



Information notice pursuant to article 13 of EU Regulation 679/2016 and to the Italian legislation on personal data protection – Quality

This Information Notice is given pursuant to article 13 of EU Regulation 679/2016 and in agreement with the Italian laws on personal data protection. According to the above legislation, the processing of the data that you provide will be performed in accordance with the principles of fairness, lawfulness and transparency, and will be adequate, relevant and limited to what is necessary in relation to the purpose for which they are processed and according to the data minimization principle.

Data controller and Data Protection Officer

The data controller is Bruno Farmaceutici S.p.A., in the person of its legal representative pro-tempore, with registered office in Rome, Via delle Ande n. 15, 00144, Phone No. 06.60506052, email info@bruno.org, certified email (PEC) amministrazione@pec.brunofarmaceutici.it, which designated a Data Protection Officer whose contact details are: dpo@brunofarmaceutici.it.

Purposes and legal basis of the processing

The processing of your data is necessary:

- a) to take the necessary actions in case you report a quality defect. The data provided will be processed to ensure proper and complete assessment of your report, and to perform the control and monitoring of marketed drugs. The above activities may involve the processing of special categories of data (known as sensible data), such as your health status data;
- b) To comply with the ensuing obligations towards Public Administrations.

The legal basis of the processing is the following:

- a. The execution of a legal obligation under article 6, sect. 1, letter c) and the performance of a task carried out in the public interest or in the exercise of official authority vested in the Controller under article 6 sect. 1, letter e). Regarding your sensitive data, the legal basis of the processing is that provided for in article 9 sect. 2 letter g) of EU Regulation 679/2016, i.e. processing is necessary for reasons of substantial public interest, on the basis of Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the right and interest of data subject. The legal basis of processing is also that such processing may be necessary for reasons of public interest in the area of public health;
- b. The execution if a legal obligation, when the processing is required to fulfill obligations towards Public Administrations or to comply with tax or accounting requirements (ensuring that the processing is adequate, relevant and limited to what is necessary in relation to the purposes for which the data are processed, according to the data minimization principle.

Mode of processing

Your personal data shall be processed by analogic and/or electronic means and include a set of operations concerning collection, registration and processing on paper, computer and electronic media, organization, structuring, storage, adaptation or modification, extraction, consultation, use, communication by transmission, dissemination or any other form of making available, comparison or interconnection, limitation, erasure or destruction.



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Your data shall be processed in a manner that is adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed and according to the data minimization principle, and shall be guided by the principles of lawfulness, fairness, transparency and accuracy.

The updated list of data processors is available at the Administration department, which you may contact for any further information regarding the processing of your data.

Communication, dissemination and storage of data

Your personal data shall be communicated to third parties, employees and/or collaborators acting in their capacity as subjects authorized to personal data processing, who will carry out the processing as instructed.

Your data may be also communicated to the relevant regulatory and pharmacovigilance authorities, including AIFA (Italian Medicines Agency) or EMA (European Medicines Agency).

To carry out its pharmacovigilance activity, Bruno Farmaceutici S.p.A. may use Service Providers selected from companies specialized in said services, that guarantee and agree to keep the utmost confidentiality with respect to the information they may receive and comply with the legislation on personal data protection. Such companies act as data processors pursuant to article 28 of the Regulation.

Finally, your data may be communicated to healthcare monitoring agencies, Public Administration bodies, judicial authority, insurance bodies and other subjects acting as independent data controller that are entitled to receive communication of personal data on the basis of a legal obligation or to enforce decisions and orders by the Authorities.

Under no circumstances shall personal data be communicated, disseminated, assigned or otherwise transferred to third parties for unlawful purposes and, in any case, without providing the relative information to the Interested Parties and obtaining their consent, where required by law. This will be without prejudice to any communication of data performed to comply with requests from Judicial or Public Security authorities in the manners and under the circumstances provided for by the law.

Personal data will be processed in the European Union and stored on servers located in Italy or within the European Union.

Data retention period

The principles of lawfulness, fairness, transparency, accuracy, appropriateness, relevance and necessity will also apply to the retention of your personal data, which will be performed using appropriate methods to ensure security and confidentiality, with and without the aid of automated means for data storage, handling and transmission.

The retention period will not exceed 10 years after conclusion of the event, after which the data will be erased and/or destroyed in compliance with the security measures provided to ensure confidentiality.

The retention period may be extended beyond the retention period set forth above if there is another condition that lawfully requires the processing without consent.

Rights of the data subject

Under articles 15-21 of EU Regulation 679/2016, you have the following rights in relation to the personal data that you have provided:

- Access and request a copy of such data;
- Request rectification;
- Request erasure;



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- Obtain limitation of processing;
- Withdraw your consent;
- Oppose to processing;
- Receive the personal data that concerns you in a structured format of common use readable by an automatic device, and transfer such data to another controller without impediments insofar as this is technically feasible.

The above-specified rights can be exercised within the limitations permitted by the law, and the above requests should be made via registered post to the address specified above or sent by certified electronic mail (enclosing a signed copy of ID) to amministrazione@epec.brunofarmaceutici.it; requests will be effective upon acknowledgment of receipt.