Collective information note on the protection of personal data in the context of studies requiring access to data from the National Health Data System (SNDS)

In accordance with the provisions of article 14 of the GDPR, this collective information notice describes the measures implemented in the context of studies which do not allow individual information and which require access to data from the National Health Data System (SNDS).

This data will not be transferred outside the European Union.

The study implemented by the **Valproate Consortium** (member companies: APOTEX EUROPE B.V; ARISTO PHARMA GMBH; ARROW GENERIQUES; BETAPHARM ARZNEIMITTEL GMBH; CONSILIENT HEALTH LIMITED; CRESCENT PHARMA LTD; DESITIN ARZNEIMITTEL GMBH; G.L. PHARMA GMBH; GENERIS FARMACEUTICA S.A.; SANDOZ/HEXAL AG; LUPIN HEALTHCARE (UK) LTD; NEURAXPHARM ARZNEIMITTEL GMBH; ORION CORPORATION; SANOFI-AVENTIS; STADA ARZNEIMITTEL AG; TECNIFAR S.A.; TEVA PHARMACEUTICALS EUROPE B.V.; VIATRIS HEALTHCARE SAS; WOCKHARDT UK LIMITED), of which LUPIN HEALTHCARE (UK) LIMITED is a member**,** as part of this system for accessing data from the SNDS, is referenced below:

• **Study:** Drug Utilisation Study extension in real life of valproate and related substances in women of childbearing age, in Europe, using
databases.

• **Data Processor:** The study is carried out by IQVIA France, which has made a compliance undertaking to the CNIL.

• **Legal basis:** In accordance with article 6 of the GDPR and article 5 of the law Informatique et Libertés, the processing carried out as part of this study is based on the legitimate interests of LUPIN HEALTHCARE (UK) LIMITED in its capacity as a healthcare industrial company, pursuing an objective of research, studies, evaluation, and innovation in healthcare. In accordance with article 9 of the GDPR, the processing of this personal data concerning health is for scientific research purposes; on July 20th 2023, the Comité Ethique et Scientifique pour les Recherches, les Etudes, et les Évaluations en Santé (CESREES) indicated that the study was in the public interest.
This study has been authorised by the Commission Nationale de l'Informatique et des Libertés (CNIL) in accordance with article 66 of law no. 78-17 of 6 January 1978, as amended (decision DR-2023-174).

• **Purpose:** The main objective of this study is to assess the impact of the implementation of the risk minimization measures (RMM) and pregnancy prevention program (PPP) on the real-world use of valproate and related substances in women of childbearing potential (WCBP) in Europe.

• **SNDS data used:** Data extracted from the Datamart de Consommation de soins Inter-Régime (DCIR) database and the Programme de Médicalisation des Systèmes d'Information (PMSI) database between 2008 and 2022.

• **Data retention period:** 6 years after availability (scheduled for 2027).

• **Data Controller:** LUPIN HEALTHCARE (UK) LIMITED , The Urban Building, 3-9 Albert Street, Slough, SL1 2BE, United Kingdom - joint data Controller with the other members of the Valproate consortium.

• **Data Protection Officer**: can be reached at dpo@lupin.com

In order to exercise their rights of access and rectification of data, as well as their rights to object to and limit the processing of such data, the persons concerned by the processing shall send their request, providing proof of their identity by any means, to the director of the Health Data Platform or to the director of the compulsory health insurance body to which they belong.

Data subjects also have the right to lodge a complaint with the Commission Nationale de l'Informatique et des Libertés (CNIL), 3 Place de Fontenoy, 75007 Paris