Concerned Member State Comments on Day 70 Preliminary Assessment Report to be sent at Day 100 at the latest

1. This document is sent by:

CMS	Denmark
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Assessors, if applicable (name e-mail, phone)	-
Date/Day of procedure	Day 100

2. This document concerns:

Procedure number	NL/H/4976/001-002/DC
Name of the medicinal product in the RMS	Sitagliptin/Metformin Sandoz
Name of the active substance	Metformin hydrochloride/ Sitagliptin hydrochloride
Applicant	Sandoz
Deadline for comments	28.02.20

3. Comments, general

3.1 Assessment of the RMS

We endorse the RMS assessment, but also have additional comments ☒

We do not fully endorse the RMS assessment, and have other comments ☐

3.2 Conclusions on the product
Our conclusion is that the product is:

Approvable, provided that satisfactory responses are given to the list of questions and/or the SmPC/PL/labelling is changed according to the comments ☐

Non-approvable ☒

3.3. List of Questions/Proposed conditions for marketing authorisation
We have grounds of potential serious risks to public health on the following part of the assessment report not already raised by the RMS as major objections

Quality ☐

Non-Clinical ☐

Clinical ☐
Risk Management Plan ☐

SmPC ☐

PL ☐

Labelling ☐

We have additional other concerns on the following part of the assessment report
Quality ☐

Non-Clinical ☐

Clinical ☐

Risk Management Plan ☐

SmPC ☐

PL ☐

Labelling ☐

Module 1 – Application related comments (including product name) ☒

4. Potential serious risk to public health

None

5. Additional other concerns

Module I – Application related comments (including product name)[1]

Other concerns not already raised by the RMS
The product name Sitagliptin/Metformin Sandoz is not considered acceptable in DK.

The propose name does not follow our recommendations for naming of medicinal products – please refer to: https://laegemiddelstyrelsen.dk/en/licensing/licensing-of-medicines/naming-of-medicines/

If it is a salt, a derivative or an ester, the generic name used should relate to the strength:

- *If the strength is stated in relation to the base, the generic name of the base should be used.*
- *If the strength is stated in relation to the salt, the generic name of the salt should be used.*

The name should be Sitagliptin/Metforminhydrochlorid Sandoz (Pease see rationale below)

[1] Please note that for 10.1 and 10.3 applications with a centrally authorised product as reference product, the product name in RMS and all CMS must be the same. It is therefore important that comments on the product name are sent early in the procedure in order to reach agreement before day 210/90.

Please note that it is not possible to reserve a product name in DK. Therefore, in the period until the product has been granted a marketing authorisation, other products could be approved with a name that could be similar or cause confusion with the current proposed product name. Other factors may also occur and cause that the applied name cannot be accepted. Please note that DK consider product names to be a national issue. Please notice a national issue in DK: The pharmaceutical form and strength are not part of the final approved name in DK. For further information on Danish practice regarding naming of medicinal products, please refer to the Danish Medicines Agency's website: http://laegemiddelstyrelsen.dk/en/licensing/licensing-of-medicines/naming-of-medicines
Rationale The strength relates to the metformin salt (metforminhydrochloride) and to the sitagliptin base. Based on this, and on the ATC-code (A10BD07 - METFORMIN OG SITAGLIPTIN) the name should be Metforminhydrochlorid/Sitagliptin Sandoz. However, for all approved CAP's with the ATC code A10BD07 the strength in the PIL and labelling is given as 50 mg/850 mg and 50mg/1000 mg, but the active substances are given as sitagliptin/metformin hydrochloride. Since it could potentially cause confusion if the order of the strengths or the active substances are approved differently for NL/H/4976, DK is willing to accept the name Sitagliptin/Metforminhydrochlorid Sandoz and the strength 50 mg/850 mg and 50mg/1000 mg, in accordance with the approved CAP's.

6. Additional information for the Applicant

Please provide the final SmPC, package leaflet and labelling in Danish within 5 working days after End of Procedure.

For the Danish SmPC, please use the official Danish template for human medicines, which can be found at our website: PRS-human.doc.

All electronic versions should be submitted as Word files. Translated text are considered working documents.

Please send section VI.2/VI of the final RMP. This sRMP will be published at our website.

If applicable, please provide the updated application form(s) incorporating all changes made during the procedure.

Please see our website for detailed information about our requirements regarding submissions:
http://laegemiddelstyrelsen.dk/en/licensing/licensing-of-medicines/marketing-authorisation/format-requirements