Information notice on the processing of Customers' personal data

(art. 13 and 14 of EU Regulation 679/2016)

Dear customer, with regard to the processing of Your personal data we hereby inform You that:

1. Data Controller and data protection officer

the Data Controller is Laboratorio Chimico Farmaceutico "A. Sella" S.r.l. (hereinafter also referred to as "Controller") VAT No. 00161860242, with registered office in Via Vicenza, n. 67 36015 Schio (VI). The Controller may be contacted by:

- e- mail at the addresses privacy@sellafarmaceutici.it (Ordinary mail) or sellafarmaceutici@cert.assind.vi.it (Certified mail);
- Telephone at no. 0445 670088;
- Ordinary mail at the address Via Vicenza, n. 67 36015 Schio (VI)

The Controller has not appointed a personal data protection officer (RPD, that is, data protection officer, DPO).

2. Data processed and methods of Processing

The Data Controller will carry out the processing of the following data:

A) for the reporter: identified data including name, surname and contact details (including address, e-mail address, telephone or fax number);

B) for the person to whom the report refers:

- name and / or initials of the patient;
- date of birth / age range, sex, weight, height;
- information on health, race or ethnic origin and sex life;
- medical history and health conditions, which could include for example:
- details of the Sella product suspected of causing the adverse event, including the dosage they took or was prescribed to them, the reason why it was taken or prescribed, and any subsequent change to their usual regimen;
- details of other medicines or remedies they are or were taking at the time of the adverse event, including the dosage taken or prescribed, the duration and the reason for taking such medicine and any subsequent change to the regimen;
- details of the adverse event that occurred, the treatment received for that event and any potential long-term effect that the adverse event has caused to their health; other information regarding the medical history considered relevant by the reporter, including documents such as laboratory reports, medicines taken in the past and pre-existing conditions.

The data may be processed both in paper form and digitally using IT tools.

3. Purposes of the data processing and legal basis

Your data are processed on the basis of the legal bases and for the Purposes indicated below:

Reasons of public interest in the area of public health and fulfilment of the legal obligation relating to the collection, analysis and reporting to the competent authorities of adverse reactions to the medicinal products manufactured (EU Reg. 1235/2010 and subsequent amendments and additions):

A. monitoring the safety profile of the products manufactured.
B. identification of any known and unknown adverse reactions, also identifying their frequency and impact;
C. improvement and enhancement of the information on suspected adverse reactions already known;
D. assessment of the causal link between administration of the medicinal product and the adverse reaction observed;
E. notification to the competent authority of such information in order to ensure that the medicinal products used present a favourable benefit/risk ratio for the population.
F. maintaining the registers and archives of the documentation relating to Pharmacovigilance, also with a view to possible Pharmacovigilance Audit activities;

Contractual relationship:

G. management of and response to allegations of liability and claims for compensation, including in court

4. Consequences of failure to provide personal data

The provision of data is necessary; refusal entails the impossibility for the Controller to act upon the request submitted, as well as to comply with the legal obligations concerning Pharmacovigilance. The processing of the data is lawful as it is based on the fulfilment of a legal obligation (for personal data) and on reasons of public

interest in the area of public health (for special categories of data) as indicated in the previous point.

5. Data retention

From their receipt and/or update, the data will be retained for a period appropriate to the purposes of the processing and in any case within the terms laid down by law. Specifically, the personal data will be anonymised within six months of the closure of the case and in any case no later than two years from the date on which the first report was made. The data relating to the pharmacovigilance report in anonymous form will be retained for as long as the product is authorised and for ten years from the expiry or revocation of the marketing authorisation of the product in the last country of marketing, save for any defence requirements of the Controller.

In relation to purpose G, retention will take place for the duration of the relationship with the data subject and the limitation period of the rights connected to it.

6. Access to and disclosure of data

The data being processed will not be disseminated; they may instead be made available in anonymous form, for the purposes indicated above, to the parties accessing the National Pharmacovigilance Network as well as to parties required to carry out Pharmacovigilance activities (AIFA, EMA, holders of the marketing authorisation of medicinal products, Italian Regions, Local Health Units, the pharmacovigilance office of hospitals or of the Scientific Institutes for Research, Hospitalisation and Health Care).

Your personal data may be processed for the purposes indicated above by:

1. employees and collaborators of the Controller as persons authorised to process the data;
2. Third parties such as professionals, consultants and entities that process data and provide services functional to the purposes indicated above (e.g. IT service providers, IT systems maintenance providers, financing companies, etc.) acting as data processors or independent controllers to whom the Controller entrusts the management of the systems or the performance of part of the processing operations on the data. The updated list of such parties is available at the company's registered office.

7. Data transfers to third countries

The Controller will not transfer Your data outside the European Union.

8. Profiling and Dissemination of data

Your personal data are not subject to dissemination nor to any entirely automated decision-making process, including profiling.

9. Your Rights

The rights granted to You, save for limitations laid down by law, include those to:

request from the Controller **access** to Your personal data, confirmation of their existence and the information relating to their processing including the updated list of the data processors; the **rectification** of inaccurate data or **the integration** of incomplete data.

- obtain the **erasure** of the data and the **restriction** of the processing where the legal requirements are met.
- **Receive in a structured format** which is commonly used and machine-readable the personal data concerning You, where the processing is carried out by automated means, in order to transmit them to another Controller or - if technically feasible - to obtain the direct transmission from the Controller to another controller.
- **withdraw** at any time **the consents** given to the processing of personal data.
- **object**, in whole or in part to the processing and where the legal requirements are met
- **lodge a complaint** with a supervisory authority and in particular with the Italian Data Protection Authority.

The rights may be exercised by sending a written request indicating in the subject line "Privacy – exercise of the rights of the data subject" by registered letter with return receipt or e-mail to the addresses of the Controller indicated above.

The full text of EU Reg. 2016/679 – General Data Protection Regulation - may be consulted on the website of the Italian Data Protection Authority and in particular Chapter III – Rights of the data subject – Articles 12 – 23.

Laboratorio Chimico Farmaceutico "A. Sella" S.r.l.