



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Feedback on SPOC Working Party activities on GLP-1 receptor agonists and insulin products shortage management

PCWP/HCPWP and all eligible organisations meeting

20 November 2024

Presented by Klaus Kruttwig
Supply and Availability of Medicines and Devices, Regulatory Science and Innovation Task Force (TRS-SAM)

An agency of the European Union





Results of the Darwin EU - Drug Utilisation Study on GLP-1 RA



Darwin EU - Drug Utilisation Study on GLP-1 RA

Aims of the study

Providing an overview of the characteristics of patients prescribed with a GLP-1 RA medicinal product and how these have changed over the past ten years. This will help contextualise what determinants might be driving the demand for GLP-1 RA vis-à-vis the observed shortage of medicines.

Status of the study

- Establishment of an expert group involved in the review of the current study and development of the study protocol for the follow-up study.
- The review of the report is ongoing and expected to be finalized in due course.
- The final report is expected to be published by the end of November 2024.
- Results will be presented at the next meetings of the MSSG, SPOC WP, and the subgroup on GLP-1 RA of the Drug Shortages Global Regulatory Working Group.



Discontinuation of selected Novo Nordisk insulin products



Discontinuation of selected Novo Nordisk insulin products

Background

- The Marketing Authorisation Holder (MAH) informed about the discontinuations of selected insulin products.
 - Levemir, NovoMix 50, Mixtard 50, Fiasp PumpCart, as well as Penfill, FlexPen, InnoLet presentations for Actrapid, Insulatard, Mixtard 30 will be discontinued over the next two years, until the end of 2026.

Actions taken

- EMA and SPOC WP are conducting a detailed impact analysis of the products' discontinuations.
- Meetings of the SPOC WP subgroup on GLP-1 RA and insulins with the MAH are being held.
- Establishment of a clinical expert group to discuss implications on patient care, including switching options.
- Discussions at the level of the Drug Shortages Global Regulatory Working Group.
- MAH provided an oral explanation at the MSSG meeting on 19 November 2024.



Feedback from the clinical expert group on insulins and GLP-1 RA

First meeting

- 18 November 2024

Main topics discussed

- Impact of the discontinuation on the treatment of patients.
- Understand challenges and concerns associated with switching patients to the vial presentation.
- Switching options to alternative products.
- Understand if healthcare professionals have already been notified in individual countries



Next steps

- Further analysis of the impact of the discontinuation of selected insulin products on the availability of insulins for patients is being conducted.
- Supporting EU/EEA countries with impact assessment.
- Further assessment of clinical parameters to be considered when switching to alternative medicinal products.
- Communication activities to inform patients and healthcare professionals.



Any questions?

Further information

klaus.kruttwig@ema.europa.eu

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Telephone +31 (0)88 781 6000

Send us a question Go to www.ema.europa.eu/contact

Follow us on  **@EMA_News**