CENTRAL PROCUREMENT & SUPPLIES UNIT
MINISTRY FOR HEALTH
UB002, Industrial Estate, San Gwann - SGN3000
Tel:(+356) 2540 4000 E-mail: info.cpsu@gov.mt

Our Ref: CPSU 0289/2019
RFP Publication Ref: 021-60013/19
Publication Date: 22/02/2019

Request for Participation (Negotiated) for the provision of Service for the treatment of HIV-positive patients

1.1 Purpose and Scope of this Request

The Central Procurement and Supplies Unit within the Ministry for Health wishes to identify economic operators interested in providing the service for the treatment of HIV-positive patients.

Advances in HIV care and treatment that keep people alive while controlling, although not curing, their conditions have led to growing numbers of people surviving with chronic conditions, including HIV infection. EACS produces the European Guidelines for treatment of HIV-positive adults in Europe. Malta, has decided to use these guidelines to manage this chronic condition, the drug resistance and the transmission of the virus.

As access to antiretroviral therapy keeps on expanding, the HIV response is evolving from a disease-specific emergency response to a chronic disease management challenge. This epidemiological transition, coupled with a fast growing number of people with other chronic diseases has considerable implications for health systems and societies. Prevention remains the cornerstone of the entire response to this epidemic. The National Health System through CPSU wishes to provide an integrated service at all levels to achieve formal collaboration.

Since the last 18 months, CPSU has explored possibilities for a HIV portfolio within the industry to changeover current therapy to the therapy as advised within the clinical chosen International guidelines and at the same time remaining sustainable with respect to budgetary implications. The objective of this Request for Participation is to identify the company/joint venture/consortium that can offer the optimal service with respect to the HIV portfolio, considering drug-drug interactions, patient tolerability issues and also target poor adherence for better treatment. The main elements to be considered in this HIV patient cohort is the fact that treatment can be optimized not just with the change in treatment but with consistent monitoring. The follow-ups of such patients is more important as patients are living longer due

to advances in therapy and thereby the continuation of care targets both HIV treatment and other co-medications, and their relevant interactions and side effects for a better quality of life.

Besides the market research within the industry CPSU has also embarked in discussions with other EU Member states with respect to affordability and sustainability. Performance-based agreements have been discussed and tested with respect to this current local scenario. CPSU is aware that data of the HIV patients is already being monitored and data collated on a weekly basis by the same local HIV clinic. On reviewing the treatments suggested in the EACS guidelines, and the relevant dossiers by the companies stating that they have reliable data on the efficacy and safety of the medicines they are representing; CPSU is requesting a cost-saving performance-based agreement model that takes into consideration package deals including but not limited to discounts.

There are circa 450 HIV patients being followed regularly by the HIV clinic – 362 are currently on treatment (Table 1). Table 2 indicates the annual consumption of the treatment being procured as a formulary medicine and as an exceptional medicine treatment.

Table 1:*Data of HIV patients on treatment (29th January 2019)*

Wherever brand name is stated, the specifications are for the active ingredient so the medicines could be also generics.

Patient	Treatment 1	Treatment 2	Treatment 3	Treatment 4
1	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150mg bd	
2	Raltegravir 400mg bd	Combivir 1 tab bd		
3	Raltegravir 400mg bd	Maraviroc 300mg bd	Tenofovir 1 tab dly	Lamivudine 150mg bd
4	Lop/rit 2 tabs bd	Combivir 1 tab bd		
5	Raltegravir 400mg bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
6	Lop/Rit 2 tabs bd	Zidovudine 300mg bd	Lamivudine 150mg dly	
7	Efavirenz 1 tab nocte	Lamividine 150mg bd	Tenofovir 245mg dly	
8	Lop/rit 2 tabs bd	Combivir 1 tab bd		
9	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd	Tenofovir 1 tab dly	
10	Efavirenz 600 mg nocte	Combivir 1 tab bd		
11	Efavirenz 600mg nocte	Combivir 1 tab bd		
12	Raltegravir 400mg bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
13	Efavirnez 600mg nocte	Combivir 1 tab bd		
14	Raltegravir 400mg bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
15	Lopinavir/ritonavir 2 tabs bd	Tenofovir 1 tab dly	Lamivudine 150 mg bd	
16	Efavirenz 600mg nocte	Combivir 1 tab bd		
17	Raltegravir 400mg bd	Combivir 1 tab bd		
18	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
19	Lop/rit 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
20	Raltegarvir 400mg bd	Kivexa 1 tab dly		
21	Lop/rit 2 tabs bd	Combivir 1 tab bd		
22	Efavirenz 600mg niocte	Combivir 1 tab bd		
23	Efavirenz 600mg nocte	Combivir 1 tab bd		
24	Lop/rit 2 tabs bd	Combivir 1 tab bd		

Patient	Treatment 1	Treatment 2	Treatment 3	Treatment 4
25	Efavirenz 600mg nocte	Tenofovir 1 tab bd	Lamivudine 150mg bd	
26	Kaletra 2 tabs bd	Combivir 1 tab bd		
27	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
28	Raltegravir 400mg bd	Combivir 1 tab bd		
29	Lopinavir/ritonavir 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
30	Lop/rit 2 tabs bd	Combivir 1 tab bd		
31	Efavirenz 600mg nocte	Lamivudine 150mg bd	TAF25mg dly	
32	Lop/rit 2 tabs bd	Lamivudine 150mg bd	Tenofovir 245mg dly	
33	Loop/rit 2 tabs bd	Combivir 1 tab bd		
34	Raltegravir 400mg bd	Combivir 1 tab bd	Tenofovir 245mg dly	
35	Raltegravir 400mg bd	TAF 25mg dly	Lamivudine 150 mg bd	
36	Lop/rit 2 tabs bd	Combivir 1 tab bd		
37	Efavirenz 600mg dly	Tenofovir 245mg dly	Lamivudine 150mg bd	
38	Nevirapine 200mg bd	Abacavir 300mg 12hrly	Lamivudine 150mg dly	
39	Efavirenz 600mg nocte	Combivir 1 tab bd		
40	Lopianvir/rit 2 tabs bd	Combivir 1 tab bd	Tenofovir 245mg bdly	
41	Raltegravir 400mg bd	TAF 25mg dly	Combivir 1 tab bd	
42	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
43	Efavirenz 600mg nocte	Combivir 1 tab bd		
44	Lop/rit 2 tabs bd	Combivir 1 tab bd		
45	Lop/rit 2 tabs bd	Combivir 1 tab bd		
46	Lop/rit 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
47	Lop/rit 2 tabs bd	Combivir 1 tab bd		
48	Lop/rit 2 tabs bd	Combivir 1 tab bd		
49	Raltegravir 400mg bd	TAF 25mg dly	Lamivudine 150mg bd	
50	Efavirenz 600mg nocte	Combivir 1 tab bd		
51	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150-mg bd	
52	Raltegarvir 400mg bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
53	Efavirenz 600mg nocte	Combivir 1 tab bd		
54	Efavirenz 600mg nocte	Combivir 1 tab bd		
55	Efavirenz + Truvada x 4 yrs			
56	Efavirenz 600mg nocte	Combivir 1 tab bd		
57	Lop/Rit 2 tabs bd	Zid/Lam 1 tab bd		
58	Raltegravir 400mg bd	Combivir 1 tab bd		
59	Lop/rit 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
60	Abacavir/lamivudine 1 tab dly	Zidovudine300mg 12hrly		
61	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150mg nd	
62	Lopinavir/ritonavir 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
63	Lop/Rit 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
64	Raltegravir 400mg bd	Combivir 1 tab bd		
65	Lop/rit 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150 mg bd	
66	Raltegarvir 400mg bd	Lamivdien 150 mg bd	Tenofovir 245mg dly	
67	Raltegravir 400mg bd	Lopinavir/ritoanvir 2 tabs bd	Lamivudine 150mg bd	
68	Raltegravir 400mg bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
69	Lop/rit 2 tabs bd	Combivir 1 tab bd		
70	Efavirenz 600mg nocte	Combivir 1 tab bd		
71	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		

Patient	Treatment 1	Treatment 2	Treatment 3	Treatment 4
72	Raltegravir 400mg bd	Maraviroc 300mg dly	Lopinavir/rit 2 tabs bd	
73	Efavirenz 600mg nocte	Combivir 1 tab bd	Tenofovir 245mg dly	
74	Lop/rit 2 tabs bd	Combivir 1 tab bd		
75	Lopinavir/ritonvir 2 tabs bd	Tenofovir 245mg dly	Zidovudine 300mg bd	
76	Lop/rit 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
77	Lopinavir/ritonavir 2 tabs bd	Kivexa 1 tab dly		
78	Lop/rit 2 tabs bd	Combivir 1 tab bd		
79	Efavirenz 600mg nocte	Combivir 1 tab bd		
80	Lopinavir/rit 2 tabs bd	Combivir 1 tab bd		
81	Efavirenz 600mg nocte	Kivexa 1 tab dly		
82	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
83	Efavirenz 600mg nocte	Tenofovir 1 tab dly	Lamivudine 150mg bd	
84	Efavirenz 600mg nocte	Abacavir/lamivudine 1 tab dly		
85	Efavirenz 600mg nocte	Combivir 1 tab bd		
86	Efavirenz 600mg nocte	Combivir 1 tab bd		
87	Nevirapine 200mg bd	Combivir 1 tab bd		
88	Efavirenz 600mg nocte	Lamivudine 150mg bd	Abacavir 300mg bd	
89	Nevirapine 200mg bd	Combivir 1 tab bd		
90	Lop/rit 2 tabs bd	Combivir 1 tab bd		
91	Lop/rit 2 tabs bd	Kivexa 1 tab dly		
92	Raltegravir 400mg bd	TAF 25mg dly	Combivir 1 tab bd	
93	Efavirenz 600mg nocte	Kivexa 1 tab dly		
94	Efavirenz 600mg dly	Combivir 1 tab bd		
95	Lop/rit 2 tabs bd	Combivir 1 tab bd		
96	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150mg bd	
97	Efavirenz 600mg nocte	Kivexa 1 tab dly		
98	Efavirenz 600mg nocte	Lamivudine 150mg bd	TAF 25mg dly	
99	Raltegravir 400mg bd	Combivir 1 tab bd		
100	Lop/rit 2 tabs bd	Tenofovir 245mg dly	lamivudine 150mg bd	
101	Lopinavir/rit 2 tabs bd	Combivir 1 tab bd		
102	Darunavir 600mg bd	Ten/emtric 1 tab dly	Ritonavir 100mg bd	
103	Raltegravir 400mg bd	Combivir 1 tab bd	Tenmofovir 245mg dly	
104	Raltegarvir 400mg bd	Maraviroc 300mg bd	Kivexa 1 tab dly	TAF 25mg dly
105	Lopinavir/r 2 tabs bd	Lamivudine 150mg bd	Tenofovir 245mg dly	
106	Efavirenz 600mg nocte	Combivir 1 tab bd		
107	Lamivudine 150mg bd	Tenofovir 245mg dly	Efavirenz 600mg dly	
108	Efavirenz 600mg dly	Combivir 1 tab bd		
109	Efavirenz 600mg nocte	Combivir 1 tab bd		
110	Lop/ritonavir 2 tabs bd	Combivir 1 tab bd		
111	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
112	Raltegarvir 400mg bd	Lop/rit 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd
113	Raltegravir 400mg bd	TAF 25mg dly	Lamivudine 100mg dly	
114	Lop/rit 2 tabs bd	Zidovudine	Lamivudine sol	
115	Efavirenz 600mg nocte	Combivir 1 tab bd		
116	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
117	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150 mg bd	
118	Efavirenz 600mg nocte	Combivir 1 tab bd		

Patient	Treatment 1	Treatment 2	Treatment 3	Treatment 4
119	Lop/rit 2 tabs bd	Combivir 1 tab bd		
120	Raltegarvri 400mg bd	Kivexa 1 tab dly		
121	Efavirenz 600mg nocte	Combivir 1 tab bd		
122	Efavirenz 600mg nocte	Combivir 1 tab bd		
123	Lopinavir/Ritonavir 2 tabs bd	Combivir 1 tab bd		
124	Lopinavir/ritonavir 2 tabs bd	Zidovudine/lamivudine 1tab bd	Raltegravir 400mg bd	
125	Lop/rit 2tabs bd	Tenofovir 256 mg dly	Combivir 1 tab bd	
126	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
127	Raltegravir 400mg bd	Combivir 1 tab bd	TAF 25mg dly	
128	Lopinavir/ritonavir 2 tabs bd	Abacavir/lamivudine		
129	Efavirenz 600mg nocte	Combivir 1 tab bd		
130	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
131	Raltegarvir 400mg bd	TAF 25mg dly	Lamivuidine 150mg bd	
132	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lmaivudine 150mg bd	
133	Lopinavir/ritonavir 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
134	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150mg bd	
135	Raltegravir 400mg bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
136	Lop/rit 2 tabs bd	Combivir 1 tab bd		
137	Nevirapine 200mg bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
138	Efavirnez 600mg nocte	Combivir 1 tab bd		
139	Efavirenz 600mg nocte	Combivir 1 tab bd		
140	Raltegravir 400mg bd	Kivexa 1 tab dly		
141	Lop/rit 2 tabs bd	Combivir 1 tab bd		
142	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150mg bd	
143	Lop/ritonavir 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
144	Lop/rit 2 tabs bd	Combivir 1 tab bd		
145	Lop/rit 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
146	Lopinavir/Ritonavir 2 tabs bd	Combivir 1 tab bd		
147	Lop/rit 2 tabs bd	Zid/lam 1 tab bd		
148	Lop/rit 2 tabs bd	Combivir 1 tab bd		
149	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150mg bd	
150	Raltegravir 400mg bd	Combivir 1 tab bd	Tenofovir 1 tab dly	
151	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150mg bd	
152	Lopinavir/r 2 tabs bd	Combivir 1 tab bd		
153	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150mg bd	
154	Lopinavir/ritonavir 2 tabs bd	Combivir 1tab bd		
155	Lop/rit 2 tabs bd	Combivir 1 tab bd		
156	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
157	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
158	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150mg bd	
159	Raltegravir 800mg bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
160	Lop/rit 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
161	Lopinavir/ritoanvir 2 tabs bd	Combivir 1 tab bd	Tenofovir 245mg dly	
162	Raltegravir 400mg bd	Lopinvair/ritonavir 2 tabs bd	Lamivudine 150mg dly	
163	Lop/rit 2 tabs bd	Combivir 1 tab bd		
164	Lop/rit 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
165	Lopinavir/ritonavir 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	

Patient	Treatment 1	Treatment 2	Treatment 3	Treatment 4
166	Lop/rit 2 tabs bd	Combivir 1 tab bd		
167	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
168	Raltegravir 400mg bd	Combivir 1 tab bd	Tenofovir 1 tab dly	
169	Lop/rit 3 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
170	Raltegarvir 400mg bd	Tenofovor 245mg dly	Combivir 1 tab bd	
171	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
172	Lop/rit 5mls bd	Combivir 1 tab bd	Tenofovir 245mg dly	
173	Lop/ritonavir 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
174	Lopinavir/ritonavir 2 tabs bd	Tenofovir 1 tab dly	Lamivudine 1 tab bd	
175	Lopinavir/rit 2 tabs bd	Combivir 1 tab bd	Tenofovir 245mg dly	
176	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
177	Lop/Rit 2 tabs bd	Combivir 1 tab bd		
178	Lop/rit 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
179	Raltegarvir 400mg bd	TAF 25mg dly	Lamivudine 150mg bd	
180	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
181	Lopinavir/ritonavir 2 tabs bd	Kivexa 1 tab dly		
182	Lop/rit 2 tabs bd	Combivir 1 tab bd		
183	Raltegravir 400mg bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
184	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
185	Raltegravir 400mg bd	Combivir 1 tab bd		
186	Raltegravir 400mg bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
187	Lop/rit 2 tabs bd	Combivir 1 tab bd		
188	Efavirenz 600mg nocte	Combivir 1 tab bd		
189	Nevirapine 200mg bd	Combivir 1 tab bd		
190	Lopinavir/ritonavir 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
191	Efavirenz 600mg nocte	Combivir 1 tab bd		
192	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
193	Lop/rit 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
194	Efavirenz 600mg dly	Combivir 1 tab bd		
195	Raltegravir 400mg 12hrly	Tenofovir 245mg dly	Lamivudine 150mg bd	
196	Efavirenz 600mg nocte	Tenofovir 1 tab dly	Lamivudine 150mg bd	
197	Nevirapine 200mg bd	Abacavir 300mg bd	Lamivudine sol 5ms dly	
198	Lop/rit 2 tabs bd	Combivir 1 tab bd		
199	Efavirenz 600mg nocte	Combivir 1 tab bd		
200	Abacavir/lamivudine 1 tab dly	Efavirenz 600mg nocte		
201	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
202	Maraviroc 300mg bd	Tenofovir 245mg dly	Aba/lam 1 tab dly	
203	Efavirenz 600mg nocte	Combivir 1 tab bd		
204	Raltegravir 400mg bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
205	Efavirenz 600mg nocte	Lamivudine 150mg bd	Tenofovir 245mg dly	
206	Lop/rit sol 5mls bd	Tenofovir 1 tab dly	Lamivudine 150mg bd	
207	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150mg bd	
208	Lop/rit 2 tabs bd	Combivir 1 tab bd		
209	Efavirenz 600mg nocte	Combivir 1 tab bd		
210	Lop/rit 2 tabs bd	Combivir 1 tab bd		
211	Lop/rit 2 tabs bd	Combivir 1 tab bd		
212	Efavirenz 600mg nocte	Combivir 1 tab bd		

Patient	Treatment 1	Treatment 2	Treatment 3	Treatment 4
213	Lopinavir/rit 2 tabs bd	Combivir 1 tab bd		
214	Lopinavir/ritonavir 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
215	Lopianvir/ritonavir 2 tabs bd	Combivir 1 tab bd	Tenofovir 1 tab dly	
216	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
217	Lop/Rit 2tabs bd	Combivir 1 tab bd		
218	Lopinavir/ritinavir 2 tabs bd	Combivir 1 tab bd		
219	Efavirenz 600mg nocte	Kivexa 1 tab dly		
220	Lop/rit paed tabs 3 tabs bd	Zidovudine 200mg 12hrly	DdI EC 1.5 x 125mg dly	
221	Lopinavir/ritonavir 2 tabs bd	Tenofovir 1 tab dly	Lamivudine 150mg bd	
222	Efavirenz 600mg nocte	Combivir 1 tab bd		
223	Raltegravir 400mg bd	Tenofovir 245mg dly	Zid/lam 1 tab bd	
224	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150mg dly	
225	Raltegravir 400mg bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
226	Lamivudine 150mg bd	Tenofovir 245mg dly	Efavirenz 600mg dly	
227	Lop/rit 2 tabs bd	Combivir 1 tab bd		
228	Lop/rit 3 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
229	Lopinavir/rit 2 tabs bd	Combivir 1 tab bd		
230	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150mg bd	
231	Efavirenz 600mg nocte	Combivir 1 tab bd	Tenofovir 245mg dly	
232	Lop/rit 2 tabs bd	Combivir 1 tab bd		
233	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
234	Lop/ritonavir 2 tabs bd	Combivir 1 tab bd		
235	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150mg bd	
236	Lop/rit 2 tabs bd	Tenofovir 245mg dly	Zidovudine 300mg bd	
237	Lop/rit 2 tabs	Combivir 1 tab bd		
238	Raltegravir 400mg bd	Combivir 1 tab bd		
239	Lop/rit 2 tabs bd	Combivir 1 tab bd		
240	Lop/Rit 2 tabs bd	Combivir 1 tab bd		
241	Efavienz 600mg nocte	Combivir 1 tab bd		
242	Lop/Rit 2 tabs bd	Combivir 1 tab bd		
243	Efavirenz 600mg nocte	Truvada 1 tab dly		
244	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150mg bd	
245	Lop/rit 2 tabs bd	Combivir 1 tab bd		
246	Darunavir 600mg 12 hrly	Ritonavir 100mg 12hrly	Tenofovir 245mg dly	Combivir 1 tab bd
247	Efavirenz 600mg nocte	Kivexa 1 tab dly		
248	Raltegravir 400mg bd	Combivir 1 tab bd	Tenofovir 1 tab dly	
249	Efavirenz 600mg dly	Combivir 1 tab bd		
250	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
251	Raltegravir 400mg bd	Kivexa 1 tab dly		
252	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150mg bd	
253	Nevirapine 200mg bd	Combivir 1 tab bd		
254	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
255	Lop/rit 2 tabs bd	Combivir 1 tab bd		
256	Efavirenz 600mg nocte	Combivir 1 tab bd		
257	Lop/rit 2 tabs bd	Combivir 1 tab bd		
258	Raltegarvir 400mg bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
259	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150 mg bd	

Patient	Treatment 1	Treatment 2	Treatment 3	Treatment 4
260	Lop/rit 2 tabs bd	Combivir 1 tab bd		
261	Lop/Rit 2 tabs bd	Combivir 1 tab bd		
262	Efavirenz 600mg nocte	Combivir 1 tab bd		
263	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150mg bd	
264	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
265	Nevirapine 200mg dly	Zidovudine 300-200mg dly	Lamivudine 150mg bd	
266	Efavirenz 600mg nocte	Combivir 1 tab bd		
267	Raltegarvir 400mg bd	Tenofovir 245mg dly	Combivir 1 tab bd	
268	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150mg bd	
269	Nevirapine 200mg bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
270	Lop/rit 2 tabs bd	Combivir 1 tab bd		
271	Raltegravir 400mg bd	Kivexa 1 tab bd		
272	Efavirenz 600mg nocte	Combivir 1 tab bd		
273	Lop/Rit 2 tabs bd	Combivir 1 tab bd		
274	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
275	Lop/rit 2 tabs bd	Combivir 1 tab bd		
276	Nevirapine 200mg bd	Abacavir/lam 1 tab dly		
277	Lopinavir/ritoanvir 2 tabs bd	Combivir 1 tab bd	Tenofovir 2435mg dly	
278	Lop/rit 2 tabs bd	Combivir 1 tab bd		
279	Raltegravir 400mg bd	Tenofovir 245mg dly	Combivir 1 tab bd	
280	Raltegravir 400mg 12hrly	Tenofovir 245mg dly	Lamivudine 150mg bd	
281	Darunavir 600mg bd	Ritonavir 100mg bd	Raltegravir 400mg bd	Tenofovir 245mg dly
282	Lop/rit 3-2 tabs bd	Efavirenz 600mg noce	Abacavir 300mg 12hrly	
283	Raltegarvir 400mg bd	Tenofovir 245mg dly	Lamivudine 150mg bd	Efavirenz 600mg dly
284	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150mg bd	
285	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
286	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
287	Lop/rit 2 tabs bd	Lamivudine 150mg bd	Tenofovir 245mg dly	
288	Lopinavir/ritonavir 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
289	Lopinavir/Ritonavir 2 tabs bd	Combivir 1 tab bd		
290	Nevirapine 200mg bd	Combivir 1 tab bd		
291	Lop/rit 3 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
292	Efavirenz 600mg nocte	Combivir 1 tab bd		
293	Lop/rit 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
294	Lop/rit 2 tabs bd	Combivir 1 tab bd		
295	Efavirenz 600mg nocte	Combivir 1 tab bd		
296	Raltegarvir 400mg bd	TAF 25mg dly	Lamivudine 150mg dly	
297	Nevirapine 200mg bd	Combivir 1 tab bd		
298	Lop/rit 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
299	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150mg bd	
300	Lop/rit 2 tabs bd	Combivir 1 tab bd		
301	Raltegravir 400mg bd	Combivir 1 tab bd		
302	Raltegravir 400mg bd	Combivir 1 tab bd		
303	Raltegravir 400mg bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
304	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd	Tenofovir 1 tab dly	
305	Efavirenz 600mg nocte	TAF 25mg dly	Lamivudine 150mg bd	
306	Raltegravir 400mg bd	Tenofovir 245mg dly	Lamivudine 150 mg bd	

Patient	Treatment 1	Treatment 2	Treatment 3	Treatment 4
307	Lop/Rit 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
308	Raltegravir 400mg bd	Combivir 1 tab bd		
309	Lop/Rit 2 tabs bd	Combivir 1 tab bd		
310	Efavirenz 600mg nocte	Combivir 1 tab bd		
311	Efavirenz 600mg nocte	Combivir 1 tab bd		
312	Lop/rit tabs 3-0-2	Lamivudine 150mg bd	Efavirenz 600mg nocte	
313	Raltegravir 400mg bd	Tenofovir 245mg dly	Zidovudine 300mg bd	
314	Efavirenz 600mg nocte	Combivir 1 tab bd		
315	Raltegravir 400mg bd	Combivir 1 tab bd		
316	Lop/rit 2 tabs bd	Combivir 1 tab bd		
317	Lop/rit 2 tabs bd	Abacavir/lamivudine 1 tab dly		
318	Lopinavir/ritonavir 2 tabs bd	Lamivudine 150mg bd	Tenofovir 245mg dly	
319	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
320	Lop/rit 2 tabs bd	Kivexa 1 tab bd		
321	Efavirenz 600mg nocte	Tenofovir 1 tab dly	Lamivudine 150 mg bd	
322	Lop/rit 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
323	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd		
324	Raltegravir 400mg bd	Combivir 1 tab bd		
325	Efavirenz 600mg nocte	Kivexa 1 tab dly		
326	Efavirenz 600mg nocte	Kivexa I tab dly		
327	Lopinavir/ritonavir 2 tabs bd	Abacavir/lamivudine 1 tab dly		
328	Lop/rit 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
329	Lopinavir/ritonavir 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
330	Lop/Rit 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
331	Lop/rit 2 tabs bd	Zidovudine 100mg tds	Lamivudine syr 50mg dly	
332	Lopinavir/ritoanvir 2 tabs bd	Combivir 1 tab bd		
333	Raltegravir 400mg bd	Combivir 1 tab bd		
334	Lop/Rit 2 tabs bd	Combivir 1 tab bd		
335	Lop/rit 2 tabs bd	Combivir 1 tab bd		
336	Nevirapine 200mg bd	Combivir 1 tab bd		
337	Lopinavir/Ritonavir 2 tabs bd	Combivir 1 tab bd		
338	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lmaivudine 150mg 12hrly	
339	Lop/rit 2 tabs bd	Combivir 1 tab bd		
340	Lopinavir/ritonavir 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
341	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150 mg bd	
342	Efavirenz 600mg nocte	Combivir 1 tab bd		
343	Efavirenz 600mg nocte	Combivir 1 tab bd		
344	Lop/rit 2 tabs bd	Kivexa 1 tab dly		
345	Raltegravir 400mg bd	Maraviroc 300mg bd	Combivir 1 tab bd	Tenofovir 245mg dly
346	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab dly	Tenofovr 245mg dly	
347	Lopinavir/ritonavir 2 tabs bd	Combivir 1 tab bd	Tenofovir 1 tab dly	
348	Nevirapine 200mg bd	Combivir 1 tab bd		
349	Raltegarvir 400mg bd	TAF 25mg dly	Lamivudine 150mg bd	
350	Efavirenz 600mg nocte	Tenofovir 245mg dly	Lamivudine 150mg bd	
351	Efavirenz 600mg nocte	Combivir 1 tab bd		
352	Lop/rit 2 tabs bd	Combivir 1 tab bd		
353	Lopinavir/ritoanvir 2 tabs bd	Combivir 1 tab bd	Tenofovir 1 tab dly	

Patient	Treatment 1	Treatment 2	Treatment 3	Treatment 4
354	Efavirenz 600mg nocte	Combivir 1 tab bd		
355	Lop/rit 2 tabs bd	Combivir 1 tbd bd		
356	Efavirnez 600mg nocte	Tenofovir 245mg dly	Lamivudine 150mg bd	
357	Efavirenz 600mg nocte	Combivir 1 tab bd		
358	Lopinavir/ritonavir 2 tabs bd	Tenofovir 245mg dly	Lamivudine 150mg bd	
359	Lopinavir/rit 2 tabs bd	Combivir 1 tab bd	Tenofovir 245mg dly	
360	Lop/rit 2 tabs bd	Combivir 1 tab bd		
361	Efavirenz 600mg nocte	Kivexa 1 tab dly		
362	Lop/rit 5mls bd	Lamivudine 100mg dly	Zidovudine syrup 300mg bd	

Table 2: *HIV treatment Annual Consumption (15th January 2019)*

S-code	HIV Treatment	Annual Consumption
A317	Zidovudine 100mg Capsules	13,000
A337	Efavirenz 600mg Tablets	34,000
A603	Nevirapine 200mg Tablets	11,220
A641	Lamivudine 150mg Tablets	67,720
A681	Ritonavir 100mg Capsules	700
A689	Didanosine 125mg EC Capsules	1,600
A697	Tenofovir 245mg Tablets	85,944
A702	Lamivudine 100mg Tablets	2,061
A707A	Lopinavir with Ritonavir 200mg/50mg Tablets or Capsules	198,000
A728	Zidovudine with Lamivudine 300mg/150mg Tablets	119,720
A821	Abacavir & Lamivudine Film-Coated Tablets	8,000
A829	Maraviroc 300mg Film-Coated Tablets	1,270
C167	Lopinavir with Ritonavir Oral Solution 400mg 100mg 5ml	22
C117	Zidovudine 50mg 5ml Syrup	25
J370	Zidovudine 10mg ml Injections	40
A914	Emtricitabine 200mg And Tenofovir Disoproxil 245mg Film Coated Tablets	60
A786	Lopinavir 100mg Ritonavir 25mg Tablets	2,848
A816	Raltegravir 400mg Tablets	45,000
A885	Abacavir 300mg Tablets	2,190
A895	Darunavir 600mg Tablets	780
A913	Tenofovir Alafenamide Fumarate 25mg Tablets	5,840
A925	Darunavir 800mg Tablets	30

Interested Economic Operators must be willing to enter into an agreement with CPSU to provide the service for a period of FIVE (5) years.

Department of Health will award the provision of the service for treatment to the cheapest offer received.

The place of acceptance of the supplies shall be as and where directed by the Department of Health, and the INCOTERM^{2010} applicable shall be **Delivery Duty Paid (DDP).**

2.1 Eligibility

The Economic Operator shall:

1. Have the entire or part of the portfolio as duly described by the updated EACS guidelines for the Infectious Disease Unit prescriber to select the optimal treatment as per last EACS updates. The recommended regimens in EACS include recommended regimens, alternative regimens and other combinations.
2. Be ready to get into a cost-saving performance-based agreement with CPSU for the next 5 years.
3. Be ready to provide the holistic service related to this chronic condition with respect to continuous monitoring, follow-ups and education to support adherence - all in line with the protocols used within the HIV clinic.

The Economic Operator shall be duly licensed to act as a pharmaceutical wholesale dealer in the member state of its establishment. In the case of a Joint Venture/Consortium, all the Economic Operators forming the Joint Venture/Consortium must be duly licensed to act as a pharmaceutical wholesale dealer in the member state of its establishment.

2.2 Award Criteria

The government is allocating funds for this project and setting a reference budget of €1,000,000 per annum. In the first year of treatment this expenditure would be including what CPSU is currently procuring with a transition plan for relevant changeovers over a 12 month period. The transition plan will be finalised by the prescribers and CPSU in liaison with contractor.

CPSU is requesting a cost-saving performance-based agreement model that takes into consideration package deals, including, but not limited, to discounts.

CPSU requires all the portfolio listed in the EACS guidelines and is ready to accept companies that are ready to collaborate as partners with CPSU for the benefit of the patient and the organization at large by making use, but not limited to, joint ventures, consortiums and/or subcontracting.

The bidder that is eligible from points 1-3 (Eligibility Section) and provides the best financial offer in line with the eligible conditions and clauses, will be awarded the cycle. The publication of results will be shared only with the bidders that are eligible from points 1-3 (Eligibility Section).

Preference will be given to the bidder offering the complete portfolio listed in the EACS guidelines. The Government reserves the right that if there is no joint collaboration multiple awards may be considered.

2.3 Special Conditions

These conditions amplify and supplement, if necessary, the General Conditions governing the contract. Unless the Special Conditions provide otherwise, those General Conditions remain fully applicable. The numbering of the Articles of the Special Conditions is not consecutive but follows the numbering of the Articles of the General Conditions. Other Special Conditions should be indicated afterwards.

Article 2: Law Applicable and Language of the Contract

2.1 The laws of Malta shall apply in all matters not covered by the provisions of the contract.

2.2 The language used shall be English.

Article 4: Communications

4.1 Further to what is stated in the General Conditions, any communication should be made to:

The Managing Director
Sourcing & Supply Chain Management - MfH,
Central Procurement & Supplies Unit,
UB002, Industrial Estate,
San Gwann, SGN 3000.

E-mail: info.cpsu@gov.mt

Article 7: Supply of Documents

7.4 Not applicable.

Article 8: Assistance with Local Regulations

8.3 As per General Conditions.

Article 9: The Contractor's Obligations

9.6 Sub-Article 9.6 is not applicable for Malta Funds.

9.7 ***Medicinal Products***
It is the responsibility of the Responsible Person/Qualified Person to make available the batch specific Quality Control Certificate upon request by the Central Procurement and Supplies Unit (CPSU).

9.8 ***Medical material & devices, food supplements, dietary foods for special medical purposes, chemicals, cosmetics and disinfectants***
The necessary documentation as determined by the competent authority in Malta is to be submitted by the contractor upon request by the Central Procurement and Supplies Unit (CPSU).

9.9 **Summary of Product Characteristics (*Medicinal Products*)**
The Contractor must ensure that a copy of the latest approved Summary of Product Characteristics (SPC) intended for the use of healthcare professionals is kept at all times by the contractor.

The contractor must make the Summary of Product Characteristics (SPC) available without delay when requested by CPSU. When the SPC is updated or revised during the period of validity of the contract, the contractor must provide CPSU with a copy of the updated or revised SPC.

9.10 **Pharmaceutical Wholesale Dealer *(Medicinal Products)***
A contractor must be duly licensed as a pharmaceutical wholesale dealer by the appropriate competent authority of the country where the contractor is registered.

The Responsible Person/Qualified Person must inform the Central Procurement and Supplies Unit (MfH) of any changes including renewal, variation, suspension or revocation of the pharmaceutical wholesale dealer/importation license as issued by the competent authority.

The Licensee and the Responsible Person/Qualified Person of the local pharmaceutical wholesale dealer/importer must ensure that Maltese legislation, conditions of license and other requirements that may be issued from time to time by the Superintendent of Public Health or the competent authority in Malta are abided with within the definitions of their individual responsibilities.

9.11 **Registration of Medicinal Products**
The Responsible Person/Qualified Person must inform the Central Procurement and Supplies Unit (Ministry for Health) of any changes to the registration status of the medicinal product issued by the competent authority during the validity period of the contract.

For a centrally authorised medicinal product, the Responsible Person/Qualified Person must inform the Central Procurement and Supplies Unit (Ministry for Health) of any changes to delegated responsibility granted by the Market Authorisation Holder to place the product on the Maltese market during the validity period of the contract.

For a medicinal product granted a temporary authorisation by the Superintendent for Public Health in accordance with Article 20 of the Medicines Act, once the product is registered, the contractor is required to submit a copy of the registration certificate as issued by the local regulatory authority (MA).

For 'special medicine' or where the medicinal products supplied is licensed in a third country, the Responsible Person of the contractor must submit a batch specific certificate of analysis or conformance (as applicable) with every batch delivered to Central Procurement & Supplies Unit (Ministry for Health)

For medicinal products registered by the contractor following the signing of the contract, a copy of the registration certificate issued by the Licensing Authority of Malta must be submitted to CPSU within 90 days from signing of the contract. If the product is not registered within the stipulated timeframe, the Contracting Authority will reserve the right to:

either:

a) purchase the product on the account of the defaulting contractor until such time that the product is registered

or:

b) register the product on behalf of the contractor at a onetime registration fee of €1,000 and an annual fee as applicable by the Licensing Authority of Malta. Furthermore, the Contracting Authority shall also charge an annual administration fee of Eur500 per year. All the above fees shall be payable by the contractor. The registration shall conform to the procedures and policies applicable by the Licensing Authority of Malta.

Article 10: Origin

10.1 No derogation is applicable.

Article 11: Performance Guarantee

11.1 The Contractor shall, within 15 calendar days of receipt of the contract, sign and date the contract and return it together with a copy of the Performance Guarantee. The copy of the Performance Guarantee forwarded to the Central Government Authority is to be endorsed by the Contracting Authority prior to submission. The Contractor is therefore obliged to forward the original Performance Guarantee to the Contracting Authority. The amount of the guarantee shall be 4% where the amount of the total contract value is between €10,000 and €500,000 exclusive of VAT, and 10% where the amount of the total contract value is €500,000 or above. Where the contract is a Framework Contract, or when a contract is awarded to one contractor over a period of years for recurrent supplies, the Performance Guarantee may cover the yearly/annual total contract value.

In the case where the contract is for a period of more than one year, the performance guarantee is to be calculated on the average value of one year (the total value of the recommended offer divided by the number of years). Performance Guarantees are to be valid for a period of 12 months, renewable every year in accordance with the duration of the Contract Agreement.

11.3 The performance guarantee shall be in the format given in Section 5 and shall be provided in the form of a bank guarantee.

11.7 As per General Conditions.

Article 12: Insurance

12.1 Supplies shall be insured against all damages at all times. The contractor shall be responsible for all damages or loss in transit up to the delivery site. For marine cargo, the contractor is to ensure that deliveries to Central Procurement and Supplies Unit (CPSU) are adequately insured.

Article 13: Performance Programme (Timetable)

The contractor agrees to make first delivery of supplies within 12 weeks from the date of notification by the Clinical Consultants. Subsequently monthly deliveries (that are to commence four (4) weeks after the first delivery) must be made by the contractor. The contractor is to ensure that throughout the treatment period adequate supplies are delivered in time to the entity making the request in order not to disrupt the patient treatment. The contractor must acknowledge that the Contracting Authority is unable to forecast with precision its requirements for the duration of the contract, consequently it must be ensured that delivery of supplies is made in accordance with the exigencies of the Contracting Authority.

The delivery of supplies in terms of this contract shall be made by the contractor in the quantities and on the dates specified by the Contracting Authority in accordance with this Article. For the purposes of assisting the contractor to plan the delivery of supplies, should there be a change in the quantity required for monthly delivery/deliveries from that stipulated in the Confirmation of Order, the Contracting Authority shall by the first day of each calendar month submit in writing to the Contractor the volume of supplies required. These shall be

delivered by no later than the stipulated period.

The Contracting Authority reserves the right that, notwithstanding having instructed the Contractor to make delivery of supplies during any particular month, be permitted to instruct the contractor not to make the delivery of supplies, in whole or in part, or to instruct the contractor to delay the delivery of supplies. The Contracting Authority shall not be liable for any damages, costs or expenses incurred by the contractor as a result of any instruction issued to the contractor not to make the delivery of supplies, in whole or in part, or to delay the delivery of supplies.

The Contracting Authority also reserves the right, notwithstanding having instructed the contractor to make a delivery of supplies during any particular month, to subsequently instruct the contractor to deliver additional supplies, which shall be delivered according to the delivery period indicated above.

The contractor is also responsible to accept (and maintain as per instructions above) multiple Confirmation of Orders for the same product, from various sites/locations as indicated by the Contracting Authority.

The contractor undertakes and is bound to maintain a stockpile of the product/s, which stockpile shall not be of an amount less than the amount required for a period of three months. The contractor undertakes to deliver the stockpile within 24 hours in case of urgency.

No minimum pre-determined order quantities shall be allowed.

Article 14: Contractor's Drawings

As per General Conditions.

Article 15: Tender Prices

15.1 As per General Conditions.

Article 16: Tax and customs arrangements

16.1 No derogation applies.
16.2 No derogation applies.

Article 17: Patents and Licences

17.1 As per General Conditions.

Article 18: Commencement Order

18.1 The Contract will come into force from the last date of the signature of the Contract, unless indicated otherwise in the Contract.

Delivery of supplies shall be carried out in accordance with the instructions issued by the Contracting Authority in terms of Article 13. The first instruction issued by the Contracting Authority in terms of Article 13 shall be deemed to be the commencement order.

Article 19: Period of Execution of Tasks

19.1 This contract shall run for a period of **60 months** from commencement date. Supplies are to be delivered within the stipulated delivery periods and in quantities instructed by the Contracting Authority in terms of Article 13.

Article 21: Delays in Execution

21.1 The contractor acknowledges that performance of his obligations within the stipulated time limit(s) is crucial for the purposes of ensuring that the Contracting Authority maintains an adequate stock of supplies. Accordingly, the contractor agrees that if the contractor fails to deliver any or all of the supplies within the time limit(s) specified in the contract and as a result of such failure by the contractor CPSU's stock of supplies is entirely depleted, the Contracting Authority shall, without formal notice and without prejudice to its other remedies

under the contract, be entitled, for every day which shall elapse between the expiry of the time limit(s) for supply and the actual date of supply, to liquidated damages equal to 5/1000 of the value of the undelivered supplies to a maximum of 15% of the total value of the contract.

In the event that the Contractor is in delay in providing any supplies to the Contracting Authority and, as a result of such delay, CPSU's stock of supplies is entirely depleted, then the Contracting Authority shall, without prejudice to and in addition to its right to claim liquidated damages set forth in the above clause, be entitled to purchase supplies from a third party and to charge to the contractor any additional costs and expenses incurred by the Contracting Authority as a result of its purchases from the third party.

Article 22: Modification to the Contract

22.1 Subject to the provisions of the Public Procurement Regulations, the CGA/CA reserves the right to vary the quantities specified in the contract. The unit prices used in the tender shall be applicable to the quantities procured under the modification.

Article 24: Quality of Supplies

24.1 Further to Article 24.1 of the General Conditions, Product shelf life should be as follows:

either
Products having a shelf life as per SPC of 24 months or more, must not be more than $^{1}/_{3}$ rd expired upon delivery to Stores.

Products having a shelf life as per SPC which is less than 24 months must not be more than $^{1}/_{6}$ th expired upon delivery to Stores.

In cases where the Marketing Authorisation Holder (MAH) / Manufacturer submits written evidence in the quote that lead time prior to release is 2 months or more, the product must not be more than $^{1}/_{3}$ rd expired upon delivery to Stores.

or

In the case when the contractor delivers to the Central Procurement and Supplies Unit (CPSU) and on its part CPSU receives items that have shelf life conditions different to those listed above, the contractor shall notify in writing CPSU with the alternative shelf life conditions of the items on date of delivery of the said items. Any expired stock delivered to CPSU as aforesaid, shall be collected by the contractor in the case that the said stock expires and CPSU shall receive a credit equivalent to the price of the expired stock. CPSU shall notify the contractor in writing with a list of items supplied by the contractor that expired and the contractor is to collect the said stock within seven (7) working days from date when the list of expired items is notified to the Contractor. If the expired items are not collected within the seven (7) day period, CPSU shall debit the Contractor's account to credit transaction equivalent to the cost of the expired stock and dispose of the expired items. All costs including the cost of disposal shall be charged to the Contractor's account.

Any infringement in this respect will render the contractor liable to a penalty of 5% of the value of the consignment. CPSU – Ministry for Health also reserves the right to purchase from third parties and charge the difference to the contractor's account.

24.2 As per General Conditions.

24.4 It shall be lawful for the Head of Department to reject without the necessity of prior legal proceedings any consignment or part thereof, which in his/her opinion does not possess the qualities required under the contract and to obtain it elsewhere, at any price, and the difference in price charged on the contractor's account, should the latter fail to replace the articles rejected within the time allowed for the purpose by the Head of Department.

24.5 **Monographs - Medicinal Products**
The Department reserves the right to request a true copy of the company in-house monograph.

24.6 ***Medicinal products***
The Responsible Person/Qualified Person must inform the Central Procurement and Supplies Unit (CPSU), within

12 hours of having come into possession, of any information concerning batch defects and withdrawal of the product from the market. The Responsible Person/Qualified Person must inform in writing the Central Procurement and Supplies Unit of any suspension or withdrawal of the authorization to place the product on the market by the Superintendent of Public Health or the competent authority in Malta. The Responsible Person/Qualified Person of the Contractor must also provide any relevant support and documentation, as necessary, for the Responsible Person CPSU to ensure the safe use of medicinal stocks.

24.7 ***Medical material & devices, food supplements, dietary foods for special medical purposes, chemicals, cosmetics and disinfectants***

The contractor must inform the Central Procurement and Supplies Unit (CPSU), within 12 hours of having come into possession, of any information concerning batch defects and withdrawal of the product from the market. The contractor must also provide any relevant support and documentation, as necessary, for CPSU to ensure the safe use of medical products.

24.8 ***Non-Medicinal Products***

All non-medicinal products that are required for pharmaceutical purposes must comply with the respective standards listed in Ph. Eur. / B.P. / B.P.C. / U.S.P., where applicable and must be accompanied by a complete and detailed quality control analysis report by a certified body. The contractor must also provide any relevant support and documentation, as necessary, for CPSU - Ministry for Health to ensure the safe use of non-medicinal products.

Article 25: Inspection and Testing

25.2 As per General Conditions.

Article 26: Methods of Payment

26.1 Payments will be made in Euro.

Payments shall be authorized by the Contracting Authority or any other entity as delegated by CPSU, and paid by the Treasury Department.

26.3 Further to the General Conditions, payment shall be effected within 60 days from the date of the Contractor's request for payment, provided that it is tied:

a) to the actual date of the 'physical receipt/acceptance' of the ordered goods and,

b) shall be subject to conformity in all respects to all contractual obligations, specifications and conditions on the date of the 'physical receipt/acceptance' of the ordered goods to the satisfaction of the Head of Department or his/her representative.

26.5 Not applicable.

26.7 Further to the General Conditions, for supplies not covered by a warranty period, the conditions to which final payments are subject, shall be as stated in Clause 26.3.

26.9 No revision of prices is allowed.

Article 28: Delayed Payments

28.1 The Contracting Authority shall pay the contractor sums due within 60 days of the date on which an admissible payment is registered, in accordance with Article 26 of these Special Conditions. This period shall begin to run from the approval of these documents by the competent department referred to in Article 26.1 of these Special Conditions. These documents shall be approved either expressly or tacitly, in the absence of any written reaction in the 30 days following their receipt accompanied by the requisite documents.

28.2 Once the deadline laid down in Article 28.1 has expired:

the contractor may, within two months of late payment, claim late-payment interest: meaning simple interest for late payment at a rate which is equal to the sum of the reference rate and at least eight percent (8%); on the first day of the month in which the deadline expired. The late-payment interest shall apply to the time which elapses between the date of the payment 'deadline (exclusive) and the date on which the Contracting Authority's account is debited (inclusive).

Article 29: Delivery

29.1 The contractor shall bear all risks relating to the goods until provisional acceptance at destination. The supplies shall be packaged so as to prevent their damage or deterioration in transit to their destination.

Delivery shall be in accordance with the instructions given by the Contracting Authority in terms of Article 13. Delivery is to be effected to CPSU or any other sites/locations as requested by the Contracting Authority and must also comply to Article 29.9.

Deliveries must comply with Good Distribution Practice Guidelines currently in force.

29.2 As per General Conditions unless any special requirements are included in the product specifications. All packaging, marking and documentation inside and outside the packages must comply with Maltese legislation currently in force.

29.3 The packaging shall become the property of the recipient subject to respect for the environment.

29.5/6 ***Medicinal Products, Medical material & devices, food supplements, dietary foods for special medical purposes, chemicals, cosmetics and disinfectants***
All products delivered to Central Procurement and Supplies Unit (CPSU) - Ministry for Health must comply with Maltese legislation currently in force.

DH markings
Each unit container or pack is to be marked 'DH'. Markings are to be printed in an indelible medium on the outer packaging of each item and must be clearly legible, otherwise the products will be rejected upon delivery. Expenses and responsibility for refused items shall be borne by the contractor.

When the packaging of a consignment is opened to place DH markings on unit containers or packs, the goods must be re-packaged again in the same manner as the original packaging of the manufacturer or supplier.

Batch Numbers
Each consignment delivered to the Central Procurement and Supplies Unit (CPSU) must be physically segregated according to batch numbers and must be clearly documented. ***Each bulk packaging (carton box) must be labelled with the batch number and quantity of items contained therein.***

The Central Procurement and Supplies Unit (CPSU) reserves the right to refuse any consignment delivered comprising more than two different batch numbers.

GS1 standards for the identification and marking of healthcare products
The requirement to use GS1 standards is applicable to Secondary packaging for products supplied either directly or via local distributors to CPSU. The requirement applicable should conform to the FMD (Falsified Medicines Directive (FMD) 2011/62/EU) which comes into effect in February 2019.

Brand owners, Importers and distributors who are responsible for labelling products will need to ensure this requirement is met.

Each product requires the following details:

Global Trade Item Number (GTIN) (Issued in full compliance with GS1 standards)
Batch/lot number
Expiry date
Serial Number

For secondary level packaging of pharmaceutical products, the GS1 DataMatrix barcode is recommended.

29.8 Consignments of goods must be strictly delivered in boxes that are appropriately packed to withstand transport and handling**.**

Products requiring controlled storage temperature
The actual date and time of arrival of such products must be notified in advance, thus enabling proper arrangements for their storage. Such products must be appropriately packed and must include specific storage instructions that are clearly indicated on the bulk packaging.
A temperature logger or any other validated system acceptable to RP CPSU that demonstrates that the storage status for such products has been maintained throughout the delivery should be used. The Central Procurement and Supplies Unit (CPSU) reserves the right to refuse consignments not abiding with the above conditions at the expense of the tenderer.

Delivery of consignments on pallets must be made on Euro pallets.

The Central Procurement and Supplies Unit (CPSU) reserves the right to make any claims on discrepancies in the quantity of items delivered within 48 hours of receipt of goods at the stores.

When consignments are to be delivered via containers, the contractor should inform in writing the relative stores of the date of delivery and the number of consignments a minimum of one week in advance. The Central Procurement and Supplies Unit (CPSU) reserves the right to refuse such consignments if prior notification is not effected. Expenses and responsibility for refused items shall be borne by the contractor.

29.9 For medicinal products which are not to be delivered to CPSU stores such as, but not limited to, radioactive medicinal products, a technical agreement between Responsible Person - CPSU and Responsible Person/Qualified Person of contractor delineating duties and responsibilities of both parties shall be agreed prior to signing of the Contract Agreement (CA).

Article 31: Provisional Acceptance

As per General Conditions.

Article 32: Warranty

32.1 As per General Conditions.

Article 33: After-Sales Service

33.1 As per details stipulated in the Technical Specifications (if applicable).

Article 35: Breach of Contract

35.3 Without prejudice to the Government's right to dissolve 'ipso jure' the contract in the case of infringement of any condition thereunder and apart from the deduction established for delay in delivery, any such infringement shall render the contractor, in each case, liable to a deduction by way of damages of 5 per cent of the value of the contract, unless the Government elects, with regard to each particular infringement, but not necessarily with regard to all infringements, to claim actual damages incurred.

Article 41: Dispute Settlement by Litigation

If no settlement is reached within 120 days of the start of the amicable dispute-settlement procedure, each Party may seek:

a) either a ruling from a national court, or
b) an arbitration ruling, in the case where the parties, that is, the Contracting authority and the Contractor, by agreement decide to refer the matter to arbitration.

Article 45: Other conditions for the supply of Blood products/derivatives (if applicable)

The contractor shall ensure that:

a) the blood products requiring refrigerated storage are transported at a temperature of 2°C - 8°C at all times, including the delivery of these products to the Central Procurement and Supplies Unit (CPSU) or any other sites/locations as required.
b) each consignment delivered is to be accompanied by an Original Declaration stating that the specific batch numbers delivered are manufactured from plasma originating from the type of donors as specified in original quote.
c) products delivered must be accompanied by an independent Certificate of Analysis from an accredited laboratory.
d) manufacturer is to keep contractor, and consequently the Department, informed of any changes in the product during the contract period.

The conditions set out in the tender should not in any way be interpreted as exonerating the Fractionation Centre, Supplier, Manufacturer from ensuring that the best possible precautions available are used to ensure that the products are in no way contaminated and safe for use on patients.

3.0 Extracts from the Public Procurement Regulations

*Part **IX** of the Public Procurement Regulations*

Appeals from decisions taken after the closing date for the submissions of an offer

270. Where the estimated value of the public contract meets or exceeds five thousand euro (€5,000) any tenderer or candidate concerned, or any person, having or having had an interest or who has been harmed or risks being harmed by an alleged infringement or by any decision taken including a proposed award in obtaining a contract, a rejection of a tender or a cancellation of a call for tender after the lapse of the publication period, may file an appeal by means of an objection before the Public Contracts Review Board, which shall contain in a very clear manner the reasons for their complaints.

271. The objection shall be filed within ten calendar days following the date on which the contracting authority or the authority responsible for the tendering process has by fax or other electronic means sent its proposed award decision or the rejection of a tender or the cancellation of the call for tenders after the lapse of the publication period.

272. The communication to each tenderer or candidate concerned of the proposed award or of the cancellation of the call for tenders shall be accompanied by a summary of the relevant reasons relating to the rejection of the tender as set out in regulation 242 or the reasons why the call for tenders is being cancelled after the lapse of the publication period, and by a precise statement of the exact standstill period.

273. The objection shall only be valid if accompanied by a deposit equivalent to 0.50 per cent of the estimated value set by the contracting authority of the whole tender or if the tender is divided into lots according to the estimated value of the tender set by the contracting authority for each lot submitted by the tenderer, provided that in no case shall the deposit be less than four hundred euro (€400) or more than fifty thousand euro (€50,000) which may be refunded as the Public Contracts Review Board may decide in its decision.

274. The Secretary of the Public Contracts Review Board shall immediately notify the Director, the Ministerial Procurement Unit and, or the contracting authority, as the case may be, that an objection had been filed with his authority thereby immediately suspending the award procedure.

275. The Department of Contracts, the Ministerial Procurement Unit or the contracting authority involved, as the case may be, shall be precluded from concluding the contract during the period of ten calendar days allowed for the submission of appeals. The award process shall be completely suspended if an appeal is eventually submitted.

276. The procedure to be followed in submitting and determining appeals as well as the conditions under which such appeals may be filed shall be the following:

(a) any decision by the General Contracts Committee, the Ministerial Procurement Unit or the Special Contracts Committee or by the contracting authority, shall be made public by affixing it to the notice-board of the Department of Contracts, the Ministerial Procurement Unit or of the office of the contracting authority, as the case may be, or by uploading it on government's e-procurement platform prior to the award of the contract if the call for tenders is administered by the Department of Contracts;

(b) the appeal of the complainant shall also be affixed to the notice-board of the Public Contracts Review Board and shall be communicated by fax or by other electronic means to all participating tenderers;

(c) the contracting authority and any interested party may, within ten calendar days from the day on which the appeal is affixed to the notice board of the Review Board and uploaded where applicable on the government's e-procurement platform, file a written reply to the appeal. These replies shall also be affixed to the notice board of the Review Board and where applicable they shall also be uploaded on the government's eProcurement platform;

(d) the authority responsible for the tendering process shall within ten days forward to the chairman of the Public Contracts Review Board all documentation pertaining to the call for tenders in question including files and tenders submitted;

(e) the secretary of the Review Board shall inform all the participants of the call for tenders, the Department of Contracts, the Ministerial Procurement Unit and the contracting authority of the date or dates, as the case may be, when the appeal will be heard;

(f) when the oral hearing is concluded, the Public Contracts Review Board, if it does not deliver the decision on the same day, shall reserve decision for the earliest possible date to be fixed for the purpose, but not later than six weeks from the day of the oral hearing:

Provided that for serious and justified reasons expressed in writing by means of an order notified to all the parties, the Public Contracts Review Board may postpone the judgment for a later period;

(g) the secretary of the Review Board shall keep a record of the grounds of each adjournment and of everything done in each sitting;

(h) after evaluating all the evidence and after considering all submissions put forward by the parties, the Public Contracts Review Board shall decide whether to accede or reject the appeal or even cancel the call if it appears to it that this is best in the circumstances of the case.

4.1 Documents required to be submitted for Participation

Interested Economic Operators are to submit a technical proposal and financial offer for the treatment/s that can be offered.

For **EACH** different treatment to be offered, the **technical proposal** should include:

- The list of medicines referring to the classes in the EACS guidelines
- Complete Technical Form for Medicinal Products [as per Form attached]
- Summary of Product Characteristics [SPC]
- Patient Information Leaflet [PIL] & Mock-up of External Packaging
- Copy of MA Registration / PI / QL or other documentation as applicable
  a) Registration Certificate as issued by the Maltese Medicines Authority for product being offered (applicable if product is locally registered).

     If the medicinal product being offered is not registered locally, it is hereby confirmed that product/s shall be registered within 90 days from award of Contract. Failure of this, the Contracting Authority reserves the right, at its own discretion:

     to purchase registered product on the account of the defaulting contractor until the product is locally registered, or

     otherwise the product shall be registered by the Contracting Authority on behalf of the Contractor at a onetime registration fee of €1,000 and an annual fee as applicable by the Medicines Authority. In the latter case the Contracting Authority shall also be charging an annual administration fee of €500 per year. Such registration shall abide to the procedures and policies as applicable by the Maltese Medicines Authority.

  b. For products that are centrally registered with EMA, a copy of the delegated responsibility as issued to the local representative by the Marketing Authorisation Holder (MAH) in

relation to the medicinal product requested through the call for offers is to be submitted only in case where the local representative of the MAH is not clearly indicated in the documents submitted. Bidders are to inform the Contracting Authority immediately of any changes to delegated responsibility granted by the Market Authorisation Holder to place the product on the Maltese market during any stage of the tendering process or during the duration of the Contract.

c. For products which hold a Parallel Distribution (PD) notice with EMA, a copy of the PD notice is to be submitted.

The offer should include the holistic services that will be offered, the type of cost-saving model that will be used (which should be described in detail), and the **financial offer** for each type of medicine and the total cost. A duly filled-in Financial Bid form (as attached) is also to be submitted.

4.2 Instructions to Interested parties

Clarification Period:

Economic Operators may submit any clarifications or request additional information from the Contracting Authority by not later than **13th March 2019 at 12.00pm.** Any requests for clarifications are to be submitted by email on **negotiation.cpsu@gov.mt**

The last date on which additional information can be issued by the Contracting Authority is **18th March 2019 at 12.00pm**. Any clarifications and additional information will be uploaded on the CPSU website in the section 'Request for Negotiation Procedure'.

Clarification notes will constitute an integral part of the original published procurement documentation, and it is the responsibility of the Economic Operators to visit the website and be aware of the latest information published online prior to submitting their Request for Participation.

Submission of Request to Participate:

Requests to Participate are to be submitted in sealed envelopes **by not later than 10.00 hrs on 25th March 2019** in the **Purple** tender box located at the Reception Area, **CPSU Offices, UB002, Industrial Estate, San Gwann - SGN 3000**. The reference number of the call should be clearly indicated on the sealed envelope.

Submissions shall, **at least** include the following information:

- Full name of Service Provider;
- Address of Service Provider;
- Full name of contact person;
- Contact Telephone Number / Mobile Number & Fax Number;
- E-mail Address;
- VAT number.
- All the information, technical documentation and Certification requested in the previous section of this call.

No links are to be provided for Technical Specifications.

Please note that ALL submissions/documentation must include the Reference number. In cases, where this information is not included, the Contracting Authority reserves the right NOT to consider the offer.

Offers submitted that do not conform to specifications and conditions will not be considered.

Please note that it is entirely the Economic Operator's responsibility to ascertain that the submission is received BEFORE the deadline for submission of Request for Participation.

Any submissions after this date and time will be automatically rejected.

All Requests for Participation should be submitted **only** in sealed envelopes
by not later than 10.00 hrs on 25th March, 2019 in the **Purple** tender box
located at the Reception Area, **CPSU Offices,**
UB002, Industrial Estate, San Gwann - SGN 3000.

The reference number of this call and the name of the Economic Operator
are to be clearly indicated on the outside of the envelope.

ANY SUBMISSIONS AFTER THIS DATE AND TIME WILL BE AUTOMATICALLY REJECTED.