

Consultation on the Review of Fees for Supplementary Protection Certificates

Purpose of the consultation:

This consultation is intended to engage with interested parties to seek their views on the proposal to review the current application and renewal fees for Supplementary Protection Certificates.

Background:

Ireland has a strong pharmaceutical industry presence and Supplementary Protection Certificates are a valuable resource to the industry. Ireland also has a growing number of companies manufacturing generic medicines, providing less expensive generic medicine equivalents for the general public and the Irish healthcare system. These generic medicines provide an alternative to branded products that are no longer protected by a patent.

Rationale for changing fees:

Fees for Supplementary Protection Certificates fall somewhat outside the rationale for keeping fees for intellectual property protection low, as the circumstances for granting SPCs are very different to those for granting patents. As a Supplementary Protection Certificate will provide patent protection to a pharmaceutical company up to a maximum of 25 years, a balance must be struck between paying a premium for continued market monopoly and allowing for entry into the market for generic medicines.

By comparing current fees charged for Supplementary Protection in all Member States of the European Union, Ireland is currently the fourth least expensive country. In cost per head of population (per million) Ireland ranks as the tenth least expensive country of the EU 27, in line with countries with a population of approximately 10 million, namely Belgium, Sweden, Portugal and the Czech Republic. The preliminary fees for consultation as set out would bring Ireland closer in line with countries with similar population size such as Denmark, Finland and Slovakia. These new fees and European averages are indicated in the tables in Annex 1.

How and when to respond

Any questions in relation to the Consultation Document should be addressed to Ms Imelda Hardiman at 01 631 2581. Responses to the consultation may be sent by e-mail marked Consultation on the Review of Fees for Supplementary Protection Certificates to ipu@deti or by post to:

Ms Síona Breathnach, Review of SPC Fees, Intellectual Property Unit, Department of Enterprise, Trade and Innovation, Earlsfort Centre, Lower Hatch Street, Dublin 2.

Responses should be received by close of business on Friday 30th July 2010. **Note:** Proposed fees are indicative only.

Country	Application fee	Cost of Renewal fee over 5 years €	Total Possible Cost (application + 5 year renewal fees)	Population (Million)	Cost (application + 5 year renewal fees) per head of population (m)	Ranking (least to most)
France	500	4500	5000	64	78.13	1
United Kingdom	291	4659	4950	62	79.84	2
Italy	404	5055	5459	60	90.98	3
Germany	300	16650	16950	82	206.71	4
Poland	388.64	7772.05	8160.69	38	214.76	5
Spain	458	11258	11716	46	254.70	6
Romania	500	6000	6500	21.5	302.33	7
Belgium	200	3420	3620	10.8	335.19	8
Portugal	400	4000	4400	10.6	415.09	9
Ireland	95	2340	2435	4.5	541.11	10
Lithuania	115.85	1737.72	1853.57	3.3	561.69	11
Czech Republic	195	5816	6011	10.5	572.48	12
Sweden	485	4850	5335	9.3	573.66	13
Netherlands	544	10000	10544	16.5	639.03	14
Greece	200	7200	7400	11	672.73	15
Denmark	402	3425	3827	5.5	695.82	16
Hungary	783	6843	7626	10	762.60	17
Finland	400	4250	4650	5.3	877.36	18
Bulgaria	255.63	7669.08	7924.71	7.6	1042.73	19
Slovakia	165.50	6306	6306	5.4	1167.78	20
Ireland proposed	300	5000	5300	4.5	1177.78	
Latvia	105.86	2823.05	2928.91	2.2	1331.32	21
Austria	250	14000	14250	8.4	1696.43	22
Estonia	102.25	3131.55	3233.8	1.3	2487.54	23
Luxembourg	18.34	1350	1368.34	0.5	2736.68	24
Malta	116.47	1048.21	1164.68	0.4	2911.70	25
Cyprus	85.43	3331.77	3417.2	0.8	4271.50	26
Luxembourg 2011	20	2150	2170	0.5	4340.00	
Slovenia	420	12716	13136	2	6568.00	27

Notes: Luxembourg intend to change the fees charged for SPCs in January 2011 (indicated in red).

Country	Application fee	Cost of Renewal fee over 5 years €	Total Possible Cost (application + 5 year renewal fees)	Ranking (least to most)
Malta	116.47	1048.21	1164.68	1
Luxembourg	18.34	1350	1368.34	2
Lithuania	115.85	1737.72	1853.57	3
Luxembourg 2011	20	2150	2170	
Ireland	95	2340	2435	4
Latvia	105.86	2823.05	2928.91	5
Estonia	102.25	3131.55	3233.8	6
Cyprus	85.43	3331.77	3417.2	7
Belgium	200	3420	3620	8
Denmark	402	3425	3827	9
Portugal	400	4000	4400	10
Finland	400	4250	4650	11
United Kingdom	291	4659	4950	12
France	500	4500	5000	13
Ireland proposed	300	5000	5300	
Sweden	485	4850	5335	14
Italy	404	5055	5459	15
Czech Republic	195	5816	6011	16
Slovakia	165.50	6306	6306	17
Romania	500	6000	6500	18
Greece	200	7200	7400	19
Hungary	783	6843	7626	20
Bulgaria	255.63	7669.08	7924.71	21
Poland	388.64	7772.05	8160.69	22
Netherlands	544	10000	10544	23
Spain	458	11258	11716	24
Slovenia	420	12716	13136	25
Austria	250	14000	14250	26
Germany	300	16650	16950	27

Notes: Luxembourg intend to change the fees charged for SPCs in January 2011 (indicated in red).

Country	application fee		year 1	year 2	year 3	year 4	year 5		total		application for extention	extention fee (year 6)
Austria	250		2200	2500	2800	3100	3400		14000			
Belgium	200		590	640	685	730	775		3420			
Bulgaria	255.63		1022.55	1278.19	1533.83	1789.44	2045.07		7669.08			
Cyprus	85.43		598.01	632.18	666.35	700.53	734.7		3331.77			
Czech Republic	195		1008	1086	1163	1241	1318		5816			685
Denmark	402		685	685	685	685	685		3425		335	2066
Estonia	102.25		626.31	626.31	626.31	626.31	626.31		3131.55			255.64
Finland	400		850	850	850	850	850		4250			
France	500		900	900	900	900	900		4500		450	900
Germany	300		2650	2940	3290	3650	4120		16650			
Greece	200		1200	1300	1400	1500	1800		7200			1200
Hungary	783		977	1171	1370	1565	1760		6843			2066
Ireland	95		468	468	468	468	468		2340		95	468
Ireland Proposed	300		700	850	1000	1150	1300		5000		300	1500
Italy	404		1011	1011	1011	1011	1011		5055			
Latvia	105.86		564.61	564.61	564.61	564.61	564.61		2823.05			564.61
Lithuania	115.85		347.544	347.544	347.544	347.544	347.544		1737.72			
Luxembourg	18.34		270	270	270	270	270		1350		0	0
Luxembourg 2011	20		410	420	430	440	450		2150			
Malta	116.47		0	244.58	256.23	267.88	279.52		1048.21			
Netherlands	544		1600	1800	2000	2200	2400		10000			1300
Poland	388.64		1554.41	1554.41	1554.41	1554.41	1554.41		7772.05			
Portugal	400		700	750	800	850	900		4000			650
Romania	500		1000	1100	1200	1300	1400		6000		500	1400
Slovakia	165.50		995.5	1327.5	1659.5	1991.50	2323.5		6306			829.5
Slovenia	420		1702	2102	2504	3004	3404		12716			
Spain	458		656	1379	2173	3047	4003		11258			
Sweden	485		970	970	970	970	970		4850		290	970
United Kingdom	291		699	815	932	1048	1165		4659			468