NewRS

Accepts, process and stores electronic applications through CESP

- Manage all submission processes
- Receives and analyzes all MRP/DCP and National submissions
- Conduct automated review and processing of submissions: Conducts the necessary quality checks on the data contained in the electronic files and ensures the consistency and continuity of the information, as the CESP provides a simple mechanism for the exchange of information/records without performing any quality control on the application data.
- Ability to add additional submission sources apart of CESP
- Define/recognize eCTD/Nees submission folder structure even simple documentation files
- Decompression of electronic submissions: It includes a system for decompressing the files (unzip) and at the same time displaying the data of the submission and makes it easy to manage the submission by the competent user of the system. An automatic validity check and connection of the information of the XML file is performed, display of the data of the eAF file, identification and display of the process number, the method of submission, the texts in the Greek language, the sequence number, etc.
- Archiving in the Repository: Submission is registered in the Repository depending on the type of submission. If it is a new drug, a new file is opened in the repository, if it is a modification/renewal of the medicinal product, it is entered in the file that belongs to the correct sequence
- Automatic submission tracking: The system periodically checks whether a new submission has been submitted to the CESP and automatically incorporates it into the list of submitted requests
- Detailed list of submissions: The list clearly separates which submissions are for human medicinal products, which submissions are for veterinary medicinal products, as well as the subject of the submission (new approval, amendment, renewal, PSURs, ASMFs, etc.)
- NewRS connection to CTS: Ability to connect a process to one and/or more processes from CTS. Automatic update for starting and completing CTS processes. Monitoring the progress of Mutual/Decentralized process without using CTS client. Automatic creation and assignment of tasks.
- Ability to receive and process eCTD file from Common Repository to create Central Worksharing processes.
- Ability to model and define a schedule per process with automatic date calculation (Day 70, Day 100, etc.).
- Create a workflow for all CESP electronically submitted requests for human and veterinary medicinal products. BPM/CMMN mechanism. Flexibility in modeling processes with features such as Ad-Hoc Tasks, Conditional Task creation, Task suspend/reset, etc. Simplified task management/completion.
- Ability to define a work package at sequence, product and document level (work resources).
- Automatic updating of file sequences based on the evaluation result (each sequence is evaluated only once).
- Ability to schedule job start based on criteria, such as RMS completion.
- Search and extract information about pending/completed tasks.
- Schedule showing the tasks and the days of the procedures.
- Detailed recording of task execution times and clock-stop periods.
- Document repository: In addition to the repository with product files (eCTD, NeeS, etc.) it is possible to store documents/documentation received from other systems besides CESP such as direct email, Eudramail and scanned documents. Ability to create tasks such as Translations review.
- Easy-to-use navigation tools: The system facilitates navigation by providing the user with quick access functions such as search, bookmark, etc.

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