DECISION

No. 13/07.06.2010

on approval of Guidelines on Romanian specific "blue box" requirements for secondary packaging of medicinal products for human use authorised through centralised procedure

The Scientific Council of the National Medicines Agency,
set up based on Order of the Minister of Public Health No. 1027/22.05.2008, as amended, reunited on summons of the National Medicines Agency President in the ordinary meeting of 07.06.2010, in accord with Article 10 of Government Ordinance No. 125/1998 related to the set up, organisation and operation of the National Medicines Agency, approved as amended through Law No. 594/2002, as further amended, agrees on the following

DECISION

Art. 1. – The Guideline on the information specific to Romania which must appear in the "Blue box" on the secondary package of medicinal products for human use authorised through the centralised procedure is approved, according to the Annex which is integral part of this Decision.

Art. 2. – At the date of the this Decision coming into force, the NMA Scientific Council Decision No. 7/29.02.2008 on approval of Guidelines on Romanian specific "blue box" requirements for secondary packaging of medicinal products for human use authorised through centralised procedure is hereby repealed.

PRESIDENT
of the Scientific Council
of the National Medicines Agency,

Acad. Prof. Dr. Victor Voicu

ANNEX

GUIDELINES
on Romanian specific "blue box" requirements for secondary packaging of medicinal products for human use authorised through centralised procedure

Art. 1. – This Guideline applies the basic prescriptions included in the "Guideline on the packaging information of medicinal products for human use authorised through the centralised procedure" published in the Notice to Applicants (NtA) in February 2008, describing how the provisions of the updated Directive 2001/83/CE, including the optional provisions in Art. 57 and 62, apply in the case of authorisations issued for centrally authorised medicinal products.

Art. 2. – Article 57 of Directive 2001/83/EC as amended provides that, notwithstanding Article 60, Member States may require the use of certain forms of labelling making it possible to indicate:

a) the price of the medicinal product;

b) the reimbursement conditions of social security organisations;

c) indication of classification in view of release;

d) identification and authenticity of medicinal products.

Art. 3. - The information specific to a Member State should be accommodated on the label in a boxed area (the so-called 'blue box'), to appear on one side of the pack. Each 'blue box' should only be presented in the official language or languages of the Member State concerned and should state the name of that Member State.

Art. 4. - The location of the 'blue box' on the package should ideally be the same for all Member States.

Art. 5. – (1) When one package is intended for marketing in several Member States, it is preferable to have only one 'blue box' on the package, which will contain different information relevant for each Member State.

(2) This could be achieved in practice for instance by printing a blank 'blue box' on this pack onto which a sticker with the appropriate Member State information can be securely affixed.

(3) When in exceptional circumstances, this cannot be achieved, each 'blue box' should ideally have the same dimensions and appear on the same side of the secondary package.

Art. 6. – As far as the legal status is concerned, it should be noted that the main categories, (medicinal product subject to medical prescription or medicinal product not subject to medical prescription), are already included in the labelling. Hence, the 'blue box' may only contain the symbols and/or the expressions used in the Member State to denote the legal status.

Art. 7. – The information specific to Romania which must appear in the "Blue Box" refer to the expressions used for the classification subcategories to be

released and to the symbols and pictograms used in accordance with provisions of Art. 772 of Law No. 95/2006 on healthcare reform, Title XVII – The medicinal product, which transpose the provisions of Art. 62 of the updated Directive 2001/83/EC.

Art. 8. – In order to standardise the classification for release between medicinal products authorised through national/mutual recognition/decentralised procedure, regulated by SCD No. 12/07.06.2010, and those authorised through the centralised procedure, the expressions used in Romania for sub classification categories of centrally authorised medicinal products shall be modified as follows:

Art. 8. – The expressions used in Romania for the classification subcategories are:

- P-RF – for medicinal products to be released in pharmacies based on medical prescriptions kept at the pharmacy (medical prescriptions which cannot be reused) (Art. 780 (2), point a) of Law No. 95/2006).

- P-6L – for medicinal products to be released in pharmacies based on medical prescriptions available for 6 months, which may be kept by the patients (medical prescriptions which can be reused) (Art. 780 (2), point a) of Law No. 95/2006).

- P-TS – for medicinal products to be released in pharmacies based on special medical prescriptions (secured prescriptions - for drugs and psychotropic substances) [Art. 780 (2), point b) of Law No. 95/2006].

-PR – for medicinal products subject to a restricted medical prescription:

- medicinal products which, although not meant for inpatient use, require a medical prescription issued by a specialist and a strict surveillance during the treatment, due to the fact that they may provoke serious adverse reactions [Art. 780 (2) c) in conjunction with Art. 781 (3), the first point of Law No. 95/2006];
- for medicinal products which are used in the treatment of diseases to be diagnosed in the hospital or institutions owning adequate diagnosing equipment, although the administration and continuation of the treatment may be performed elsewhere [Art. 780 (2) c) in conjunction with Art. 781 (3), the second point of Law No. 95/2006];
- for medicinal products which can only be used in the hospital due to their pharmaceutical characteristics or to their novelty or public health interests [Art. 780 (2), point c) in conjunction with Art. 781 (3), first point of Law No. 95/2006].

Art. 9. – The symbols and pictograms used in Romania, in accordance with provisions of Art. 772 of Law No. 95/2006 transposing Art. 62 of Directive 2001/83/EC, amended, are the following:

- The distinctive sign for medicinal products contraindicated to vehicle drivers.

- The international warning symbol for inflammable materials, for the medicinal products containing such materials.

- The international warning symbol for radiopharmaceuticals.

Art. 10. – The manner in which the specific information for Romania should be included in the “Blue Box” is presented in Annex 1 which is integral part of this Guideline and which is also published in the Annex to the “Guideline on the information concerning the labelling of medicinal products for human use authorised through centralised procedure” from Notice to Applicants (NtA).

ANNEX 1

Romanian specific "blue box" requirements for secondary packaging of medicinal products for human use authorised through centralised procedure

ROMANIA

Price

There is no requirement for the price to appear on the label. Nevertheless, according to national legislation, the price will be placed locally in the blue box by the pharmacist.

Reimbursement conditions

There is no requirement for reimbursement conditions to appear on the label.

Classification of medicinal products for release

The following specifications should appear in the "Blue Box":

- P-RF – for medicinal products to be released in pharmacies based on medical prescriptions kept at the pharmacy
- P-6L – for medicinal products to be released in pharmacies based on medical prescriptions available for 6 months, which may be kept by the patients
- - P-TS – for medicinal products to be released in pharmacies based on special medical prescriptions (secured prescriptions - for drugs and psychotropic substances)
- P-RF/R – for medicinal products subject to restricted medical prescription

Identification and authenticity

The bar code is accepted on the label, but not required.

Local representatives

It is accepted, but not required. Name, telephone number and/or e-mail shall be mentioned. The address may also be included, depending on the available space, if it is mentioned on the leaflet.
Information under Article 62 of Directive 2001/83/EEC: symbols and pictograms

Medicinal products contraindicated to vehicle drivers must have a distinctive sign – an equilateral triangle with the top up, of white colour, with red sides and with the length of 10 mm and the thickness of 1.5 mm, having in the centre an exclamation mark of black colour, triangle framed in a square of white colour with the side of 15 mm:

Medicines containing flammable materials must bear the international warning symbol:

Radiopharmaceuticals should bear the international warning symbol: