# **Submission checklist for health technology developer**

**For Single Technology Assessment of Medicinal Products**

The following checklist is mandatory and must be submitted [as pdf] alongside the STA dossier.

|  |  |
| --- | --- |
| Company |  |
| Medicinal Product | *INN/Brand®* |
| Relevant therapeutic indication |  |
| IDXXXX\_XX (if the assessment is ordered from Bestillerforum RHF) |  |

Prior to submitting, ensure that all requirements below are met and checked. Failure to complete the checklist, or incorrectly checking boxes, will result in delayed initiation of the evaluation.

|  |  |
| --- | --- |
| Check if yes |  |
|[ ]  The dossier is using NoMA’s Submission Template and is in accordance with NoMA’s Guidelines.  |
|[ ]  The completed STA submission dossier is submitted in .docx and .pdf format.Appendices or accompanying files containing embedded documents are submitted in .docx format.  |
|[ ]  Full text copies for the most relevant efficacy studies and all references used as the basis for input data in the health economic analyses and in calculations of severity and budget impact are included.*Files must follow a naming convention. E.g., Author, Year.* *Include compressed EndNote library (.enlx including enl-file and data folder) if available.* |
|[ ]  The cost-effectiveness model and budget impact model [if submitted] follows the requirements described in the Guidelines, chapter 12.2.  |
|[ ]  The budget impact model [if submitted] is based on NoMA’s BIA template and submitted as .xlsx-file.  |
|[ ]  The submitted files follow the naming conventions described in this document. |

Complete the table below, listing all files and documents included in the submission package. Add rows as needed.

|  |  |
| --- | --- |
| File name | Brief description of content |
| <Aspirin ID2022\_017 Checklist.docx> | < Completed Submission checklist > |
| <Aspirin ID2022\_017 Submission dossier.docx> | < STA dossier, main document >  |
| <Aspirin ID2022\_017 Submission.pdf> | < PDF copy of STA dossier > |
| <Aspirin ID2022\_017 CEM.xlsm> | < Cost effectiveness model, containing incorporated budget impact calculations > |
| <Aspirin ID2022\_017 References.zip> | < .zip-file containing PDF-files of cited references > |
| <Aspirin ID2022\_017 HSUV SLR.docx> | < Complete documentation of systematic literature search for health state utility values used in cost effectiveness model > |
| <Aspirin ID2022\_017 ITC.pdf> | < Complete study report of indirect treatment comparison used to inform relative efficacy used in cost-effectiveness model > |

**Naming convention**

All documents in the submission should be named in accordance with the specified file-naming convention and saved in the specified format, as outlined below. The international non-proprietary name (INN) and order-ID number (if relevant) should be included at the start of all file names. Please do not use all capital letters or underscores in the filename.

This chapter may be deleted prior to submission.

Table 1. File naming convention and format for medicinal products considered for funding by the regional health authorities (ordered by Bestillerforum RHF)

|  |  |  |
| --- | --- | --- |
| Type of file | File naming convention | File format |
| Submission template | <INN Order ID Submission dossier>  | .docx and .pdf |
| Cost-effectiveness model | <INN Order ID CEM>  | .xlsx or similar |
| Budget impact model | <INN Order ID BIM>  | .xlsx or similar |
| References | <INN Order ID references>  | .zip |
| Submission checklist | <INN Order ID Checklist>  | .pdf |

Table 2. File naming convention and format for medicinal products considered for public funding through the National Insurance Scheme (ordered by NoMA)

|  |  |  |
| --- | --- | --- |
| Type of file | File naming convention | File format |
| Submission template | <INN Submission dossier>  | .docx and .pdf |
| Cost-effectiveness model | <INN CEM>  | .xlsx or similar |
| Budget impact model | <INN BIM>  | .xlsx or similar |
| References | <INN references>  | .zip |
| Submission checklist | <INN Checklist>  | .pdf |