

Annex I

Costing sheet

Tenderers must use the following table to submit their tender; **no other format is admissible.**

Tenderers should not include ranges of prices. Tenderers must provide each price requested and may not propose any different pricing structure.

Any tender not conforming to these instructions shall be eliminated.

Tenderers should submit this sheet in separate binders or folders which must be clearly labelled. It should also be submitted on a separate CD from the rest of the tender.

Prices should be submitted in Euro, shall be fixed and inclusive of all costs and expenses incurred in providing the services as described. Abnormally low prices will not be accepted and may result in elimination of the tender.

The Agency is, as a rule, exempt from all taxes and duties, and in certain circumstances is entitled to a refund for indirect tax incurred such as value added tax (VAT), pursuant to the provisions of Articles 3 and 4 of the Protocol on the Privileges and Immunities of the European Union. Tenderers must therefore give prices which are exclusive of any taxes and duties and must indicate the amount of VAT separately.

Name of tenderer:

A	TOTAL SET UP COST (including initial set up AND pilot phase, as per service description item 3.1.IX)	
B	ALL INCLUSIVE TOTAL MONTHLY PRICE (for tasks and deliverables as per service description items 3.1.II to VIII)	
B.1	substance groups 1 to 10 (Annex VII-A)	
B.2	substance groups 1 to 20 (Annex VII-A)	
B.3	substance groups 1 to 30 (Annex VII-A)	
B.4	substance groups 1 to 40 (Annex VII-A)	
B.5	substance groups 1 to 50 (Annex VII-A)	
B.6	substance groups 1 to 75 (Annex VII-A)	
B.7	substance groups 1 to 100 (Annex VII-A)	
B.8	substance groups 1 to 125 (Annex VII-A)	
B.9	substance groups 1 to 150 (Annex VII-A)	
B.10	substance groups 1 to 175 (Annex VII-A)	
B.11	substance groups 1 to 200 (Annex VII-A)	
B.12	substance groups 1 to 225 (Annex VII-A)	
B.13	substance groups 1 to 250 (Annex VII-A)	
B.14	substance groups 1 to 275 (Annex VII-A)	
B.15	substance groups 1 to 300 (Annex VII-A)	
B.16	Herbal substance groups 1 to 50 (Annex VII-B)	
B.17	Herbal substance groups 1 to 100 (Annex VII-B)	
C	UNIT PRICE	
C.1	Cost per word for translation of literature article from non-EU language into English	
C.2	Cost per word for translation of literature article from EU language into English	
C.3	Ad hoc screening of scientific and medical literature in the context of a signal evaluation and/or benefit risk assessment of a medicinal product or a class of medicinal products	

Date:

Signature of authorised representative:

(Print name):

Position in Company:

Scenario for evaluation of price:

Tenderers are advised that the following scenario and calculation shall be used to compare the tenderers' prices. The prices used in this calculation shall be taken from the above table by the evaluation committee.

The grand total of this scenario will be considered as "Tenderer's price" in the following formula which shall be used to calculate the points to be awarded for price:

$$\frac{\text{Lowest price x weighting for price (30\%)}}{\text{Tenderer's price}}$$

Tenderers should note that this scenario has been established for evaluation purposes only and is not binding on the Agency as a future purchase or indicative of any future purchase.

	Scenario
Year 1	i. Set up costs
	ii. Monitoring of scientific and medical literature and entry of relevant information into EudraVigilance (incl. quality management, service and operations management and periodic reporting) • Substance groups: 1-50 • Herbal substance groups: 1-100
	iii. Translations: Total of 50 articles (3000 words each) • 30 articles non-EU language to English • 20 articles EU language to English
	iv. One ad hoc screening • SABA (Short Acting Beta Agonists) and use in pregnancy
	Total cost of first year's activities - A
Year 2	i. Monitoring of scientific and medical literature and entry of relevant information into EudraVigilance (incl. quality management, service and operations management and periodic reporting) • Substance groups: 1-100 • Herbal substance groups: 1-100
	ii. Translations: Total of 50 articles (3000 words each) • 30 articles non-EU language to English • 20 articles EU language to English
	iii. One ad hoc screening • Combined hormonal contraceptives and risk of thromboembolism
	Total cost of second year's activities – B
Year 3	i. Monitoring of scientific and medical literature and entry of relevant information into EudraVigilance (incl. quality management, service and operations management and periodic reporting) • Substance groups: 1-150 • Herbal substance groups: 1-100

	ii. Translations: Total of 50 articles (3000 words each) • 30 articles non-EU language to English • 20 articles EU language to English
	iii. One ad hoc screening • Nicotinic acid and related substances - acipimox, xantinol nicotinate and negative benefit risk balance
	Total cost of third year's activities – C
Year 4	i. Monitoring of scientific and medical literature and entry of relevant information into EudraVigilance (incl. quality management, service and operations management and periodic reporting) • Substance groups: 1-200 • Herbal substance groups: 1-100
	ii. Translations: Total of 50 articles (3000 words each) • 30 articles non-EU language to English • 20 articles EU language to English
	iii. One ad hoc screening • Medicines containing cyproterone acetate 2mg and ethinylestradiol 35 micrograms and risk of thromboembolism
	Total cost of fourth year's activities – D
Year 5	i. Monitoring of scientific and medical literature and entry of relevant information into EudraVigilance (incl. quality management, service and operations management and periodic reporting) • Substance groups: 1-250 • Herbal substance groups: 1-100
	ii. Translations: Total of 50 articles (3000 words each) • 30 articles non-EU language to English • 20 articles EU language to English
	iii. One ad hoc screening • Diclofenac and cardiovascular safety
	Total cost of fifth year's activities – E

Year 6	i. Monitoring of scientific and medical literature and entry of relevant information into EudraVigilance (incl. quality management, service and operations management and periodic reporting) • Substance groups: 1-300 • Herbal substance groups: 1-100
	ii. Translations: Total of 50 articles (3000 words each) • 30 articles non-EU language to English • 20 articles EU language to English
	iii. One ad hoc screening • Flupirtine and hepatotoxicity
	Total cost of sixth year's activities – F
The overall total cost over six years shall be used by the evaluation committee as “Tenderer's price” for the purposes of evaluation and will be composed of A+B+C+D+E+F as set out above.	