation of a CIP 13 code, with no statement of a CIP 7 code for all new marketing authorization presentations and substitutions.

3. New outer packagings for medicinal products

The schedule defined in liaison with the pharmaceutical industry is as follows:

January 1, 2008: first batch released with the EAN 128 syntax with Data Matrix marking, incorporating the 13-character CIP code on the outer packaging;

December 31, 2010: all medicinal product batches will be released with the new EAN 128 code, using Data Matrix marking, incorporating the CIP 13 code, batch number and expiration date.

Thus, a transitional scale-up stage for the system – between January 1, 2008, and December 31, 2010 – is to be implemented and will be characterized by the following:

For marketing authorizations granted prior to January 1, 2009, (with a 7-character code), the secondary packaging (outer packaging) will bear:

- Either, for packaging lines not equipped with the Data Matrix system: the CIP 7 code, in characters, and barcode 39 (current system) and the CIP 7 code on the social security sticker also;
- Or, for packaging lines equipped with the Data Matrix system: direct switching to the Data Matrix system and the CIP 13 code, i.e., the CIP 13 code, in characters, with Data Matrix marking

incorporating the CIP 13 code, batch number and expiration date, and the CIP 13 code on the social security sticker, except in 2008 (CIP 7), in order to enable upgrading of open-care pharmacies' software and data transmission standard B2.

For marketing authorizations granted after January 1, 2009, (with a 13-character code), the secondary packaging (outer packaging) will bear:

- For packaging lines not equipped with the Data Matrix system: the CIP 13 code, in characters, together with, on the outer packaging, barcode 39 or 128 legible for open-care pharmacies, and the CIP 13 code on the social security sticker also;
- For packaging lines equipped with the Data Matrix system: direct switch to the Data Matrix system and the CIP 13 code, i.e., the CIP 13 code, in characters, with Data Matrix marking incorporating the CIP 13 code, the batch number and expiration date, and the CIP 13 code on the social security sticker.

The latter solution will obviate the need to change packaging twice in a three-year period.

The dates used are the packaging line exit and not the batch release date.

For medicinal products that are not social security reimbursed and do not bear a social security sticker, and whose packaging lines are not yet equipped with a Data Matrix system, the switch to CIP 13 will be subject to the same schedule. The packaging will thus feature the barcode and the CIP 13 code, in characters, prior to Data Matrix system set-up to supersede the barcode.

The technical changes stated above are not subject to prior authorization pursuant to the regulations governing pharmaceutical establishments since the changes are information technology (IT) changes and intrinsic changes in the packaging machines.

Each pharmaceutical company is responsible for informing its manufacturing sites and distribution facilities of the new provisions applicable throughout France.

Any medicinal products released prior to January 1, 2009, with the old 7-character CIP code may be marketed until their expiration date. This necessitates the IT capability of reading both codes.

Lastly, it should be noted that the batch number and expiration date, in characters, on the outer packaging are to remain legible for the patient (cf. Article R. 5121-138 of the Public Health Code).

4. Batch traceability obligation for all pharmaceutical establishment transactions

Under the terms of current article R. 5124-58 of the Public Health Code, a pharmaceutical establishment of a company or organization cited in article R. 5124-2 conducting wholesale, distribution free of charge or wholesale distribution, is to retain, as a minimum, for each incoming or outgoing transaction, the transaction date, the name of the medicinal or other pharmaceutical product, the quantity received or supplied, and the name and address of both the supplier and the recipient.

The new wording of article R. 5124-58 of the Public Health Code, currently under revision, provides that, for each transaction involving incoming or outgoing medicinal products in all pharmaceutical establishments, the batch number and expiration date are also to be retained.

Thus, for delivery to a legal entity or person accredited to dispense medicinal or other pharmaceutical products, the above information is to be stated on the documents accompanying the delivery. For a medicinal product, the document is also to state the pharmaceutical form of the product. The information is to be retained in the form of invoices, computer records or any other appropriate form. The supplier and recipient are to retain that information and make it available for competent inspection for a term of five years. For blood derivatives, the pharmaceutical establishment is also to comply with the provisions of article R. 5121-185 and R. 5121-195 of the Public Health Code.

The above information may be recorded on any medium, including computer media, generated by the computerized transactions between the pharmaceutical establishment and its customer(s).

The security of not only commercial but also pharmaceutical data constitutes the rationale for systematic use of computer systems (e.g. Electronic Data Interchange (EDI)) for the transactions between the various operators, from marketing through delivery to accredited recipients. AFSSAPS is highly favorable to the systematization, as soon as possible and in line with the schedule for set-up of the various coding components for packagings.

The systematization of transaction traceability is to be implemented progressively, in the timeliest manner possible, by December 31, 2010, on which date all marketed medicinal products are to bear the new coding in Data Matrix format.

Marketed medicinal products not bearing Data Matrix marking, such as CIP 7 medicinal products, are also subject to the traceability obligations, which are to be implemented at the latest, by December 31, 2010.

5. – Set-up monitoring

A coding and traceability monitoring group will be set up with the representatives of the professionals involved.

Signed in Paris on February 21, 2007-07-19

The Director General
J. MARIMBERT

(1) The present notice will be published in the special Bulletin Officiel of the Ministry of Health and Solidarity under number 2007/2 bis, and posted on the Ministry of Health and Solidarity website: <http://www.santesolidarites.gouv.fr> on the 'documentation' page.