

DENTONS

# FARMAKON 2026

Prehľad aktuálnych legislatívnych opatrení EÚ dopadajúcich na dostupnosť liekov



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CMA je vytvorený doplnkovo k Pharma package ako reakcia na problém s nedostupnosťou liekov v EÚ

## Critical Medicines Act,

ktorý predstavuje Nariadenie, ktorým sa stanovuje rámec na posilnenie dostupnosti a bezpečnosti dodávok kritických liekov, ako aj dostupnosti a prístupnosti liekov spoločného záujmu.

## Pharma package pozostávajúci z:

- Nariadenie, ktorým sa stanovujú postupy Únie pri povoľovaní liekov na humánne použitie a vykonávaní dozoru nad nimi a určujú pravidlá platné pre Európsku agentúru pre lieky.
- Smernica o kódexe Únie o liekoch na humánne použitie.

Pharma package je core legislatívy, ktorý sa tvoril dlhodobou (2020-2026)

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**S** Ordinary legislative procedure

**#1 Commission proposal**

European Commission submits legislative proposal to the European Parliament



Column initiative

A quarter of the member states

European Investment Bank



European Central Bank



European Parliament

**#2 1st reading in the Parliament**

During its 1st reading, the European Parliament examines the Commission's proposal and may adjust or amend it.

**#3 1st reading in Council**

During its 1st reading, the Council may decide to accept Parliament's position in which case the legislative act is adopted, or it may amend Parliament's position, and return the proposal to Parliament for a 2nd reading.

**#4 2nd reading in Parliament**

Parliament examines Council's position and approves it, in which case the act is approved, or rejects it, in which case the act will not enter into force and the whole procedure is ended, or proposes amendments and returns the proposal to Council for a 2nd reading.

The legislative proposal is not adopted

The legislative proposal is adopted

The legislative proposal is adopted

The vast majority of proposals are adopted at this stage

The legislative proposal is adopted

**#5 2nd reading in Council**

Council examines Parliament's 2nd reading position and either approves all of Parliament's amendments meeting the criteria outlined, or does not approve all amendments, leading to the convening of the Conciliation Committee.

**#6 Conciliation**

The Conciliation Committee, composed of an equal number of MEPs and Council representatives, tries to reach agreement on a joint text. If unsuccessful, the legislative act will not enter into force and the procedure is ended. If a joint text is agreed, it is forwarded to the European Parliament and Council for a 3rd reading.

The legislative proposal is not adopted

The legislative proposal is not adopted

**#7a 3rd reading in Parliament**

The European Parliament examines the joint text and votes in primary. It cannot change the wording of the joint text. If it rejects or fails to act on it, the act is not adopted and the procedure is ended. If it approves by Parliament and Council, the act is adopted.

**#7b 3rd reading in the Council**

Council examines the joint text. It cannot change the wording. If it either rejects or does not act on it, and it will not enter into force and the procedure is ended. If it approves the text and the Parliament also approves it, the act is adopted.

The legislative proposal is not adopted

**Proposal adopted**

Once both European Parliament and Council have approved the final text of a legislative proposal, it is published by the President and Secretary-General of both institutions. After signature, the texts are published in the Official Journal and become official.

- Regulations are directly binding throughout the EU as of the date set down in the Official Journal.
- Directives lay down the results to be achieved in every member state, but leave it up to national governments to decide how to bring their laws in line with these goals. Each directive specifies the date by which the national laws must be adopted.
- Decisions apply in specific cases, involving particular authorities or individuals and are fully binding.

**Proposal not adopted**

If a legislative proposal is rejected at any stage of the procedure, or the Parliament and Council cannot reach a compromise, the proposal is not adopted and the procedure is ended. A new procedure can start only with a new proposal from the Commission.

Zdroj: <https://www.europarl.europa.eu/about-parliament/en/parliaments-powers/legislative-powers>

## Critical Medicines Act

Predmet

**Kritické  
lieky**

**Vstupy  
na výrobu  
kritických  
liekov**

**Lieky  
spoločného  
záujmu**

## Critical Medicines Act

Základný cieľ

**Zabezpečiť dostupnosť kritických liekov v EÚ**

**Podpora  
výroby  
v EÚ**

**Diverzifikácia  
distribúcie**

**Strategické  
partnerstvá**

# Critical Medicines Act

Nástroje

Strategické projekty

Nové kritéria pre VO

Kolaborácia ČŠ pri realizácii VO

Tvorba zásob a rezerv

Vytváranie strategických partnerstiev

Zriadenie Koordinačnej skupiny pre kritické lieky

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# Pharma Package

Registrácia liekov

Podpora vývoja antibiotík

Poradenstvo a zrýchlené procesy

Orphan deznácia

Pediatrické lieky

Farmakovigilancia a bezpečnosť

Reklama liekov

Podmienky vstupu G a B

Monitoring dostupnosti liekov

Fungovanie EMA a regulačných procesov

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**ĎAKUJEM ZA POZORNOSŤ!**



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