European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

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COMMITTEE OF EXPERTS ON THE CLASSIFICATION OF MEDICINES AS REGARDS THEIR SUPPLY (CD-P-PH/PHO)

Evidence-based classification review for Ricinus communis L., oleum

(ATC code A06AB05)

2025

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Introduction

The availability of medicines with or without a medical prescription has implications for patient safety, accessibility of medicines to patients and responsible management of healthcare expenditure.

The decision on prescription status and related supply conditions is a core competency of national health authorities. The conditions of the supply of medicines vary considerably in Council of Europe Member States due to different interpretation and implementation of the provisions and since important additional classification criteria are not harmonised.

The Committee of Experts on the Classification of Medicines as Regards their Supply (CD-P-PH/PHO) is co-ordinated by the European Directorate for the Quality of Medicines & HealthCare (EDQM, Council of Europe) and its work programme is based on Committee of Ministers Resolution CMRes(2018)1 on the classification of medicines as regards their supply. The CD-P-PH/PHO reviews the national legal supply status of medicinal products for human use, performs assessment according to Guidelines on key considerations in issuing recommendations on the classification of active substances as regards their supply (prescription and non-prescription status) and issues recommendations on the classification of medicines and their supply conditions to health authorities of the Council of Europe Member States parties to the European Pharmacopoeia Convention. It is important to note that the CD-P-PH/PHO does not issue recommendations on the classification of particular medicinal products, but on active substances with their respective Anatomical Therapeutic Chemical (ATC) codes.

The approach to the classification of herbal medicines described below was endorsed by the CD-P-PH/PHO in November 2025, and has no legal status.

Classification of herbal medicines

This section outlines the rationale behind the CD-P-PH/PHO's recommendations related to herbal medicines with a complete ATC code (consideration of a herbal medicine with an incomplete ATC code may be justified only in very rare cases).

The term "Herbal medicines" can be understood in different ways. In the context of the CD-P-PH/PHO recommendations, herbal medicines are medicines with a complete ATC code containing an active substance based on "herbals" – plants or parts of plants with a marketing authorisation based on well-established use application. "Non-herbal" medicines and food supplements are out of the scope of this document. The approach to traditional use herbal medicines is outlined in the document; however, these medicines are not assessed by the CD-P-PH/PHO.

The CD-P-PH/PHO assessment can contribute to the harmonisation of the classification and conditions of supply of herbal medicines across the Member States.

The European Union (EU) legislation sets out various regulatory pathways to obtain a marketing authorisation of a herbal medicine; however, information on the authorisation type is not included in the labelling of medicines. Consequently, the regulatory pathway behind these medicines, which partly determines their classification and supply conditions, is not clear to patients and sometimes even to healthcare professionals.

The regulatory pathway for herbal medicines in the EU is illustrated below (European Medicines Agency (EMA) website; "Member State" refers here to EU Member States):

Regulatory pathway	Main requirements on safety and efficacy	Where to apply
Traditional use registration (Article 16a(1) of Directive 2001/83/EC)	• No clinical tests and trials on safety and efficacy are required as long as sufficient safety data and plausible efficacy are demonstrated • Involves assessment of mostly bibliographic safety and efficacy data • Must have been used for at least 30 years, including at least 15 years within the EU • Are intended to be used without the supervision of a medical practitioner and are not administered by injection	• National competent authority of a Member State for national, mutual recognition and decentralised procedures
Well-established use marketing authorisation (Article 10a of Directive 2001/83/EC)	• Scientific literature establishing that the active substances of the medicinal products have been in well-established medicinal use within the EU for at least ten years, with recognised efficacy and an acceptable level of safety • Involves assessment of mostly bibliographic safety and efficacy data	• National competent authority of a Member State for national, mutual recognition and decentralised procedures • EMA if centralised procedure applies
Stand-alone or mixed application (Article 8(3) of Directive 2001/83/EC)	• Safety and efficacy data from the company's own development or a combination of own studies and bibliographic data	• National competent authority of a Member State for national, mutual recognition and decentralised procedures • EMA if centralised procedure applies

Medicines authorised via a traditional use authorisation are intended to be used without the supervision of a medical practitioner, i.e. have a non-prescription status. The CD-P-PH/PHO will identify herbal medicines with a complete ATC code authorised as traditional herbal medicines only, and for which a monograph has been issued by the Committee on Herbal Medicinal Products (HMPC) of the EMA. As traditional herbal medicines are out of scope of the evaluation by the CD-P-PH/PHO, the conditions of the monograph are followed and non-prescription status is recommended without any evaluation. These medicines are shown in Table 1.

Table 1 - Herbal medicines with a complete ATC code with traditional use authorisation only and an HMPC monograph

INN (ATC code)	Monograph available on
Crataegi folium cum flore (C01EB04)	https://www.ema.europa.eu/en/medicines/herbal/crataegi-folium-cum-flore
Centellae asiatica herba, incl. combinations (D03AX14)	https://www.ema.europa.eu/en/medicines/herbal/centellae-asiaticae-herba
Lavandulae aetheroleum (N05BX05)	https://www.ema.europa.eu/en/medicines/herbal/lavandulae-aetheroleum
Althaeae radix (R05CA05)	https://www.ema.europa.eu/en/medicines/herbal/althaeae-radix
Pruni africanae cortex (G04CX01)	https://www.ema.europa.eu/en/medicines/herbal/pruni-africanae-cortex

These medicines have monographs available, based on Article 16d(1), Article 16f and Article 16h of Directive 2001/83/EC, as amended (traditional use). Therefore, these medicines should be non-prescription according to the conditions of the monographs. The EMA list of HMPC monographs with traditional use authorisation only is very long; however, most of the medicines do not have an ATC code or have an incomplete ATC code, and therefore they are not included in Table 1.

For the other regulatory pathways, the classification outcome can be different, and it is important to establish conditions of supply and a recommendation on the classification.

For well-established use herbal medicines with a complete ATC code, regardless of whether there is a monograph issued by the HMPC (see Table 2), the CD-P-PH/PHO will assess the conditions of supply and issue a recommendation on the classification.

Table 2 - Herbal medicines with a complete ATC code with well-established use authorisation, with or without an HPMC monograph, on the EMA herbal medicines list

Agni casti fructus (G02CX03)	Menthae piperitae aetheroleum (A03AX15)
Capsici fructus (M02AB01)	Planataginis ovatae semen or Plantaginis ovatae seminis tegumentum or Psylli semen (A06AC01)
Cimifugae rhizoma (G02CX04)	Rhamni purshianae cortex (A06AB07)
Gingko folium (N06DX02)	Ricini oleum (A06AB05)
Hederae helicis folium (R05CA12)	Sabalis serrulatae fructus (G04CX02)
Hippocastani semen (C05CX03)	Sennae folium and/or Sennae fructus (A06AB06)
Hyperici herba (N06AX25)	Valerianae radix (N05CM09)
Lini semen (A06AC05)	

The Evidence-based classification review (EBR) for Ricinus communis L., oleum (castor oil, Ricini oleum), one of these medicines, is provided below.

Well-established use herbal medicines with an incomplete ATC code are listed in Table 3 for information only.

Table 3 - Herbal medicines with an incomplete ATC code with well-established use authorisation, with or without an HPMC monograph, on the EMA herbal medicines list

Aloes folii succus siccatus (A06AB)	Rhei radix (A06AB)
Echinaceae purpurae herba (R05X)	Salicis cortex (N02BG)
Frangulae cortex (A06AB)	Valerianae radix/Lupuli flos (N05CM)
Menthae piperitae folium (A03AX)	Vitis viniferae folium (C05CX)
Plantaginis ovatae seminis tegumentum (C10AX)	Zingiberis rhizome (A04AD)

Regulatory pathways are not applicable to non-EU countries; however, the rationale related to the classification of herbal medicines provided by the CD-P-PH/PHO could be considered in any setting.

Evidence-based classification review

Note: The document Guidelines on key considerations in issuing recommendations on the classification of active substances as regards their supply (prescription and non-prescription status) should be consulted.

1. Active substance

Ricinus communis L., oleum (castor oil, Ricini oleum)

2. ATC code

A06AB05

3. First level assessment

3.1 Characteristics of the active substance

Products containing castor oil (virgin and refined) have been registered as traditional herbal medicinal products or have well-established use in some Member States.

The Quality Drafting Group of the HMPC is of the opinion that virgin castor oil and refined castor oil are comparable because the refining process affects impurities only, which means that active ingredients are not changed by the process [1].

The medicinal use of castor oil has been documented in several medicinal handbooks throughout a period of at least 30 years, including at least 15 years within the EU.

Therefore, the castor oil (virgin and refined) is a well-known substance.

3.2 Pharmaceutical form/route of administration

Available in solid or liquid forms. To be taken orally [2].

3.3 Intended therapeutic indication

Laxative for short-term use in cases of occasional constipation, based on available clinical data (well-established use).

Conclusion of First level assessment

It is not definitely concluded that the active substance should have prescription status applied. Second level assessment is required to further evaluate the appropriate supply status.

4. Second level assessment

4.1 Assessment of use

The indication – occasional constipation – is a very common condition that can be easily identified by patients. Patients are accustomed to going to a pharmacy to obtain medicine for this condition.

Identified risk(s): prolonged use without medical supervision can pose a risk (masking effect leading to delayed diagnosis and tolerance); however, this is common to laxative medicines. The approach followed is to restrict the duration of use without medical supervision in the package leaflet.

4.2 Safety profile

4.2.1 Direct risks

Toxicity

Reproductive toxicity data revealed no toxic effect, while developmental studies in pregnant rats suggested that castor oil may have an influence on the initiation of labour. These data are correlated with the recent identification of the EP3 receptor as the *in vivo* mediator of the castor oil effects on the motility of the uterus and the intestine [3].

No carcinogenicity data are available [1,4].

Contraindications, special warnings and precautions for use

Castor oil is contraindicated in patients with known hypersensitivity to castor oil, intestinal obstruction and stenosis, atony, appendicitis, inflammatory colon diseases (e.g. Crohn's disease, ulcerative colitis), abdominal pain of unknown origin, severe dehydration state with water and electrolyte depletion [1,4].

According to the WHO monograph [5], the use of high doses of castor oil during pregnancy and lactation is contraindicated.

Interactions

Hypokalaemia (resulting from long-term laxative abuse) potentiates the action of cardiac glycosides and interacts with antiarrhythmic medicinal products.

Concomitant use with diuretics, adrenal corticosteroids and liquorice root may enhance loss of potassium.

Concomitant use of antihistamines may reduce the laxative action of castor oil [1,4].

Adverse reactions

Side effects have been reported with castor oil. These include nausea, vomiting abdominal pain and severe diarrhoea [1,4].

4.2.2 Indirect risks

Masking effect and delayed diagnosis

The prolonged use of laxatives can delay the diagnosis or mask the effects of other conditions; restriction of the duration of use can mitigate this risk.

Misunderstanding of posology

The posology should be clear in the package leaflet to avoid misunderstanding.

Intentional overdose, misuse and dependence

Laxative medicines can be used incorrectly (misuse), for example to aid weight loss or in people with eating disorders, which can result in long-term use. Restriction of the duration of use to 1 week can mitigate this risk. It is also important to promote literacy regarding the use of laxative medicines to mitigate the risk.

Tolerance

The prolonged use of laxatives can lead to tolerance. This risk should therefore be considered for castor oil, even if no specific data on the tolerance to castor oil are available. However, this risk can be mitigated by restricting use to 1 week.

Antimicrobial resistance

Not applicable.

4.3 Strength, posology and treatment duration

Strength

According to marketed medicinal product data, the strengths available are: capsule, 1000 mg, 500 mg; oral liquid 100%.

Posology

Adults and the elderly

Daily dose: 2-5 g (2.1-5.3 mL) as a single dose. Normally it is sufficient to take this medicine up to two to three times a week. The use in children and adolescents under 18 years of age is not recommended.

Duration of treatment

One week without medical supervision. If the symptoms persist during the use of the medicinal product, a doctor or pharmacist should be consulted [1,4].

4.4 Special populations (paediatric, elderly, hepatic and renal impairment, pregnancy and breast-feeding, others)

The use of castor oil in children and adolescents under 18 years of age is not recommended due to a lack of adequate efficacy and safety data.

Use during pregnancy is contraindicated because castor oil can affect labour.

Use during lactation is contraindicated because it may pass into breast milk.

No fertility data are available [1,4].

Risk mitigation measures: see section 4.5.

4.5 Risk mitigation measures

Table 4 - Identified risk and mitigation measures

Identified risk(s)	Mitigation measures
Masking effect, delayed diagnosis and tolerance	Package size for 1 week Duration of treatment: 1 week
Pregnancy and lactation	Contraindication in pregnancy and lactation should be stated in the package leaflet.
Children	The use of castor oil in children is not recommended; therefore, this information should be in the package leaflet.

4.6 Post-marketing data

The use of castor oil (virgin and refined) is documented in several medicinal handbooks throughout a period of at least 30 years, including at least 15 years within the EU.

4.7 Public health/Socioeconomic impact

The classification as non-prescription is in line with the classification of other laxative medicines and no specific risks regarding castor oil use impacting public health have been identified.

Conclusion of Second level assessment

The assessment of this level allows the decision that the active substance, under described conditions, could have **non-prescription status**.

RECOMMENDATIONS FOR LEGAL CLASSIFICATION

Non-prescription status.

Under the conditions described in this document, the active substance has non-prescription status.

REFERENCES

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