

Pripomienkovanie článkov Európskeho liekopisu

Štátny ústav pre kontrolu liečiv informuje odbornú verejnosť o možnosti pripomienkovania návrhov nových a revidovaných článkov pred ich zaradením do Európskeho liekopisu.

Aktuálne vydanie **Pharmeuropa (37.3)** dáva možnosť **do 30.9.2025** pripomienkovať

Skúšobné metódy a všeobecné texty:

- 2.5.46. Phenolic antioxidants in plastic materials
- 2.6.42. Test for procoagulant activity in immunoglobulin preparations
- 2.8.27. Determination of estragole
- 5.2.14. Substitution of *in vivo* method(s) by *in vitro* method(s) for the quality control of vaccines
- 5.34. Additional information on gene therapy medicinal products for human use

Materiály na výrobu obalov a obaly:

- 3.1.3. Polyolefins
- 3.1.5. Polyethylene with additives for containers for parenteral preparations and for ophthalmic preparations
- 3.1.6. Polypropylene for containers and closures for parenteral preparations and ophthalmic preparations
- 3.1.7. Poly(ethylene - vinyl acetate) for containers and tubing for total parenteral nutrition preparations
- 3.2.1. Glass containers for pharmaceutical use

Monografie:

Adalimumab concentrated solution/Adalimumabi solutio concentrata (3147)
Alectinib hydrochloride/Alectinibi hydrochloridum (3219)
Bosentan monohydrate/Bosentanum monohydricum (3250)
Calcium hydroxide/Calcii hydroxidum (1078)
Carmellose calcium/Carmellosum calcicum (0886)
Daptomycin/Daptomycinum (3034)
Fluorescein sodium/Fluoresceinum natricum (1213)
Glutamic acid/Acidum glutamicum (0750)
Glycerol dibehenate/Glyceroli dibehenas (1427)
Glycerol distearate/Glyceroli distearas (1428)
Iopamidol/Iopamidolum (1115)
Iron sucrose concentrated solution/Ferri sacchari solutio concentrata (2753)
Lauromacrogol 400/Lauromacrogolum 400 (2046)
Neotame/Neotamum (3218)
Octyldodecanol/Octyldodecanolum (1136)
Polyoxypropylene stearyl ether/Polyoxypropyleni aether stearylicus (2602)
Primula flower/Primulae flos (2540)
Ropivacaine hydrochloride/Ropivacaini hydrochloridum (2800)
Sorbic acid/Acidum sorbicum (0592)
Sulfadiazine/Sulfadiazinum (0294)
Sulfamethoxazole/Sulfamethoxazolum (0108)
Sulfanilamide/Sulfanilamidum (1571)
Testosterone isocaproate/Testosteroni isocaproas (1737)

Lieky:

Alectinib hydrochloride capsules/Alectinibi hydrochloridi capsulae (3220)

Rastlinné drogy:

Lemon verbena leaf/Verbenae citriodora folium (1834)

Primula flower/Primulae flos (2540)
Sage leaf (Salvia officinalis)/Salviae officinalis folium (1370)
Sage leaf (Salvia officinalis), cut/Salviae officinalis folium minutatum (3201)
Saw palmetto fruit/Sabalus serrulatae fructus (1848)
Spine date seed/Ziziphi spinosae semen (2613)
Verbena herb/Verbenae herba (1854)

Homeopatické prípravky:

Belladonna for homoeopathic preparations/Atropa belladonna ad praeparationes homoeopathicas (2489)

Tradičná čínska medicína:

Fritillaria cirrhosa bulb/Fritillariae cirrhosae bulbus (2586)

Očkovacie látky:

Bluetongue vaccine (inactivated)/Vaccinum febris catarrhalis inactivatum (2899)
Influenza vaccine (split virion, inactivated)/Vaccinum influenzae inactivatum ex virorum fragmentis praeparatum (0158)
Influenza vaccine (surface antigen, inactivated)/Vaccinum influenzae inactivatum ex corticis antigeniis praeparatum (0869)
Influenza vaccine (surface antigen, inactivated, virosome)/Vaccinum influenzae inactivatum ex corticis antigeniis praeparatum virosomale (2053)
Influenza vaccine (surface antigen, inactivated, prepared in cell cultures)/Vaccinum influenzae inactivatum ex cellulis corticisque antigeniis praeparatum (2149)
Influenza vaccine (whole virion, inactivated)/Vaccinum influenzae inactivatum ex viris integris praeparatum (0159)

Imunoglobulíny:

Human normal immunoglobulin for intravenous administration/Immunoglobulinum humanum normale ad usum intravenosum (0918)
Human normal immunoglobulin for subcutaneous administration/ Immunoglobulinum humanum normale ad usum subdermicum (2788)

Návrh na vyradenie (suppression) článkov z Európskeho liekopisu:

Ephedrine/Ephedrinum (0488)
Ephedrine hemihydrate/Ephedrinum hemihydricum (0489)
Ephedrine hydrochloride, racemic/Ephedrini racemici hydrochloridum (0715)
Ouabain/Ouabainum (0048)

Úplné znenie aj s vyznačením zmien je dostupné na stránke EDQM <https://pharmeuropa.edqm.eu/home> .
Termín pripomienkovania je **do 30. septembra 2025**.
Pripomienky posielajte na Liekopisné oddelenie ŠÚKL (liekopis@sukl.sk), ktoré sprostredkuje ich doručenie do EDQM.