Experience with Notified Body Interactions for Drug-Device Combination Products

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If, ....a device is placed on the market in such a way that the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, that single product shall be governed by Directive 2001/83/EC.

The relevant essential requirements of Annex I to this Directive (MDD) shall apply as far as safety and performance-related device features are concerned.
Medical Device Regulation - MDR (Article 117)

Unchanged

• Content of the **underlying definitions** and **regulatory principles**

New!

• Requirement to obtain a **Notified Body opinion** for the device constituent parts with the relevant General Safety and Performance Requirements (Annex I)
Annex I – Change in Requirements

Medical Device Directive
13 clauses

Medical Device Regulation
23 clauses

New requirements
Extension/clarification of existing requirements
Device history

1925
INSULIN NOVO AND THE NOVO SYRINGE

1985
NOVOPEN®

1989
NOVOLET®
Novo Nordisk current insulin device portfolio

Needles

NovoFine®, NovoFine® Plus and NovoTwist®

Pen-injectors

NovoPen® 4

NovoPen® 5  NovoPen® Echo

Prefilled pen-injectors

FlexPen®  InnoLet®

FlexTouch®
Development process for prefilled pen-injectors

- The Quality Management System (QMS) fulfils requirements for both drug cGMP and device QMS.

- The device QMS covers both development of devices (CE marked) and the device constituent part of drug-device combination (DDC) product.

- The device QMS ensures that the device constituent part of DDC is developed to comply with Annex I of the Medical Device Directive 93/42/EEC.

- The device QMS is certified according to EN ISO 13485:2016 by the Notified Body (Lloyd's Register Quality Assurance Limited (LRQA)).
Notified Body Verification of Annex I (MDD)

- NN has for many years requested LRQA to review documentation for the device constituent part of DDC products.

- These devices are included in the assessment during QMS surveillance audits, the technical files are sampled by LRQA and the technical documentation assessed for compliance with relevant Essential Requirements of Annex I, MDD.

- LRQA follow the notified body procedures and assessment criteria and have the technical competencies required when performing the review.
**Process for interaction with Notified Body**

**Planning**
- Introduce new product
- Timeline and process
- Documentation

**Review**
- Review conducted
- Review report issued with deficiencies
- Follow-up on deficiencies

**Reporting**
- Final report
- New product on Notified Body letter “Record of Verification”
Record of Verification

• The Quality Management System for the products included demonstrate

• Compliance of the technical documentation with the relevant Essential Requirements detailed in Annex I, Medical Device Directive 93/42/EEC

• Compliance with the requirements of the EN ISO 13485:2016
Submission to Health Authorities

Novo Nordisk is including the “Record of Verification” from the Notified Body in submissions to Health Authorities
Notified Body “opinion” as required in article 117 of the MDR

- Current NN process for a Notified Body opinion would satisfy the requirement introduced with the MDR for a Notified Body opinion
Guidance and clarifications needed for the future

- **Timing and process** for the interaction with the Notified Body needs to be clarified
Guidance and clarifications needed for the future

- **Scope** of the Notified Body review (opinion) versus scope of the Health Authority review

- **Documentation** to be provided for Notified Body review and Health Authority review
Thank you