POLICY STATEMENT ON THE PROCESSING OF PERSONAL DATA PURSUANT TO ARTICLE 13 OF REGULATION (EU) NO 2016/679

Dear Sir/Madam,

We thank you for sharing the possible problems encountered in the use of a medicine marketed by DOC Generici s.r.l. (hereinafter "**DOC**" or the "**Data Controller**") and wish to inform you of the following, in accordance with the provisions of Regulation (EU) 2016/679 (also known as the "***GDPR***"), in relation to the processing of your personal data. If you are not the data subject, this notice is sent to you on the assumption that you are legally able to disclose to us the issues in question on behalf of the data subject and that, if appropriate, you will provide the following information to the data subject.

1. **Data Controller. Data Processors, Data Protection Officer.**
   The Data Controller is DOC Generici s.r.l., with registered office at Via Turati 40, 20121 Milan – email privacy@docpharma.com. An up-to-date list of any data processors is available from the Data Controller.
   The Data Protection Officer, appointed by the Data Controller, may be contacted through:
   - ordinary post, at Via Turati 40 – 20121 Milan, c/o of the Data Protection Officer;
   - email: DPO@docpharma.com.

2. **Purpose and legal basis of the processing.**
   The data and information ("**Data**") will be processed by Doc, in the course of its normal activities, for the following purposes and with the following legal bases of processing:

   - for pharmacovigilance purposes, i.e. to fulfil our obligations under Italian and European legislation on the safety and efficacy of medicinal products. This legislation requires us to provide the health authorities with information on possible adverse reactions resulting from use or exposure to one of our medicinal products and to respond to any requests from the competent authorities. The reports sent usually only contain the subject's initials and year of birth;
   - to comply with requests made by the authorities;
   - contact details only - to contact you if necessary or to respond to your further requests;
   - where necessary, to ascertain, exercise or enforce a right in court or administrative proceedings.

   You consent is not required for the processing of your data for the above purposes as it is necessary in order to fulfil legal obligations pursuant to Articles 6, c. 1 C) and 9, c. 2 B) of the GDPR or to pursue the legitimate interest of the Data Controller, pursuant to Article 6, paragraph 1 F) and 9, c. 2 F) GDPR.

3. **Recipients or categories of recipients.**
   The Data may be disclosed or made accessible to the following persons, who, as the case may be, have been appointed by the Data Controller as data processors or persons authorised to process the data, or who will act as independent data controllers:
   - Individuals (employees or third parties) who work in our corporate organization and have been specifically designated or authorized to comply with a statutory pharmacovigilance obligation.

- consultants, doctors, experts, insurers, public and private authorities and entities needing knowledge of the data as part of proceedings or obligations (including legal obligations) resulting therefrom, or when used to ascertain, exercise or enforce a right in court or administrative proceedings.

4. Transfer of Data to third countries.

The Data Controller shall process the Data without transferring it outside the European Economic Area ("***EEA***"). If technical or organisational requirements, including any arising in the future, make such a transfer necessary or if such a transfer takes place in any event, the Data Controller shall ensure that the Data is transferred in accordance with the provisions of the GDPR, and in particular Articles 45, 46 and 49 thereof.

5. Processing methods.

Your Data is processed using manual, electronic and telematic tools, using methods that safeguard the security and confidentiality of the data.

6. Retention period.

The Data will be stored, by implementing the security measures required by law, in our archives and at our IT service provider, whose archives may be located abroad, including in third countries outside the European Union. The retention period will be determined from time to time, on the basis of the circumstances of the case, the type of data and the obligations of diligent registration and fair verification established by Legislative Decree No. 219 of 24 April 2006, but the retention period may not in any case exceed 10 (ten) years following the withdrawal of the authorisation to place the medicinal product on the market.

7. Rights of data subjects.

Data subjects are granted the rights set out in Articles 15 to 22 of the GDPR. For example, each data subject may therefore:

- obtain, if one of the conditions established in Article 17 of the GDPR applies, the erasure of the personal data concerning him or her;
- obtain, in the cases provided for in Article 18 of the GDPR, a restriction on processing;
- where conditions are fulfilled, receive personal data concerning him or her in a structured, commonly used and machine-readable format and ask for it to be sent to another data controller, if technically feasible;
- object at any time to the processing of their personal data carried out for the legitimate interest of the Data Controller. In the event of an objection, the personal data will no longer be processed, provided that there are no legitimate reasons to proceed with the processing that prevail over the interests, rights and freedoms of the data subject or to establish, exercise or enforce a right in court.

8. Right to lodge a complaint with the Guarantor.

Each data subject may lodge a complaint with the Data Protection Authority if he or she believes that the rights he or she holds pursuant to the GDPR have been infringed, in the manner indicated on the Data Protection Authority's website accessible at: www.garanteprivacy.it.