Notice pursuant to Article 13 of EU Regulation 2016/679 of the European Parliament and of the Council of 27 April 2016 (General Data Protection Regulation "GDPR") - Undesired/Side Effects (Adverse Reactions)

In accordance with the current personal data protection regulations (below the "Regulations"), BOUTY S.P.A. (below the "Company") as the "Controller" of the processing, whose identification details are provided below, is required to provide certain information regarding the use of your personal data.

1. Purposes of the processing

Your personal data will be processed for the *"Management of reports related to adverse reactions"*. The data sent to us, either in paper form or by email or in any other form, will be processed for all the requirements related to pharmacovigilance.

The data will be collected and processed exclusively for the proper performance of activities related to and instrumental to the purposes of pharmacovigilance such as, for example: (i) identification of any unknown adverse reactions; (ii) improvement and enhancement of the existing information on suspected adverse reactions; (iii) assessment of the causal link between the administration of the drug and the observed adverse reaction; and (iv) the reporting of that information to the competent authority to ensure that the drugs used have a favourable benefit/risk balance for the population.

2. Nature of the provision of the data and consent

The provision of the data for the purposes referred to in point 1 of this notice is optional, but essential for the performance of the activities indicated. In any event, consent to the processing of the data for these purposes is not necessary because the processing is essential for the fulfilment of a legal obligation that BOUTY S.P.A. is subject to.
We inform you that the fulfilment of a legal obligation pursuant to Article 6.1(c), and for reasons of public interest in accordance with Article 9.2(g),(i) of the GDPR, constitute the grounds for the lawfulness of the processing of your data for the purpose stated in this notice.

3. Methods of processing the data

The personal data provided may be processed through manual, computer and electronic means, using criteria strictly related to the purposes for which the data were collected and in any case designed to guarantee the security and confidentiality of the data processed and ensure that the processing is carried out anonymously.

Scope of "internal" circulation of the data

The data may be used by Company personnel who have been assigned a specific role and have been given suitable operational instructions to prevent the loss, destruction, unauthorised access or processing of the data. Your personal data will only be made accessible to persons, within the company organisation, that need the data because of their job or hierarchical position, with a duty of confidentiality.

Data processors - The data may also be used by third parties that perform activities on behalf of the Company. These third parties act as data processors and/or persons in charge of the processing, under the direction and control of the Company.

4. Storage of the data

The Data will be kept for the period strictly necessary to achieve the purposes for which they were collected. In any event, the criterion used to determine this period is based on compliance with the terms permitted by the applicable laws and the principles of minimisation of the processing and rational management of archives.

5. Communication of the data

In accordance with the laws and regulations that we are subject to, we may be required to communicate the data to the Ministry of Health, other authorities and healthcare associations in third countries outside the EU

and to legitimate recipients in accordance with the law and the regulations. These parties will act as independent Data Controllers. With regard to the possible transfer of the Data to third countries outside the EU, including countries that may not provide the same level of protection envisaged by the applicable legislation, we inform you that the transfer of data abroad is subject to specific guarantees for the protection of personal data through the adoption of standard contractual clauses.

6. Rights of the data subject

You have the right to be informed at any time about your data held by the individual controllers, i.e. by the Company and the parties referred to above that we communicate your data to, and how they are used. You also have the right to have the data updated, supplemented, corrected or erased, to request their portability or restriction of processing, in the cases provided for by law, and to object to the processing of the data unless the individual controllers have a legitimate interest in the data. For the exercise of your rights, as well as the more detailed information about the parties or categories of parties to which the data are communicated and/or transferred or who have access to them as data processors or persons in charge of the processing, you can contact our data privacy officer, at BOUTY S.P.A., by e-mail at privacy@ibsa.ch or farmacovigilanza@ibsa.ch or at the address indicated below to the attention of the data privacy officer.
Lastly, we remind you that you have the right to lodge a complaint with the competent Authorities if you consider that your rights have not been respected or that you have not received a response to your requests in accordance with the law.

7. Data Controller

The data controller is BOUTY S.P.A., with registered office in Via Vanvitelli, 4 – 20129 Milano, Italy.

8. Data Protection Officer

The Company uses a Data Protection Officer or DPO.
The DPO can be contacted via the following communication channel: mmemtsa@privintelligent.com.