**MHRA PORTAL SUBMISSION**

Information Processing Unit
Area 3
Medicines and Healthcare products Regulatory Agency (MHRA)
10 South Colonnade
Canary Wharf
London
E14 4PU

Lodi, 15/12/2025

**Subject: Submission of Variation Application Dossier(s) for Tirosint 13, 25, 50, 75, 100, 125, 150, 175 and 200 micrograms soft capsules**

Dear Sirs,

We are pleased to submit our Variation Application Dossier for a Type IB procedure.
The application concerns a single variation.

The details are as follows:

| | |
|---|---|
| **Name of the medicinal product(s):** | Tirosint |
| **Pharmaceutical form(s) and strength(s):** | Capsule, soft<br>13, 25, 50, 75, 100, 125, 150, 175 and 200 micrograms |
| **INN/active substance(s):** | Levothyroxine Sodium |
| **ATC Code(s):** | H03AA01 |
| **Marketing Authorisation Number(s):** | PL 21039/0057 - 13mcg soft capsules<br>PL 21039/0058 - 25 mcg soft capsules<br>PL 21039/0059 - 50 mcg soft capsules<br>PL 21039/0060 - 75 mcg soft capsules<br>PL 21039/0062 - 100 mcg soft capsules<br>PL 21039/0064 - 125 mcg soft capsules |

IBSA Farmaceutici Italia Srl

PL 21039/0066 - 150 mcg soft capsules

PL 21039/0067 - 175 mcg soft capsules

PL 21039/0068 - 200 mcg soft capsules

**Type of the Variation Application(s)**: A.2.b - Change in the (invented) name of the medicinal product

When appropriate, please indicate type of change (for Type IB and Type II variations only):

- ☐ Indication
- ☐ Paediatric Indication
- ☐ Safety
- ☐ Following Urgent Safety Restriction
- ☐ Quality
- ☐ Annual variation for human influenza vaccines
- ☒ Other

☒ We confirm that the electronic submission has been checked with an up-to-date and state-of-the-art virus checker.

The variation application affects the SmPC, labelling and package leaflet. Clean and tracked versions are enclosed as word files in the working documents together with the SmPC fragments.
The mock-ups have been updated only as regards the name of the medicinal product. No other change in the texts, design or colours was made.

eCTD Sequence number 0008
The application is submitted via MHRA portal.

Yours sincerely,

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