



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 March 2011

Status Summary of EURS - April 2011

EURS – Present Status

The EMA is using since November 2010 EiY release 2.8.1.52 HF6 from Extedo in production. This version of EURS has proved to be stable and no major problems have been reported since last November.

EURS – Further Developments in the Medium Term

After experiencing software problems in 2010, the EMA's main goal for 2011 is to maintain a stable version of EURS in production without critical defects.

However, seen the adoption of new eCTD validation criteria which have to be applied by the 1st of September 2011, the EMA is currently planning to deploy a new EiY release (EiY 3.1) before the 1st of September 2011, which shall contain the new validation criteria. Further functionality to be included in EiY 3.1 is under discussion with Extedo. It was proposed during a web conference with the EURS subgroup, that all the NCAs send their requirements before the 25th of March to Extedo. Extedo will then validate the requirements and communicate in the 3rd week of April which requirements can be included in the next major release (EiY 3.1) and which requirements potentially will have to wait or are subject to further discussion. Software stability and the new validation criteria are the only mandatory requirements for EiY release 3.1 .

The EiY 3.1 release needs to undergo and pass extensive system and user acceptance testing before a deployment in production can be considered. System testing is scheduled to start in June.

EURS – Communication across the user community

As there are currently a number of different Extedo EURS software releases in use by NCAs, it is the intention to re-instate a higher level of harmonisation across Europa around the introduction of the EiY release 3.1 later this year. Ideally all the NCAs shall have moved to EiY 3.1 before the end of 2011.

Seen the increasing importance of EURS in the review process for electronic submissions it is proposed to revise the mandate and the processes of the EURS subgroup in order to allow better communication and more transparency between the TIGes and the EURS subgroup. This will give the NCAs through their TIGes delegates better visibility of the ongoing EURS development and technical support. Better visibility and improved communication will allow for more useful discussion and decision making and better coordination regarding the rollout and deployment of new EURS releases.

