

Pharmacovigilance Risk Assessment Committee

Jana Mladá

O čem dnes?

-  Pharmacovigilance Risk Assessment Committee
-  Hodnocení a jich závěry
-  Praktický dopad na registrace v ČR



PRAC

 **Pharmacovigilance Risk Assessment
Committee = farmakovigilanční výbor pro
posuzování rizik léčiv**

 **První zasedání 7/2012**

1 člen + 1 náhradník každý členský stát



6 členů jmenovaných EK



1+1 pacient



1+1 ZP



Referraly

Referraly – EU arbitráže

 **Bezpečností problém** - postup pro naléhavé záležitosti stanovený EU (§93h,i Zol; 107i směrnice)

Přehodnocení B/R

- podle článku 31 směrnice – národní registrace
- podle článku 20 směrnice – centralizované registrace

Referraly

- 🌀 **PRAC doporučení pro CMDh a CHMP**
- 🌀 **CHMP** – EC rozhodnutí pro centralizovanou registraci
- 🌀 **CMDh** – konsensus; jinak EC
- 🌀 **Rozhodnutí EC** – implementace do národních registrací
- 🌀 **Informace na webu EMA:**
- 🌀 **Find medicine → Human med. → Referrals**



▼ Human medicines

European public assessment reports

Patient safety

Pending EC decisions

Withdrawn applications

Paediatrics

Rare disease designations

Medicines under evaluation

Medicines for use outside the EU

▼ Referrals

Article 5(3) opinions

Veterinary medicines

Herbal medicines for human use

[Home](#) [Find medicine](#) [Human medicines](#) [Referrals](#)

Tetrazepam-containing medicines

[Email](#) [Print](#) [Help](#) [Share](#)

Summary

Key facts

Data submission

All documents

Procedure started

Under evaluation

PRAC recommendation

CMDh Position

European Commission final decision



Current status:
Position provided
by CMDh

More information on tetrazepam-containing medicines

- ▶ [Meeting highlights from the Pharmacovigilance Risk Assessment Committee \(PRAC\) 8-11 April 2013](#)
- ▶ [Meeting highlights from the Pharmacovigilance Risk Assessment Committee \(PRAC\) 7-10 January 2013](#)

Recommendation to suspend tetrazepam-containing medicines endorsed by CMDh

Following the recent recommendation by the [Pharmacovigilance Risk Assessment Committee \(PRAC\)](#), the Co-ordination Group for [Mutual Recognition and Decentralised Procedures – Human \(CMDh\)](#) has endorsed by majority the [PRAC](#) recommendation to suspend the marketing authorisations of tetrazepam-containing medicines across the European Union (EU). The [CMDh](#), a body representing EU Member States, is responsible for ensuring harmonised safety standards for medicines authorised via national [marketing authorisation](#) procedures across the EU.

Tetrazepam, a medicine of the benzodiazepine class, is used in several EU Member States to treat painful contractures (such as in low back pain and neck pain) and spasticity (excessive stiffness of muscles).

The [CMDh](#) position will now be sent to the European Commission, which will take a legally binding decision throughout the EU.

The review of tetrazepam was triggered by the French [National Agency for the Safety of Medicine and Health Products](#) (ANSM), following reports of serious skin reactions with this medicine in France. Having assessed all available data on the

Signály – hodnocení a prioritizace

Signály – ukončená hodnocení doporučení PRAC

 Žádost o změnu do 30 dní od doporučení PRAC

 Informace v zápisu z jednání a na stránce CMDh

Home Find medicine Regulatory Special topics Document search News & events Partners & networks About us Quick links

What we do
Who we are
How we work
Committees
CHMP
PRAC
Overview
Members
Meetings
Agendas, minutes and highlights
CVMP

Home About Us Committees PRAC Agendas, minutes and highlights

PRAC: Agendas, minutes and highlights

Email Print Help Share

This page lists the **agendas, minutes** and **meeting highlights** from the [Pharmacovigilance Risk Assessment Committee \(PRAC\)](#) plenary meetings.

PRAC meeting highlights

- ▶ Meeting highlights from the [Pharmacovigilance Risk Assessment Committee \(PRAC\)](#) 8-11 April 2013
- ▶ Meeting highlights from the [Pharmacovigilance Risk Assessment Committee \(PRAC\)](#) 4-7 March 2013
- ▶ Meeting highlights from the [Pharmacovigilance Risk Assessment Committee \(PRAC\)](#) 4-7 February 2013
- ▶ Meeting highlights from the [Pharmacovigilance Risk Assessment Committee \(PRAC\)](#) 7-10 January 2013
- ▶ Meeting highlights from the [Pharmacovigilance Risk Assessment Committee \(PRAC\)](#) 26-29 November 2012
- ▶ Meeting highlights from the [Pharmacovigilance Risk Assessment Committee \(PRAC\)](#) 29-31 October 2012
- ▶ Meeting highlights from the [Pharmacovigilance Risk Assessment Committee \(PRAC\)](#) 1-3 October 2012
- ▶ [Pharmacovigilance Risk Assessment Committee \(PRAC\)](#) elects chair and vice-chair

Table of contents

Další agendy PRAC

-  Plány pro řízení rizik
-  PSURy
-  PASS
-  FV inspekce
-  Dotazy od CHMP, členských států

Odneste si domů

-  **PRAC** = farmakovigilanční výbor pro posuzování rizik léčiv
-  **PRAC** – doporučení pro CMDh a CHMP – potvrzení EC – implementace do národních registrací
-  **PRAC** – informace jsou přehledně na webu EMA