Release note for version 3.0 of the EU VNeeS Specification (Jan 2022)

Section of the document	Change
4 File Format & Source	The VNeeS specification now discourages only files sizes larger than 200 MB.
7.(b) Folder structure for initial Marketing Authorisation Application	The new Annex to Regulation 2019/6 allows that the pharmaceutical quality data for the finished product may be included in the dossier in CTD format. Where Part 2 is presented in the CTD format, it also requires that the quality overall summary (QOS) shall be used for the critical expert report on quality.
7.(e) Active Substance Master Files	Folder structure requirements for ASMF were moved from main guidance text to separate table 5 in the annex. The new Annex to Regulation 2019/6 allows that the pharmaceutical quality data for the active substance may be included in the dossier in CTD format. In addition, for separate ASMF submissions received from the holder agencies had accepted that it could be in eCTD version 3.2.2 format.
7.(f) Platform Technology Masterfile	New brief section to clarify requirements for a Platform Technology Masterfiles.
7.(g) Submission structure for post-authorisation submissions	Clarification of requirements for applications for the new SPC harmonisation procedure according to Section 4 of Regulation (EU) 2019/6. Folder structure requirements for application for a change in prescription status were revised according to new legislation and moved from main guidance text to a separate table in the annex (table 9).
7.(i) files	The VNeeS specification now discourages only files sizes larger than 200 MB. Additional requirements were added for final product information files to be uploaded to UPD (file size, naming conventions).
Annexed tables	Table 1: Revised folder structure for a pharmaceutical product according to the Annex II to Regulation (EU) 2019/6 (as amended). Table 2: New folder structure for biological veterinary medicinal products other than immunologicals Table 3: Revised folder structure for an immunological product. Note that optional submission of a Part 5 and Part 6 is no longer in compliance with the requirements according to Regulation (EU) 2019/6. Table 5: Folder structure requirements for ASMF moved from main guidance text to a new, separate table in the annex. Table 6: New folder structure for an application for a Vaccine Antigen Master File (VAMF). Table 7: New example of a folder structure for mixed VNeeS and CTD submissions where the quality part is provided in CTD folder structure. Table 8: New example of a folder structure for mixed VNeeS and CTD submissions where the Applicant's Part is provided within a CTD folder structure. Table 9: Folder structure requirements for application for a change in prescription status revised and moved from main guidance text to a new, separate table in the annex. Note that only Table 1 to Table 4 are used as basis for technical validation of folder structures and folder/file naming, whereas Tables 5 to 9 should be understood only as exemplary structures for these submissions.
VNeeS_011	Additional hyperlinks to a file from different TOCs, pointing to a folder not within the same dossier part of that TOC, will not lead to validation failure.

VNeeS_BP002	Warning only if file size is larger than 200 MB.
Throughout text	Submission options other than CESP and gateway are removed from the guidance. References to hard media are deleted. Text was aligned to revised legislation: - Renewals of full marketing authorisation are no longer applicable - Extensions are now variations under a specific classification code - Type IA replaced by variations not requiring assessment (VNRAs) - PSURs are replaced by signal management - Term "detailed and critical summaries" replaced by "critical expert reports" - Term "repeat use" replaced by "subsequent recognition" Minor amendments were made as the separate guidance on "Exceptions to the VNeeS format" was largely obsolete and therefore withdrawn. Editorial changes like updated references.