# Industriens rammer for godkjennelse av legemidler og produktinformasjon

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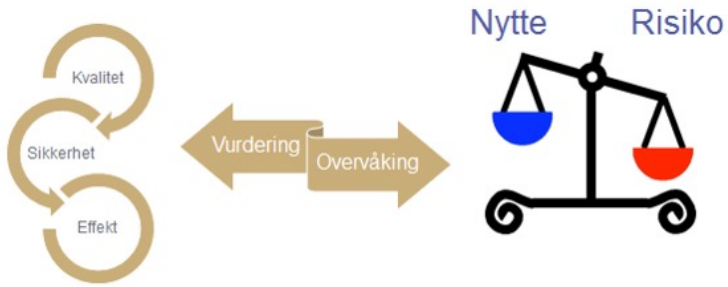
# KVALITET – SIKKERHET – EFFEKT

# Prosedyre

- **National Procedure (NP)**
  - Nasjonal godkjenning
  - Variable tidslinjer
- **Mutual Recognition Procedure (MRP)**
  - Nasjonal godkjenning
  - Variable tidslinjer
- **Desentralised Procedure (DCP)**
  - Nasjonal godkjenning
  - Variable tidslinjer
- **Centralised Procedure (CP)**
  - Én MT
  - Samtidig
  - Alle medlemsland



L 311/86 EN Official Journal of the European Communities 28.11.2001

*Article 57*

Notwithstanding Article 60, Member States may require the use of certain forms of labelling of the medicinal product making it possible to ascertain:

— the price of the medicinal product,

— the reimbursement conditions of social security organizations,

— the legal status for supply to the patient, in accordance with Title VI,

— identification and authenticity.

*Article 58*

The inclusion in the packaging of all medicinal products of a package leaflet shall be obligatory unless all the information required by Articles 59 and 62 is directly conveyed on the outer packaging or on the immediate packaging.

*Article 59*

1. The package leaflet shall be drawn up in accordance with the summary of the product characteristics; it shall include, in the following order:

(a) for the identification of the medicinal product:

— the name of the medicinal product, followed by the common name if the product contains only one active substance and if its name is an invented name; where a medicinal product is available in several pharmaceutical forms and/or several strengths, the pharmaceutical form and/or the strength (for example, baby, child, adult) must be included in the name of the medicinal product,

— a full statement of the active substances and excipients expressed qualitatively and a statement of the active substances expressed quantitatively, using their common names, in the case of each presentation of the medicinal product,

— the pharmaceutical form and the contents by weight, by volume or by number of doses of the product, in the case of each presentation of the product,

— the pharmaco-therapeutic group, or type of activity in terms easily comprehensible for the patient,

(c) list of information which is necessary before taking the medicinal product:

— contra-indications,

— appropriate precautions for use,

— forms of interaction with other medicinal products and other forms of interaction

(e.g. alcohol, tobacco, foodstuffs) which may affect the action of the medicinal product,

— special warnings;

this list must:

— take into account the particular condition of certain categories of users (e.g. children, pregnant or breastfeeding women, the elderly, persons with specific pathological conditions),

— mention, if appropriate, potential effects on the ability to drive vehicles or to operate machinery,

— detail those excipients, knowledge of which is important for the safe and effective use of the medicinal product and included in the guidelines published pursuant to Article 65;

(d) the necessary and usual instructions for proper use, in particular:

— the dosage,

— the method and, if necessary, route of administration,

— the frequency of administration, specifying if necessary, the appropriate time at which the medicinal product may or must be administered,

and, as appropriate, depending on the nature of the product:

— the duration of treatment, where it should be limited,

— the action to be taken in the case of an overdose (e.g., symptoms, emergency procedures),

— the course of action to take when one or more doses have not been taken,

— indication, if necessary, of the risk of withdrawal effects;

# Pakningsvedlegget bygger på informasjonen i SPC*


*SPC= Summary of product characteristics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# Committees

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## Pharmacovigilance Risk Assessment Committee (PRAC)

Share

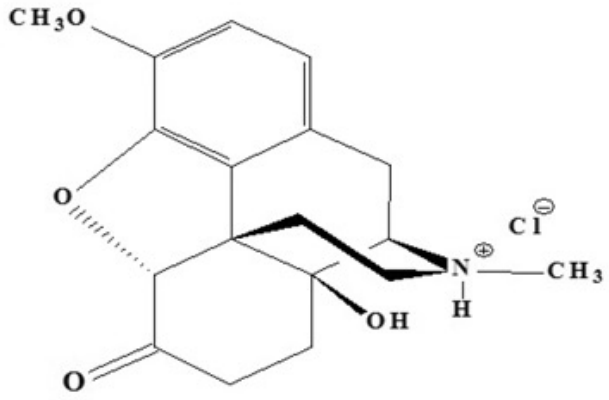
**The Pharmacovigilance Risk Assessment Committee (PRAC) is the European Medicines Agency's (EMA) committee responsible for assessing and monitoring the safety of human medicines.**

The PRAC was formally established in line with the pharmacovigilance legislation which came into effect in 2012 to help strengthen the safety monitoring of medicines across Europe.

### Role of the PRAC

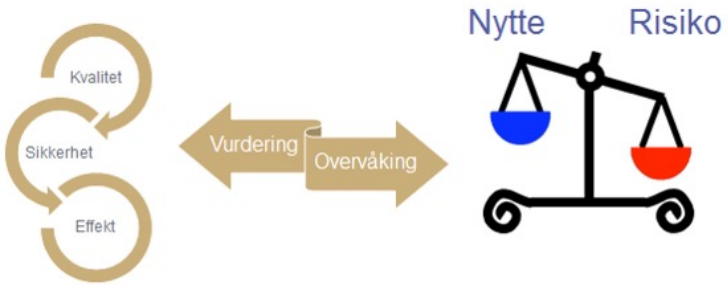
## Nasjonale sikkerhetstiltak

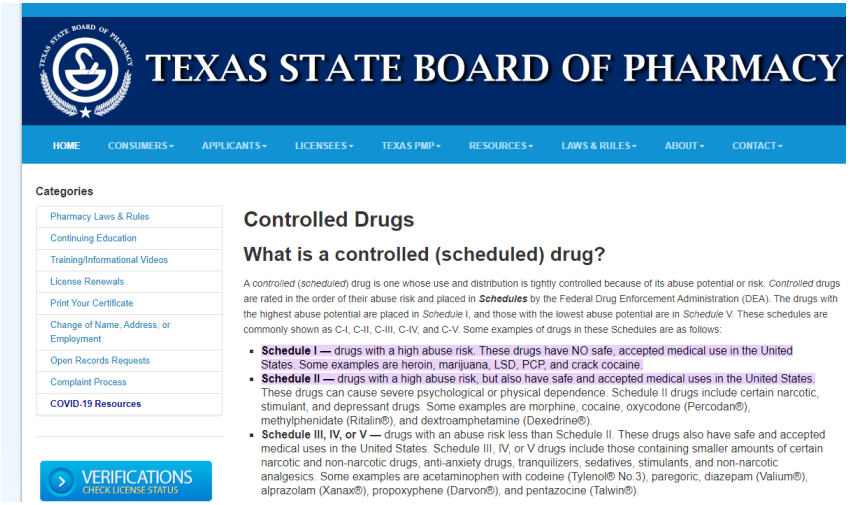
- A- og B-preparater
- Sjekkliste med spørsmål før forskrivning
- Veiledere for helsepersonell og pasienter
- Sikkerhetsrutiner på apotek




$C_{18}H_{21}NO_4 \bullet HCl$ MW 351.83

**"Delayed absorption as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug."**



# Boxed Warning

**WARNING: ADDICTION, ABUSE AND MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; NEONATAL OPIOID WITHDRAWAL SYNDROME; and CYTOCHROME P450 3A4 INTERACTION**

***See full prescribing information for complete boxed warning.***

- **OXYCONTIN exposes users to risks of addictions, abuse and misuse, which can lead to overdose and death. Assess each patient's risk before prescribing and monitor regularly for development of these behaviors and conditions. (5.1)**
- **Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase. Instruct patients to swallow OXYCONTIN tablets whole to avoid exposure to a potentially fatal dose of oxycodone. (5.2)**
- **Accidental ingestion of OXYCONTIN, especially in children, can result in a fatal overdose of oxycodone. (5.2)**
- **Prolonged use of OXYCONTIN during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available. (5.3)**
- **Initiation of CYP3A4 inhibitors (or discontinuation of CYP3A4 inducers) can result in a fatal overdose of oxycodone from OXYCONTIN. (5.14)**

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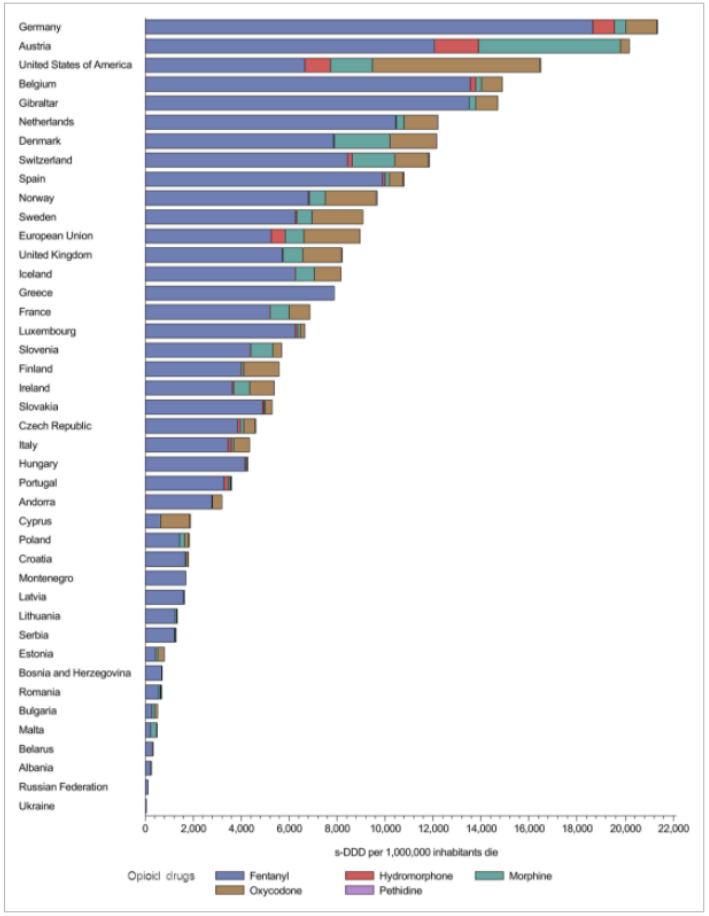



**Figure 1** Open in figure viewer | PowerPoint

Stacked bar chart for the consumption of fentanyl, oxycodone, morphine, hydromorphone, pethidine in 40 European countries, the European Union as a whole, and the United States of America, in 2014–2016. s-DDD: defined daily doses for statistical purposes



FORSKNINGSFUNN

# Flere dør av en overdose sterke smertestillende medisiner

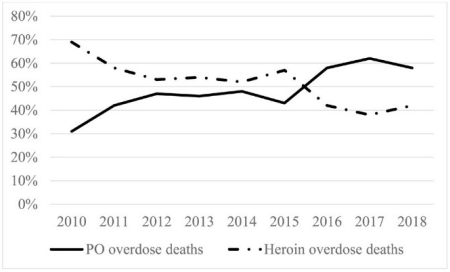
Publisert 24.10.2022 Oppdatert 25.10.2022

Det har vært en økende trend med overdosedødsfall som følge av sterke smertestillende medisiner med opioider i perioden 2010 til 2018.

*Illustrasjonsfoto: Colourbox.com*

Del/tips Skriv ut

Det viser en studie fra FHI. Studien er publisert i International Journal of Drug Policy. I 2010 skyldtes 30 prosent av dødsfallene sterke smertestillende medisiner med opioider, og 70 prosent skyldtes heroin. I 2018 hadde fordelingen endret seg til henholdsvis 60 og 40 prosent.




*Figur 1: Andel overdosedødsfall forårsaket av sterke smertestillende medisiner med opioider (616 personer) eller heroin (651 personer) mellom 2010 og 2018 i Norge.*

# PRAC-rapport 2021- MedDRA: Misbruk, avhengighet og brå seponering

**Amendments to be included in the relevant sections of the Product Information** (new text **underlined and in bold**, deleted text ~~strike through~~)

**Summary of Product Characteristics**

- Section 4.4

A strengthened warning should be added as follows:

***Opioid Use Disorder (abuse and dependence)***

***Tolerance and physical and/or psychological dependence may develop upon repeated administration of opioids such as oxycodone. Iatrogenic addiction following therapeutic use of opioids is known to occur.***

***Repeated use of [product name] may lead to Opioid Use Disorder (OUD). Abuse or intentional misuse of [product name] may result in overdose and/or death. The risk of developing OUD is increased in patients with a personal or a family history (parents or siblings) of substance use disorders (including alcohol use disorder), in current tobacco users or in patients with a personal history of other mental health disorders (e.g. major depression, anxiety and personality disorders).***

***Patients will require monitoring for signs of drug-seeking behavior (e.g. too early requests for refills). This includes the review of concomitant opioids and psycho-active drugs (like benzodiazepines). For patients with signs and symptoms of OUD, consultation with an addiction specialist should be considered.***

Remove sentence (or similar wording) if present: *"~~However, when used as intended in patients with chronic pain the risk of developing physical or psychological dependence is markedly reduced~~"*

Remove sentence (or similar wording) if present: *"~~There are no data available on the actual incidence of psychological dependence in chronic pain patients~~"*

Remove sentence (or similar wording) if present: *"~~Oxycodone has an abuse profile similar to other strong opioid agonists and may be sought and abused by people with latent or manifest addiction disorders. There is potential for development of psychological dependence (addiction) to opioid analgesics, including oxycodone. [Product name] should be used with particular care in patients with a history of alcohol or drug abuse.~~"*

**Package Leaflet**

Note: depending on formulation (e.g., capsules or injection) "*taken*" (capsules) or "*used*" (injections) should be used.

-Regarding Opioid Use Disorder:

- Section 2. What you need to know before you take/use [product name]

Warnings and precautions

Remove sentence (or similar wording) if present:
*"~~If this medicine is used as intended in patients suffering from chronic pain states, the risk for physical and psychological dependence is low~~."*

The following changes are recommended:
Talk to your doctor or pharmacist before taking/using [product name] if you:
[…]

***~~- are or have ever been addicted to alcohol or drugs, or have a known opioid dependence;~~***
***- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction").***
***- You are a smoker.***
***- You have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.***

*[…]*
***Repeated use of [product name] may lead to dependence and abuse which may result in life-threatening overdose. If you have concern that you may become dependent on [product name], it is important that you consult your doctor.***

# Takk for oppmerksomheten

Bildene er ikke mine – de er fra ulike websider