Guidance on the Zipped Submissions, File and Folder names for the Common European Submission Platform (CESP)

Background

The purpose of this document is to describe the requirement for users of the CESP system on the correct use of Zip files, folder and file names for submissions transferred using the CESP system.

Over the last few months CESP has seen a significant increase in the size and volume of submissions passing through the system and a number of issues have been noticed in relation to the content and structure of the submissions received that we would like to bring your attention. To ensure that your submissions are received and processed correctly it is important that you follow these basic guidelines submission.

Folder and File Naming

File and folder naming conventions for both human and veterinary electronic submission are described on the eSubmission website and these guidelines should be followed when creating your electronic submission:

- Human Medicines: http://esubmission.emea.europa.eu/tiges/tigesdocuments.html
- Veterinary Medicines: http://esubmission.emea.europa.eu/tiges/vetesub.htm

Point to note based on submissions received that should be considered when creating a submission:

- Naming of files with special characters
 - A number of files have been created and uploaded using non ascii characters, when naming your files please do not use any special characters in the file name for example ä, Ä, é, Ö, Ö, ü, Ü, ß, &, æ, ç, û, etc.
- File names and Path length
 - Please note that file names and paths should not exceed 240 characters, a number of submissions received have prefixed the product / substance name to the file and path name, maximum length of file / path name in windows is 256 characters.

Zip File Usage Common Issues and Resolutions

The cesp system is a simple a delivery system, many agencies require that all submissions received are "decompressed" before delivery, CESP carries out the function before delivery to each agency. If you are creating a zip file for your submission you should zip the contents that you would normally have placed on a CD/DVD.

Acceptable Zip format:

- 1. WinZip from 11.0 through 17.5
- 2. Microsoft Compressed file formats

Below is a list of common issues that we have encountered.

Id	Issue Description	Outcome	Resolution
1	Zip file contains embedded zip files which when decompressed include subsequent zip files. E.g. 1 zip decompressed created 17	system has to decompress multiple zip files with the one submission in decompressing multiple zip files	Do NOT embed multiple zip files within another zip file. Single zip file to be used should contain all folders and files for that
	additional zip files which created two top level folders per zip file i.e. 34 top level folders		submission.
2	User uploaded two zip files within the one submission, when the first zip file is decompressed it creates for example a "0000 and 0000-working documents directory". The second zip file then gets decompressed and the user has used the same directory names for the second zip file.	If the user has used the same folders names in both zip file submissions the contents of the first directory will be overwritten or amended by the second decompressed zip file.	If uploading two zip files within the one delivery, ensure that when decompressed the folder names are not the same.
3	Zip file uploaded created with unsupported software	Zip file will be delivered to agency without being decompressed	User will be requested to resubmit with new number and using supported zip software.