

EWG M2 Recommendation to the ICH Steering Committee
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
Controlled Vocabularies Recommendation - Genericode

Version 1.0 - 11JUNE2015

Title: Genericode

Background:

It is recognized that there is need to define a standard format for defining code lists (also known as enumerations or controlled vocabularies). Code lists are a vital component of many IT (information technology) systems and contain a list of language-independent (often numerical) code values that are used in messages. For each code value there is a short label and sometimes a longer note to define the meaning of the code. In principle, labels and notes may be in any language but the meaning or definition of codes is often originally specified using the English language. Translation of these into other official languages helps with the correct application of the code but does not alter the assigned code itself. The correct correlation between code and translated meaning needs surveillance to ensure consistent usage of the code across linguistic borders.

Recommendation:

The M2 EWG recommends that code lists be enumerated based on the genericode standard. Genericode is an OASIS committee specification defined by a W3C XML Schema. The XML format is designed to support interchange or distribution of machine-readable code list information between systems. Genericode is not designed as a run-time format for accessing code list information.

Conditions:

None

Remarks:

OASIS is a non-profit consortium that drives the development, convergence and adoption of open standards for the global information society. Genericode is managed by the OASIS Code List Representation TC.