



POLIGRAFICO
E ZECCA
DELLO STATO
ITALIANO

**General Terms and Conditions of Supply for
Italian Security Labels for Pharmaceutical Products**

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Article 1 Subject of the Conditions and Possible Amendments

1.1. These General Conditions, drawn up pursuant to articles 1341 and 1342 of the Italian Civil Code, govern the relationship between the Istituto Poligrafico e Zecca dello Stato S.p.a. (hereinafter also Poligrafico) and the pharmaceutical companies (hereinafter also Customers) for the supply of self-adhesive pharmaceutical labels with progressive numbering, exclusively produced by Poligrafico

pursuant to Article 1, para. 2 of Article 2, para. *10-bis* of the Law no. 559 et seq. of 13 July 1966, and pursuant to Art. 29 of the Ministry of Economy and Finance Decree of 4 August 2003 as amended, the subsequent Ministry of Economy and Finance Decree of 23 December 2013 and, lastly, pursuant to Article 1 of the Ministry of Health Decree of 30 May 2014.

1.2. These General Terms and Conditions may also be amended as a result of subsequent provisions of law and/or regulations, and shall be made known to Customers by means of appropriate advertising on the portal "Portale Unico Valori Bollini Farmaceutici". However, such changes will not have retroactive effect and will be applicable with effect from subsequent requests for delivery of supplies.

Article 2 Reference legislation

For all matters not directly governed by these General Terms and Conditions, the supply relationship shall be deemed to be governed by the regulations in force concerning Italian security labels for pharmaceutical products and, in particular, by the regulatory sources listed below:

- Ministry of Health Decree of 6 July 1999 on 'Approval of the guidelines on good distribution practices for medicinal products for human use Annex 1';
- Ministry of Economy and Finance Decree of 4 August 2003, as amended, on 'New instructions for the regulation of supervision and control over the production of security papers, common printed matter and official publications';
- Decree of the Ministry of Health of 30 May 2014, on 'Progressive numbering of security labels affixed to the packaging of medicinal products placed on the market in Italy';
- Ministry of Health Decree of 11 May 2018, which introduced amendments to the Decree of 15 July 2004, stating: 'Establishment of a central database to monitor the packaging of medicines within the distribution system';
- 'Guidelines for the Preparation and Transmission of Files to the Central Database', published in March 2023 and prepared by the Ministry of Health - Directorate General for Digitisation, Health Information System and Drug Tracking Statistics.

Article 3 Processing of Personal Data

Pursuant to Article 13 of EU Regulation 2016/679 (GDPR), we inform you that the data provided will be processed for purposes related to the fulfilment of contractual relationships. For said reasons, failure to indicate said data will preclude the conclusion of the contract. Processing will be carried out using procedures, including computerised procedures, with logic relating to the purposes indicated and in all cases in such a way as to guarantee the security and confidentiality of the data. The personal data acquired will not be disseminated. . The Data Controller is Istituto Poligrafico e Zecca dello Stato S.p.a. The Customer's data are also processed by "Appointed Internal Data Processors" as well as by subjects specifically authorised to process the data by the Data Controller, pursuant to the GDPR. All information concerning the processing of personal data is available at the following link <https://www.ipzs.it/ext/privacy.html> The Customer enjoys the rights set out in Articles 15-18 and 21 of the EU Regulation 2016/679 by virtue of which he/she may request and obtain, among other things, information about the data concerning him/her and about the purposes and methods of processing; he/she may also request that the data be updated, rectified, supplemented, erased, anonymised and blocked, and may also object to the processing of his/her data. These rights may be exercised by sending a request to the Data Protection Officer (DPO) at the following address: Via Salaria, 691 - 00138 Rome, or by e-mail to the following addresses: privacy@ipzs.it or rpd@pec.ipzs.it. Furthermore, we would like to inform you that the exercise of the above rights may be limited, delayed or excluded - pursuant to Article 2-undecies of Legislative Decree 196/2003 as amended - if it could result in actual and concrete prejudice to the conduct of defensive investigations, to the exercise of a right in court, and to the confidentiality of the identity of the employee who,

pursuant to Law no. 179, reports the wrongdoing of which it has become aware by reason of their post (so-called whistleblowing). Lastly, it should be noted, pursuant to Article 13, par. 2(d) of the GDPR, that the data subject has the right to lodge a complaint with the Garante per la Protezione dei dati personali or another supervisory authority in accordance with Article 77 GDPR.

Article 4 Persons Entitled to Purchase Italian Security Labels for Pharmaceutical Products

Italian security labels for pharmaceutical products can be purchased by the following parties:

- Pharmaceutical companies **holding** the marketing authorisation for the medicinal product indicated by the relevant AIC code published in the Official Journal of the Italian Republic or in the Official Journal of the European Union following scientific evaluation by the EMA (European Medicines Agency);
- Pharmaceutical companies **that represent** the marketing authorisation holder of the medicinal product bearing the AIC code published in the Official Journal of the Italian Republic or in the Official Journal of the European Union following scientific evaluation by the EMA (European Medicines Agency) in Italy;
- **Manufacturers of** the medicinal product indicated by the relevant AIC code published in the Official Journal of the Italian Republic or in the Official Journal of the European Union following scientific evaluation by the EMA (European Medicines Agency);
- Companies **licensed** to sell the medicinal product indicated by the relevant AIC code published in the Official Journal of the Italian Republic or in the Official Journal of the European Union following scientific evaluation by the EMA (European Medicines Agency);
- Companies **delegated** to purchase by the Marketing Authorisation Holder.

Article 4.1 Title to purchase

The entitlement to purchase must be proven by one of the following titles:

- Publication of the Marketing Authorisation (MA) for the medicinal product in the Official Journal of the Italian Republic ;
- Publication of the Marketing Authorisation (MA) for the medicinal product in the Official Journal of the European Union;
- Mandate of legal representation in Italy, signed in acceptance by AIFA
- Licence for the sale of medicines issued by AIFA
- Purchase authorisation issued by the AIC holder expressly stating the latter's commitment to promptly provide notification of any changes.

Article 5 Order Management

Orders are handled exclusively and wholly via the portal “Portale Unico Valori Bollini Farmaceutici” (www.portaleunicovalori.ipzs.it/bollini/login).

To be authorised for use of the Portal, the company interested in purchasing Italian security labels for pharmaceutical products must complete and submit the online form available at <https://www.portaleunicovalori.ipzs.it/bollini/accreditamento/start> to the Poligrafico

Following the request for registration on the Portal, the Company will receive the General Terms and Conditions of Supply and a notice regarding the request for credentials for access to the Portal at the e-mail address indicated on the form. Both documents must be digitally signed by the legal representative of the applicant company and sent to the pec address: protocollo@pec.ipzs.it.

In the event that the pharmaceutical company is not in possession of a digital signature, the documentation must be signed by hand by the legal representative and sent, by courier or recorded mail with return receipt, to the following address

ISTITUTO POLIGRAFICO E ZECCA DELLO STATO S.P.A.

Via Salaria, 691

00138 Rome

Attention: Protocol

Once accreditation is complete, a guided procedure will allow the customer to easily send orders and follow their progress using the online tracking service on the Portal.

The operating methods for placing orders are set out in detail in the downloadable User Manual in pdf format published on the Portal and available at: <https://www.portaleunicovalori.ipzs.it/bollini/login>.

Please note that the security labels can be ordered in multiples of 50 and for a minimum quantity of no less than 250. The Portal will therefore not allow the requesting company to place orders for quantities that do not meet these conditions.

Article 6 Production and Supply of Italian Security Labels for Pharmaceutical Products

6.1. The security labels will be produced after the order is sent by the Customer and will be delivered by the Poligrafico to the courier by the date indicated in the order summary as the date of shipment.

6.2. For the "ex-works" supply hypothesis referred to in Article 11.1 letter b), the date of shipment stated in the order summary will correspond to the date by which the security labels produced will be available at the Poligrafico Production Site in Via Salaria no. 691 in Rome or Via Leone XIII no. 333 in Foggia, for collection by the customer.

6.3. Delivery of the Italian security labels for pharmaceutical products to the Customer will be carried out within 60 (calendar) days from receipt of the order (taking into account the shipping requirements expressed by the pharmaceutical company during the order processing phase, by selecting the available shipping times on Portale Unico Valori Bollini Farmaceutici, or subsequently indicated in writing and shared with the Poligrafico) and unless otherwise determined by the Ministry of Health or the Italian Drug Agency in exceptional cases and for public health reasons.

It should be noted in this respect that the aforementioned 60 (calendar) days are calculated from the first day following the date on which the order is received.

Article 7 Emergency Procedure Orders

Without prejudice to the provisions of Article 6.3., the Customer can request a supply by activating the urgency procedure, which provides that the ordered security labels for pharmaceutical products are produced and delivered to the courier (or are made available for collection by the Customer, in the case of "ex-works" supply) within 5 or 15 working days (Monday to Friday) from the date of the order.

This service must be agreed with the Poligrafico and entails the following additional charges on the invoice:

- Priority with urgency at 5 working days: € 500.00;
- Priority with urgency at 15 working days: € 300.00.

It should be noted that the above terms refer exclusively to the delivery of the finished product to the carrier (or to the availability of the product for collection by the Customer, in the case of "ex-works"

supply) and do not take into account the time required to ship the product to the consignee (delivery times in Italy, including the Islands, range from 1 to 3 working days, excluding the day of collection).

Article 8 Standard Procedure Orders

If there are no reasons of urgency, the Customer may request that the security labels for pharmaceutical products be produced and delivered to the courier (or be made available for collection by the Customer, in the case of "ex-works" delivery) in accordance with the following timetable:

- Priority of 30 working days from the date of placing the order;
- Priority of more than 30 working days from the date of placing the order.

In this case too, the above deadlines refer exclusively to the delivery of the finished product to the carrier appointed by Poligrafico and do not take into account the time required to ship the product to the addressee (delivery times range from 1 to 5 working days, excluding the day of collection, for deliveries on the Italian mainland; from 1 to 7 working days, excluding the day of collection, for deliveries to the Islands).

There are no additional costs for the standard procedure.

It should be noted that in the case of standard orders with a priority of more than 30 working days from the time the order is sent, the Customer can select the "shipping date" during the order entry phase, which is to be understood as the date by which the security labels will be produced and delivered to the courier or, for the hypothesis of "ex-works" supply, as the date by which the security labels produced will be made available at the production site for collection by the Customer.

In the event that, due to an operational requirement of the Pharmaceutical Company, the Customer selects as priority a date later than the 60th calendar day from receipt of the order, Poligrafico shall proceed with the supply of the security labels as indicated on the Portal and the 60 calendar days term provided by Article 4 paragraph 2 letter c) of Ministerial Decree. 30 May 2014 shall only run from the dispatch date selected by the Customer.

However, this does not prejudice the possibility for the parties to agree on different delivery times further to written and justified request by the Customer.

This also does not prejudice the Customer's right to select both standard and urgent requests (MIXED ORDERS) when placing the order.

Article 9 Amendments to and cancellations of orders

9.1. Once submitted to Poligrafico, orders can no longer be amended but can be cancelled under the conditions set out below.

9.2. The supply request submitted to the Poligrafico pursuant to Article 8 (standard procedure orders) can be cancelled, without any charge, within the cancellation deadline indicated to the user on the portal "Portale Unico Valori Bollini Farmaceutici" with the words "*Cancellable by 23:59:59 of dd-mm-yy*". Cancellation can be made by clicking on the CANCEL button.

In any case, it will not be possible to cancel orders made with urgent requests as well as urgent requests made together with standard requests (so-called mixed orders).

9.3. In cases where the Customer has requested a standard supply with a delivery period of more than 30 working days from placing the order, the period of time in which the Customer may cancel the order will be extended by 1 working day for every 5 days of increase in the delivery period (e.g.: for a 35-day supply the cancellation period will be 3 working days, for a 40-day supply the period will be 4 working days).

9.4. Extraordinary cancellation (with penalty). After the expiry of the time limits provided for in Articles 9.2 and 9.3 and as long as the order is in "**confirmed**" status on the Portal, the Customer can proceed with cancelling the order by using the specific "Cancellation Request" function available on the Portal itself; in this case Poligrafico reserves the right to charge the pharmaceutical company a lump sum of € 250.00 as an administrative management fee. This amount will be charged to the Customer by means of a specific debit note.

9.5. In any event, cancellation will not be possible on orders for which the printing process has already begun, nor on mixed orders as referred to in 9.2 above.

In such cases, therefore, the Poligrafico will proceed to supply the ordered security labels for pharmaceutical products and invoice the relative costs.

Article 10 Invoicing and Payment

10.1. Invoices shall be issued in accordance with current legislation, made out to the purchasing company and sent to the address indicated by the customer in the request for supply delivery.

10.2. The prices charged are set out in the price list in Appendix 1 and do not include VAT, which, where applicable by law, must be calculated separately.

10.3. Payment for the supply must be made within 60 days from the date of the invoice (end of the month) by means of bank transfer to the bank account indicated on the invoice.

10.4. In the event of non-payment, delayed or partial payment of an invoice or a debit note, Poligrafico also reserves the right to apply prepayment terms to the supply subsequently requested by the Customer; in this case, the security labels will be produced and supplied by Poligrafico only after receipt of payment from the Customer.

10.5. In the event of non-payment of the invoices, Poligrafico will proceed to send the Customer three reminders by certified email, or - if the Customer does not have a certified email address - by e-mail or by recorded letter with return receipt, ordering payment of the balance of the supply. If, notwithstanding the third reminder, the Customer does not proceed with payment of the overdue invoices, Poligrafico reserves the right to proceed - as an alternative to the provisions of the preceding Article 10.4 and taking into account the extent of the Customer's debt - with the immediate blocking of deliveries for material already ordered and the blocking of orders.

10.6. This is without prejudice, in any event, to actions - also judicial - to protect Poligrafico's interests.

Article 11 Methods of Delivery

11.1. The security labels for pharmaceutical products will be delivered to customers within Italian borders as follows:

a) Purchasing company with recipient establishment in Italy

If the customer has indicated an establishment in Italy for consignment, the security labels are supplied "*ex-works indicated by the AIC holder in Italy, with packaging and transport methods suitable for guaranteeing their safety*", as required by Article 4(2)(b) of the Ministry of Health Decree of 30 May 2014.

Poligrafico is therefore responsible for the risks and expenses inherent in transportation to the place of consignment, which will be carried out by a carrier appointed by Poligrafico.

An individual transport document will be prepared for each delivery made.

b) **Purchasing company with recipient establishment abroad - Supply "ex works**

In the event that the customer has indicated an establishment abroad for delivery, the security labels for pharmaceutical products are supplied ex works Poligrafico, EXW according to Incoterms 2010.

The security labels will therefore be made available to the Customer, who shall collect them at its own expense, at the Poligrafico's production sites in Rome (Via Salaria n. 691) or in Foggia (at Via Leone XIII no. 333), depending on the indication provided in the notification email that the Customer will receive via the Portal, after confirmation of the order by Poligrafico.

Once the Customer has been informed of the availability of the ordered quantity at the indicated production site, it must book collection via the Portal, indicating all necessary data for the collection and attaching the consignment note. In the absence of the aforementioned data and documentation, booking of the aforementioned collection will not be possible.

The Customer bears the risks and burdens of transport, as well as the documentation relating thereto. Transport will be organised by and at the expense of the Customer (who may send his own means of transport or appoint a carrier of his choice) and will be accompanied by the carrier's consignment note.

It is the responsibility and onus of the customer collecting directly or of the courier appointed by the customer to apply the consignment note on the packages to be collected.

The Customer must collect the security labels within 60 calendar days from the date on which they are made available for collection at one of Poligrafico's production facilities. If this period expires without the security labels being collected, the ordered and produced security labels will be destroyed and the Customer will be charged the cost of the supply and the cost of destruction plus VAT, if due.

11.2. The information on the Consignee of Goods is entered by the Customer on the portal "Portale Unico Valori Bollini Farmaceutici". It is not possible to change the Consignee of Goods indicated in the order after the supply request has been submitted to the Poligrafico.

Any errors in delivery or shipment due to inaccurate and/or incomplete typing on the portal "Portale Unico Valori Bollini Farmaceutici" of the data relating to the Consignee of Goods during the order processing phase shall not be attributable to Poligrafico.

The customer is therefore obliged to verify the correctness of the data entered before confirming and placing the order.

Article 12 Product Specifications and Packaging Methods

The security labels for pharmaceutical products are made on a three-layer security backing (so-called triplex) and are equipped with the technical characteristics provided for in the Ministry of Health decree of 30 May 2014, as listed in Annex A of the same decree.

The material is produced in reels, the diameter of which varies according to the number of security labels it contains. The maximum reel diameter is 38.7 cm and corresponds to a reel of no. 18,000 security labels. The width of the reels is 4.2 ± 0.1 cm.

The reels are produced from pressed cardboard cores with an inner diameter of 7.6 ± 0.1 cm and an outer diameter of 8.6 ± 0.2 cm. The core thickness, on the other hand, is 0.50 ± 0.05 cm.

Each reel contains only one AIC code. The minimum number of security labels set up per reel is n. 5,000; if the order quantity is less than 5,000, the minimum number of security labels per reel will correspond to the total number of security labels ordered.

The packaging information are selected by the customer when processing the order, subject to Poligrafico's production/technical requirements.

Each reel will be accompanied by a sticker bearing information about the production in question, namely OCR-A (AIC without initial "AIC" and any letters after the "\"), the lot_bol (start of numbering), the Poligrafico's production order, the label maker's internal identification lot, the name of the speciality, the customer's order number, the product code, the number of security labels inside the reel, the numbering of the security labels on the reel.

The security labels for pharmaceutical products can be supplied to the customer inside single boxes, in multiple boxes containing 3 single boxes, or by using multiple boxes and then directly inserting the reels without using the single boxes.

At the customer's request, it will be possible to receive a numbered sample (from a minimum of 10 to a maximum of 80 security labels) for each type of security label purchased. The number of sample security labels will be taken into account in the total order quantity. The required samples will be included in a stand-alone package.

The material will be prepared for delivery of up to 4 packages on Europallets measuring 70 cm x 100 cm and for delivery of 5 packages on Europallets measuring 80 cm x 120 cm, unless different arrangements are requested and shared with Poligrafico.

The products will be accompanied by a declaration of conformity signed by the Quality Department of the production site, containing the following data:

- Order references;
- Commercial name of the pharmaceutical product;
- Customer;
- A.I.C. holder;
- Quantity of security labels and numbering;
- Quantity of reels and number of security labels per reel;
- AIC Code;
- OCR-A code;
- Date on which the checks were carried out;
- Result of the following checks, with evidence of which of them are performed automatically by the labelling machine:
 - o Colours;
 - o Registration;
 - o Text;
 - o Security label size;
 - o Die-cutting;
 - o Step;
 - o Support integrity;
 - o Issue of security labels for pharmaceutical purposes;

- Number of security labels per reel;
- Outer diameter;
- Inner diameter;
- Correspondence to barcode no. 39 with OCR-A;
- Sequencing with Poligrafico order;
- Anti-fragmentation detection, code 39.
- Labelling and interleaved barcode matching of barcode with OCR code and 2/5;
- Numbering sequence and reporting of any missing numbers;
- Code Readability and Quality.

With reference to the strength of the adhesive, it should be noted that the relevant check is carried out by the Poligrafico on the Triplex paper used for the production of the security labels for pharmaceutical use..

The documentation is placed inside an envelope, which in turn is enclosed in a recognisable box containing:

- a summary of the shipment, package by package, with a maximum of 5 unnumbered samples;
- the numbering machine report with a summary of the information on the labels described above.

Article 13 Product Preservation/Storage Conditions

13.1. The security labels should be stored in a dry place at a constant room temperature, avoiding exposure to direct sunlight with optimal temperature conditions between 20 - 25 °C and relative humidity conditions between 35 - 60%. For better storage, however, it is recommended to use rooms with a relative humidity between 50 - 60%.

13.2. It is the Customer's responsibility to comply with the aforementioned product storage conditions. Any non-conformity of the product attributable to non-observance of the preservation and/or storage methods described above - by the Customer or the carrier appointed by them - shall therefore not be attributable in any way to Poligrafico, not even by way of warranty.

Article 14 General Product Warranty

Poligrafico guarantees the perfect suitability of the security labels for their intended use and their immunity from defects.

The security labels produced by Poligrafico are covered by a 12-month warranty for any conformity defects. The warranty period runs from the date of delivery of the security labels to the Customer.

The warranty does not cover defects and damages attributable to the Customer and to use and storage/storage methods deviating from the ones set out in these general terms and conditions, including the case that the self-adhesive security labels do not maintain satisfactory levels of adhesive hold.

In the event of a report of "non-conformity", in order to benefit from the warranty, the Customer must fill in and send the appropriate complaint form on "Portale Unico Valori Bollini Farmaceutici" using

the "Add Complaint" function. The report, sent via the Portal, must be accompanied by appropriate photographic documentation proving the reported defect.

Within 2 working days of receipt of the report, and after assessing the need to withdraw the security labels, Poligrafico will send the Customer the "Security Label Return Form" and all the instructions concerning the withdrawal and the subsequent steps by e-mail.

Within 7 working days of receipt of the duly completed and initialled "Security Label Return Form" from the Customer, Poligrafico will organise the collection of the materials via the authorised carrier.

Verification will be carried out within 5 working days from the date on which the material is received.

In any case, Poligrafico is not responsible for any placing on the market of products with non-compliant security labels.

In the event that the Customer does not return the duly completed and initialled "Security Label Return Form" to Poligrafico within 30 working days of receiving it, the report shall be deemed forfeited, with the consequent impossibility of sending a new report concerning the same security labels.

It is understood that after the warranty period has expired, any claims by the Customer will not be accepted.

Article 14.1 Sampling method for the products to be verified

Without prejudice to the provisions of point 14.2 below - Poligrafico will carry out an appraisal on the security labels returned by the Customer and reported as "non-compliant", to ascertain the authenticity of the material and a conformity check. These checks are carried out by sampling in accordance with the criteria of UNI EN ISO 186 for the sampling of paper and cardboard, on a number of units (reels) calculated as follows: square root of (no. of reels +20) = no. of reels to be sampled. If the result thus obtained should contain decimals, it will be rounded up or down depending on whether the decimal is greater than or less than 5, respectively.

Please note that the above calculation will not be applied if the number of reels returned is less than or equal to 5. In that case, the entire quantity will be verified.

Example:

up to 5 reels - they will all be picked;

10 reels - the number to be sampled is $5[\sqrt{(10+20)} = 5.48 \text{ approximated to } 5]$;

25 reels - the number to be picked is $7[\sqrt{(25+20)} = 6.70 \text{ rounded up to } 7]$;

50 reels - the number to be picked is $8([\sqrt{(50+20)} = 8.37 \text{ approximated to } 8]$;

For each reel subjected to verification, a sample of security labels (min. 100) will be checked for correspondence with the declared numbers.

Article 14.2 Conditions for the Return of Material

In order to complete the return procedure and verifications referred to in Article 14.1, the returned security labels for pharmaceutical products must be reassembled on a reel and sealed in suitably sealed boxes, with the necessary reference codes on them:

- a. Product code;
- b. Progressive serial numbers;
- c. Name of the pharmaceutical company;
- d. Return form.

If just one of the return conditions is not met, Poligrafico reserves the right not to accept the return and to return the goods to the Customer.

If the return is not accepted, it shall be the Customer's responsibility to re-package the security labels for pharmaceutical products in accordance with all of the above conditions and to request Poligrafico to re-arrange collection of the security labels for pharmaceutical products through the authorised courier.

For this purpose, it shall not be necessary for the Customer to send a new complaint via the appropriate function on “Portale Unico Valori Bollini Farmaceutici”, since the return shall be made with the same serial numbers as those used in the complaint already opened.

It is understood that the shipping costs (for the return of the non-conforming item and the re-collection of the security labels to be checked) incurred by Poligrafico shall be borne by the Customer.

Article 14.3 Outcome of verifications

In the event of non-compliance of only some of the reels out of the total number of reels included in the specific supply, Poligrafico will issue a credit note for the amount equal to the value of the non-compliant reels.

In the event of non-compliance of the entire supply, Poligrafico shall issue a credit note for the amount equal to the value of the returned security labels, increased by the start-up fee and the eventual cost paid for the orders with urgency procedure as per Article 7.

Products found to be authentic and compliant will be returned to the Customer, who will be charged for shipping costs.

The security labels found to be non-compliant will be destroyed by Poligrafico, which will communicate the relevant number series to the Ministry of Health's NSIS system.

Article 15 Destruction of Security Labels

At the end of the warranty period of 12 months from delivery of the security labels to the Customer, in the event of any non-conformity found that renders the product unusable, the pharmaceutical company will proceed at its own care and expense to destroy the said security labels by shredding or incineration, notifying the Ministry of Health and sending the appropriate report (**Annex 2**) to the pec address: dgsi@postacert.sanita.it, in accordance with the Guidelines for the preparation and transmission of files to the Central Data Bank - March 2023 (available at: https://www.salute.gov.it/imgs/C_17_pubblicazioni_1066_allegato.pdf).

The pharmaceutical company will destroy the security labels by shredding or incineration even if the security labels become obsolete due to ownership or denomination or for any other cause that does not allow their applicability, also notifying the Ministry of Health by sending the relevant destruction report, according to the procedures set forth in the previous paragraph.

Article 16 Penalties

In the event of a delay in the execution of the supply with respect to the delivery deadlines indicated in Articles 7 and 8 of these general terms and conditions of supply, the pharmaceutical company can submit a complaint via the "Add Complaint" function.

In this case, with reference to orders made via the urgency procedure under Article 7, the Customer can request - even for a single day's delay, (by entering on the Portal the special "non-compliance" notice referred to in the aforementioned Article 14) - the issuance of a credit note for the delay in the

delivery or making available of security labels for collection for the value corresponding to the 5-day or 15-day urgency cost item

For all other orders handled under the standard procedure, once the time limit indicated in Article 8 has passed, Poligrafico shall incur a penalty for each day of delay equal to 0.5% of the value of the order line, up to a maximum of 10% of the order.

It is understood that the delay is incurred after the maximum time limit set by the courier for the actual delivery of the security labels to the addressee.

It is also understood that no amount will be refunded to the Customer if the delay is due to causes not attributable in any way to Poligrafico.

Article 17 Contacts

Any communication concerning the supply contract shall be forwarded to Poligrafico by one of the following methods:

- by post to the following address: IPZS – Gestione Clienti – Anticontraffazione e Tracciabilità – Via Salaria, 691 – 00138 Rome;
- by telephone, by calling the IPZS Customer Service free of charge on the toll-free number 800864035, selecting the pharmaceutical security labels option;
- by e-mail to: bollini@ipzs.it;
- by certified e-mail to: protocollo@pec.ipzs.it.

Article 18 Applicable Law and Jurisdiction

The contract for the supply of security labels for pharmaceutical products between the Customer and Poligrafico is concluded in Italy and governed by Italian law.

For any dispute related to the supply contract and not amicably settled, the Court of Rome shall have exclusive jurisdiction, with the Customer expressly waiving the jurisdiction of any other forum.

Article 19 Code of Ethics and Prevention of Corruption

The Customer expressly declares that it is aware of the provisions of Legislative Decree no. 231 of 8 June 2001 and the principles, norms and standards set out in the Organisation, Management and Control Model (hereinafter, the 'Model'), the Code of Ethics (hereinafter, the 'Code') of Law no. 190 of 6 November 2012, as amended and supplemented, and of the Anti-Corruption and Transparency Prevention Plan (hereinafter referred to as "P.P.C.T") as well as - in the context of the ISO 37001-certified Anti-Corruption Management System - of the Poligrafico Group's Anti-Corruption Policy available on the institution's website at the following link <https://www.trasparenza.ipzs.it/it/societa-trasparente/disposizioni-general/atti-general.html>

Given the above, the Customer, also promising for its employees and/or collaborators, pursuant to and for the purposes of Article 1381 of the Civil Code, undertakes to:

1. comply with the principles and values contained in the Code and maintain a conduct in line with the Model and the P.T.P.C. and, in any case, such as not to expose Poligrafico to the risk of the application of penalties provided for by the above-mentioned Legislative Decree no. 231/2001 as amended and by Law no. 190/2012 as amended;

2. not to behave and/or perform or omit acts in such a way as to induce employees and/or collaborators of Poligrafico to violate the principles of the Code or to behave in a manner not compliant with the Model and the P.T.P.C.

Failure by the Customer to comply with these obligations constitutes a serious breach of contract and will entitle Poligrafico to terminate the Contract with immediate effect, pursuant to Article 1456 of the Civil Code, without prejudice to the right to compensation for further damages.

SIGNATURE

Pursuant to and for the purposes of Articles 1341 and 1342 of the Italian Civil Code, the Contractor expressly declares that it approves all the above clauses, and in particular those in Articles: 6 (Production and supply of security labels); 7 (Emergency procedure orders); 8 (Standard procedure orders); 9 (Changes and cancellation of orders); Art. 10 (Invoicing and payment); Article 11 (Method of delivery); Article 13 (Product storage/storage conditions); Article 14 (General Product Warranty); Article 14.2 (Conditions for returning material); Article 14.3 (Outcome of verifications); Article 16 (Penalties); Article 18 (Applicable Law and Jurisdiction); Article 19 (Code of Ethics and Prevention of Corruption).

SIGNATURE

Annex 1 Italian Security Labels for Pharmaceutical Products Price List

Fixed fee for each individual request for security labels
for pharmaceutical use
Set-up fee

Euro 150.00

Fee per single request for security labels for pharmaceutical products
referring to the same AIC code
Required quantities over 25,000 pcs

Euro 21.80 (per 1,000 pcs)

Fee per single request for security labels for pharmaceutical products
referring to the same AIC code
Required quantities of less than 25,000 pcs

Euro 23.98 (per 1,000 pcs)

Surcharge for requests for pharmaceutical security labels
for pharmaceutical use
emergency procedure at 5 working days

Euro 500.00

Surcharge for requests for pharmaceutical security labels
for pharmaceutical use
emergency procedure at 15 working days

Euro 300.00

The above prices do not include VAT, which, where applicable by law, must be calculated separately.

These prices do not include transport costs, which shall only be borne by the Poligrafico in the case of delivery free at destination (see Article 11.1 of these General Terms and Conditions), whereas for "ex-works" deliveries these costs shall be borne by the Customer.

Annex 2 Report of destruction of unusable security labels for pharmaceutical use

Ministero della Salute
Direzione generale della digitalizzazione, del sistema informativo sanitario e della statistica
Tracciabilità del farmaco – Linee guida per la trasmissione dei dati – Ufficio 4
Marzo 2023

Allegato B – Verbale di distruzione bollini farmaceutici inutilizzabili

Verbale di distruzione bollini farmaceutici inutilizzabili

Luogo _____ Data _____

Al Ministero della Salute
Direzione generale della digitalizzazione, del sistema informativo sanitario e della statistica –
Ufficio 4
dgsi@postacert.sanita.it

Il sottoscritto _____

legale rappresentante dell'azienda _____

DICHIARA

che il personale sotto elencato:

Nominativo	Ufficio e/o Struttura di appartenenza

ha operato la distruzione di bollini delle seguenti specialità:

Seriale del Bollino dal	al	Denominazione Bollino	AIC	Quantità distrutta	Data Distruzione	Motivazione inutilizzabilità del Bollino
						(specificare)

Id upload: _____ del: _____

Consapevole delle responsabilità legate alla gestione delle carte valori, il sottoscritto dichiara altresì di aver operato la distruzione ai sensi della normativa vigente in materia.

Riferimenti per eventuali ulteriori comunicazioni:

Nominativo	
Telefono	
PEC o Email	

Luogo _____ Data _____

Firma
Timbro