MAH: ……

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **API name1** | **Drug product name** | **MA number** | **Secondary amine present in API** | **NDSRI(s): Chemical structure, IUPAC name, CAS number (if available)2, 3** | **CPCA classification of NDSRI(s)3**  | **Reference for CPCA classification3 ,4** | **Analytical Results in DP (ng/d) (if available)3**  | **Remark** |
| …… | …… …… …… | …… …… …… | [ ]  Yes -> go to next column[ ]  No  |  | …… | …… | …… | …… |
| …… | …… …… …… | …… …… …… | [ ]  Yes -> go to next column[ ]  No |  | …… | …… | …… | …… |
| …… | …… …… …… | …… …… …… | [ ]  Yes -> go to next column[ ]  No  |  | …… | …… | …… | …… |
| …… | …… …… …… | …… …… …… | [ ]  Yes -> go to next column[ ]  No |  | …… | …… | …… | …… |
| …… | …… …… …… | …… …… …… | [ ]  Yes -> go to next column[ ]  No  |  | …… | …… | …… | …… |
| …… | …… …… …… | …… …… …… | [ ]  Yes -> go to next column[ ]  No |  | …… | …… | …… | …… |

1 All synthetic APIs for human use under responsibility of MAH are to be listed.

2 Only nitroso derivatives of the API are currently in scope (no nitrosylated impurities of the API).

3 To be filled out only if secondary amine is present in API.

4 e.g. EMA Appendix 1, FDA Recommended AI Limits for Certain Hypothetical NDSRIs (Table 1). If CPCA classification has been performed by MAH, please provide justification for assignment of classification.

Place and date: ……

Signature and typed name: ……

To be submitted via e-mail to market.surveillance@swissmedic.ch as Word file (mandatory) and as pdf file.

Change history

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Valid and binding as of: | Description, comments (by author) | Visum Autor /Autorin |
| 01 | 31.10.2023 | First version provided | sac |