IMPORTANT INFORMATION RELATING TO A PERMANENT CESSATION OF MARKETING

14 April 2023

Re: Permanent cessation of the marketing of Strattera® (atomoxetine) hard capsules

Dear Doctors,

Eli Lilly Italia S.p.A. would like to inform you of the permanent cessation of marketing of Strattera® (atomoxetine) hard capsules.

Strattera is currently available in Italy in the form of 10, 18, 25, 40, 60, 80 and 100 mg hard capsules. Eli Lilly Italia S.p.A. will cease to market Strattera hard capsules in Italy **from 30 September 2023**. The cessation of marketing of this medicinal product is due to supply constraints, not to problems concerned with safety and efficacy. Once the current batches of Strattera hard capsules have expired, no further batches of the medicine will be available.

To ensure the safe discontinuation of treatment with Strattera hard capsules and, if necessary, switch to alternative therapy,

- patients should consult their prescribing doctor and should not stop taking Strattera hard capsules without such consultation;
- prescribing doctors are advised not to issue new or repeat prescriptions for Strattera hard capsules;
- prescribing doctors are advised to re-assess patients currently undergoing treatment and switch to a suitable alternative;
- pharmacists are advised to refer patients to their doctor or to another prescribing doctor for treatment advice;
- information on the discontinuation of treatment with Strattera hard capsules is provided in the Summary of Product Characteristics and the Package Leaflet, which can be consulted on the AIFA Drug Database by clicking on the following link_

https://farmaci.agenziafarmaco.gov.it/bancadatifarmaci/farmaco?farmaco=037063

For updates on the status of shortages, please refer to the list of medicinal product shortages published on the AIFA website https://www.aifa.gov.it/web/guest/farmaci-carenti.

Reporting of adverse events

Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system on https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse. Adverse events can be reported by contacting Eli Lilly Italia S.p.A. on the toll-free number: 800-117678.

This letter does not provide a complete description of the risks associated with Strattera. Please contact Eli Lilly Italia S.p.A. on the toll-free number 800-117678 if you have any questions about the information in this letter, or about the safe, effective use of Strattera. Yours sincerely,

AIFA would like to take this opportunity to remind all Healthcare Professionals of the importance of reporting suspected adverse drug reactions, since it offers an indispensable tool for confirming a favourable benefit-risk ratio under actual conditions of use. Reports of suspected adverse reactions to drugs must be sent to the pharmacovigilance manager of the facility to which the practitioner belongs. This notice is also published on the AIFA website (www.aifa.gov.it). Regular consultation of this site is recommended for the best professional information and service to citizens.