AIFA - ITALIAN BLUE-BOX[11] REQUIREMENTS TO APPEAR IN THE OUTER LABELLING OF CENTRALISED MEDICINAL PRODUCTS FOR HUMAN USE ON THE ITALIAN MARKET (art. 57 and 62 Directive 2001/83/CE as amended)

1- Price

The price for the public (art. 73.1r D.Lvo 219/2006) should be reported as: "Prezzo: Euro xxx" or "Prezzo: € xxx".

For medicinal products reimbursed by the National Health Service (NHS), the price for the public should be the one reported in the AIFA Determination net, where applicable, of price reductions provided for in AIFA Determinations 3 July 2006 and 27 September 2006, published, respectively, in the Official Journal of the Italian Republic General Series n. 156 7 July 2006 and n. 227 29 September 2006.

For medicinal products not subject to medical prescription (SOP and OTC) the price is not required on the labelling (art. 1(801) Law n. 296 of 27 December 2006).

For radiopharmaceuticals ready to use, radionuclide generators and precursors (notwithstanding the classification for reimbursement by NHS) if the price is reported as “Euro xxx” this is meant to be the price per pack. Otherwise, the reference unit should be stated, e.g. price per activity unit: “Euro xxx/MBq”, etc.

2- Authenticity/Traceability

As per D.Lgs. n. 10 6 February 2025, medicinal products subjected to medical prescription and medicinal products not subjected to medical prescription included in Annex II of **Commission Delegated Regulation (EU) 2016/161 (except for medicinal products subjected to medical prescription listed in Annex I of Commission Delegated Regulation (EU) 2016/161)** shall include a device printed on “carta valori”[2].

Medicinal products not subjected to medical prescription listed in Annex I of Commission Delegated Regulation (EU) 2016/161 should apply a peelable sticker (art. 54 of Directive 2001/83/CE art. 73.1-p-bis D.Lvo 219/2006 implemented by Decree of the Ministry of Health 30 May 2014 “Numerazione progressiva dei bollini apposti sulle confezioni dei medicinali immessi in commercio in Italia”) issued by the Printing and State Mint **(Istituto poligrafico e zecca dello stato)** carrying the unique identifier in human-readable format and as two-dimensional barcode, as per **Commission Delegated Regulation (EU) 2016/161 2 October 2015, D.M. 20 May 2025, Technical specifications issued on 6 March 2025** e **AIFA Determination DTS 56-2025 17 July 2025**.

National identification number (“numero di AIC”) in human-readable format must appear on the outer label (or immediate label if the outer one is lacking) as well as on the peelable sticker/unique identifier.

The peelable sticker (“bollino ottico”) or the device printed on “carta valori” should be applied on the outer packaging avoiding an impact on the readability of packaging information.

3- Reimbursement

For medicinal products reimbursed by NHS and applying the peelable sticker (“bollino ottico”), the text **"Confezione dispensata dal SSN"**, printed in the area underneath the sticker, should appear once the latter has been removed by pharmacists (art. 73.1s D.Lvo 219/2006).

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[1] For definition of Blue Box and additional information see NOTICE TO APPLICANTS - GUIDELINE ON THE PACKAGING INFORMATION OF MEDICINAL PRODUCTS OR HUMAN USE AUTHORISED BY THE UNION

[2] Reference is made to art. 13 of D.lgs. 6 February 2025, n. 10 reporting that, from 9 February 2025 to 8 February 2027, it is still possible to include “bollino farmaceutico” as per art. 5-bis of D.lgs. 30 December 1992, n. 540, also on these medicinal products as a replacement of the device printed on “carta valori”.

For medicinal products not applying the peelable sticker (“bollino ottico”) and reporting the device printed on “carta valori”, **no specific sentence on reimbursement is required**.

4- Classification for supply

Art. 73.1q and art. 88, 89, 90, 91, 92, 93, 94, 96

D.Lvo 219/2006	**Type of medical prescription**	**Text to be reported**
(art.96)	Medicinal products not subjected to medical prescription (OTC)	Medicinale di automedicazione (+ pictogram, see point 11. a)
	Medicinal products not subjected to medical prescription (SOP)	Medicinale non soggetto a prescrizione medica (+ pictogram, see point 11.a)
(art.88)	Medicinal products subjected to medical prescription (RR)	Da vendersi dietro presentazione di ricetta medica
(art.89)	Medicinal products subjected to medical prescription to be renewed each time (RNR)	Da vendersi dietro presentazione di ricetta medica utilizzabile una sola volta
Medicinal products subjected to restrictive medical prescription (art. 91)	Medicinal products to be used only in hospital setting or in similar facilities (OSP) (art. 92)	Uso riservato agli ospedali <o alle cliniche e alle case di cura *[if expressly specified in the AIFA determinazione]*>. Vietata la vendita al pubblico.
	Medicinal products to be dispensed on prescription from hospital centers or specialists (RRL) (art. 93)	Da vendersi dietro presentazione di ricetta medica su prescrizione di centri ospedalieri o di specialisti *[indicate the type of facility or specialist authorized for the prescription]*
	Medicinal products to be dispensed on prescription to be renewed each time from hospital centers or specialists (RNRL) (art. 93)	Da vendersi dietro presentazione di ricetta medica utilizzabile una sola volta su prescrizione di centri ospedalieri o di specialisti *[indicate the type of facility or specialist authorized for the prescription]*
	Medicinal products to be used only by the specialist (USPL) (art. 94)	Uso riservato allo specialista *[indicate the specialist authorized for the prescription]*. Vietata la vendita al pubblico.
	Medicinal products subjected to special medical prescription (DPR 309/1990 as amended)	Da vendersi dietro presentazione di ricetta ministeriale a ricalco
(art.90)	Medicinal products containing narcotic and psychotropic substances (DPR 309/1990 as amended)	Medicinale soggetto alla disciplina del DPR 309/90 e s.m.i. <tabella medicinali sezione <A><B><C><D><E>> <Allegato III bis>

The text must be marked with a double red line as in the example shown above (Decree of the Ministry of Health 26 March 1979)

5- Local representative optional and only if mentioned in the package leaflet[3]
The following information may be reported if the readability of mandatory text on the label is not compromised: "Rappresentante locale: name, phone and/or e-mail address, logo, postal address."

6- Distributor/who, on the basis of a specific agreement with the Marketing Authorisation Holder, manages the actual marketing of the medicinal product in Italy (art. 73.2 D.Lvo 219/2006) optional and subject to notification to AIFA.
The following information may be reported if the readability of mandatory text on the label is not compromised: "Concessionario di vendita: name, postal address, logo".

7- For equivalent medicinal products (biosimilars are considered excluded) (Law 149 July 26 2005) the following statement should be reported: "Medicinale equivalente"

8- If relevant, the following statement should be reported: "Non assumere contemporaneamente bevande alcoliche" (art. 65 Directive 2001/83/CE, art. 73.1g D.Lvo 219/2006)

9- If relevant, the following statement should be reported: "Può alterare la capacità di guidare veicoli e di usare macchinari" (art. 65 Directive 2001/83/CE, art. 73.1g D.Lvo 219/2006)

10- For medicinal products for intravenous use containing potassium amount equal or above 1 mEq/ml, the following statement in red font should be reported: "Potassio (K), diluire prima della somministrazione: mortale se infuso non diluito" (AIFA determination 11 November 2005)

11- Pictograms

a. for medicinal products NOT subject to medical prescription (SOP and OTC) the following pictogram should be reported (Decree of the Ministry of Health 1 February 2002):

Diameter: Ø17 mm

b. for medicinal products containing the active substances listed in decrees amending Law 376/2000 which are issued annually by the Ministry of Health (see also World Anti-Doping Agency https://www.wada-ama.org/en/what-we-do/prohibited-list), the following pictogram should be reported (Decree of the Ministry of Health 19 May 2005):

[3] NOTICE TO APPLICANTS - GUIDELINE ON THE PACKAGING INFORMATION OF MEDICINAL PRODUCTS OR HUMAN USE AUTHORISED BY THE UNION: “The 'local representative' may be indicated in the blue box on the labelling by name, telephone number and/or e-mail address and logo (optional). Postal address may be included if space permits (should not interfere with the legibility of the text which must mandatory appear on the outer packaging).”

Diameter: Ø17 mm

12- for medicinal products **NOT** to be used **exclusively** in hospital setting or in similar facilities (OSP) (art. 92 D.Lvo 219/2006) and containing one or more of the following opioids: buprenorphine; codeine; dihydrocodeine; fentanyl; hydrocodone; hydromorphone; methadone; morphine; oxycodone; oxymorphone; sufentanyl; tapentadol, tramadol; petidine (https://www.aifa.gov.it/documents/20142/847366/comunicazione_nuove_avvertenze_etichette_oppioidi_22.06.2020.pdf/1af21a63-a563-9108-faf4-fb1631871992), the following statement in the following format should be included**:**