

EUROPEAN PROCEDURES

Published on Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych (<https://archiwum.urpl.gov.pl>)

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According to Article 44 (5)td of the Polish Act on biocidal products, the applicant should pay the fee for completeness check and the fee for evaluation of dossier simultaneously. If during the process of the application evaluation it turns out that a full assessment is not required, the Office for Registration will reimburse the payment for evaluation.

All fees in the table below apply to the registration of a single biocidal product. In case of biocidal product family the registration fees are 200 % of the fees for a single product.

Fees for mutual recognition procedure are 12,5% of a total fee for full procedure.

Application Type	Completeness check [PLN]	Evaluation [PLN]	Total fee [PLN]
Application for national authorisation			
national authorisation (NA-APP)	2 500	47 500	50 000
product identical with (one of) the representative product(s) assessed for the purpose of the substance approval (NA- APP)	2 500	2 500	5 000
national authorisation in mutual recognition procedures (NA- MRP/NA-MRS)	N/A	N/A	6 250
national authorisation of same biocidal product (NA-BBP/NA-BBS)	2 500	N/A	2 500
Application for renewal of national authorisation NA-RNL			
in case of full evaluation	2 500	35 000	37 500
in case of non-full evaluation	2 500	10 000	12 500
National authorisation cancellation (NA-CCL)	5	5	10
Application for union authorisation			
union authorisation (UA- APP)	15 000	135 000	150 000
product identical with (one of) the	2 500	37 500	40 000

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representative product(s) assessed for the purpose of the substance approval (UA-APP)			
Application for renewal of union authorisation			
in case of full evaluation	N/A	100 000	100 000
in case of non-full evaluation	N/A	40 000	40 000
Application for national authorisation according to simplified procedure			
national authorisation according to simplified procedure (SA-APP)	500	9 500	10 000
product identical with (one of) the representative product(s) assessed for inclusion in Annex I (SA-APP)	500	500	1 000
Application for provisional authorisation			
provisional authorisation	1 000	4 000	5 000
product identical with (one of) the representative product(s) assessed for the purpose of the substance approval	500	500	1 000
application for renewal of provisional authorisation	250	250	500
Change of national authorisation when Poland is RMS			
major change	2 500	17 500	20 000
minor change	1 000	2 000	3 000
administrative change	500	500	1 000
Change of national authorisation when Poland is CMS			
major change	2 500	N/A	2 500
minor change	1 000	N/A	1 000
administrative change	500	500	1 000
Application for parallel trade permit			

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parallel trade permit (PP-APP)	1 000	1 000	2 000
amendment of parallel trade permit (PP-AAT)	250	250	500

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