

Annex VIII

TEST - “Monitoring of Scientific and Medical Literature and the Entry of Relevant Information into EudraVigilance”

A.	Perform a scientific and medical literature search for the following five substance groups as per annex VIII-A and annex VIII-B of the tender specifications focusing on suspected serious and non-serious adverse reactions related to: i. Paracetamol ii. Hydrochlorothiazide iii. Ibuprofen iv. Valeriana v. Eucalyptus
B.	Based on point A, perform the literature search for the following time period: i. 1 November 2013 to 19 March 2014
C.	Based on point A and B, perform a scientific and medical literature search using the following literature reference databases: i. Medline ii. Proposed journal/reference database(s) for the purpose and scope of the supply of daily, accurate and exhaustive scientific and medical literature as outlined under chapter 3 of the tender specifications, table item no. II.a and II.b.
D.	Based on the results of C, perform a screening to identify valid individual cases of suspected serious adverse reactions for the substance groups outlined under point A.

Summary of the test (maximum 100 points) to be presented in an Excel spreadsheet:

- 1. For point A: describe the search string applied for each of the five substance groups and the applied reference database(s) (max 20 points)**
- 2. For point B and C: provide the search results individually for each of the five substance groups as follows (max 40 points):**
 - i. The title of each article
 - ii. The name of the author(s) for each article
 - iii. The name of the journal for each article

- iv. The DOI or where not available the URL or other adequate reference number for the article
- v. Release date
- vi. The name of the reference database

3. For point D: provide the results of the screening for each of the five substance groups individually as follows(max 40 points):

- i. The title of each article
- ii. The name of the author(s) for each article
- iii. The name of the journal for each article
- iv. The DOI or where not available the URL or other adequate reference number for the article
- v. Release date
- vi. The name of the reference database
- vii. For each article the number of valid individual cases of adverse reactions as described in the article classified as serious or non-serious
- viii. The adverse reactions described in the article