



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Annex X

Estimation of ICRSs per annum

Tenderers are requested to describe the methodology for predicting annual numbers of serious ICRSs (EEA and non-EEA) and non-serious ICRSs (EEA) per year as part of the literature monitoring service for the substance groups outlined below.

The description of the methodology will be taken into account in the qualitative evaluation of the tender.

Methodology description for predicting annual numbers of serious ICRSs (EEA and non-EEA) and non-serious ICRSs (EEA)

Substance groups	Indicative number of serious ICRSs (EEA and non-EEA) to be processed annually based on aforementioned methodology	Indicative number of non-serious ICRSs (EEA only) to be processed annually based on aforementioned methodology
Substance groups 1-5		
Substance groups 1-10		
Substance groups 1-20		
Substance groups 1-30		
Substance groups 1-40		
Substance groups 1-50		



Substance groups	Indicative number of serious ICSRs (EEA and non-EEA) to be processed annually based on aforementioned methodology	Indicative number of non-serious ICSRs (EEA only) to be processed annually based on aforementioned methodology
Substance groups 1-100		
Substance groups 1-200		
Substance groups 1-300		
Herbal substances 1-100		