

Draft Legislation

of the Federal Ministry of Health

Twenty-Fifth Ordinance amending the Annexes to the Narcotic Drugs Act [Betäubungsmittelgesetz]

A. Problem and objective

Three new psychoactive substances (NPS) which are associated with severe intoxication and deaths in misuse for intoxication purposes in Germany have been detected on the drug market: etomethazene, fluoro-etonitazene and fluoro-etonitazepyne.

The objective is to prevent these hazardous substances from spreading further.

B. Solution

The three substances are being added to Annex II to the Narcotic Drugs Act (BtMG) on the basis of § 1(2) BtMG.

This Ordinance is adding these three new psychoactive substances (NPS) to Annex II BtMG in order to protect the health of individuals and the population. This is intended to curtail the spread and abuse of these harmful NPS and facilitate criminal prosecution.

C. Alternatives

None.

D. Budgetary expenditure without compliance costs

Any additional material or staffing requirements at federal level resulting from the amendment to Annex II of the BtMG are to be offset financially and in terms of positions in the respective section of the budget.

E. Compliance costs

E.1 Compliance costs for citizens

There are no additional compliance costs for citizens.

E.2 Compliance costs for businesses

There are no additional compliance costs for businesses.

E.3 Administrative compliance costs

Additional administrative compliance costs are only minimal. No significant budgetary expenditure for the federal government is to be expected as a result of the Draft Regulation.

F. Additional costs

None.

Draft legislation of the Federal Ministry of Health

Twenty-Fifth Ordinance amending the Annexes to the Narcotic Drugs Act [Betäubungsmittelgesetz]*

Dated ...

On the basis of § 1(2) of the Narcotic Drugs Act [Betäubungsmittelgesetz] in the version as promulgated on 1 March 1994 (Federal Law Gazette I p. 358) after consultation with experts:

Artikel 1

In Annex II of the Narcotic Drugs Act in the version published on 1 March 1994 (Federal Law Gazette I p. 358), last amended by Article 1 of the Ordinance of 29 November 2024 (Federal Law Gazette 2024 I No 379), the following heading are inserted into the existing list in alphabetical order:

INN	Other non-proprietary or common names	Chemical names (IUPAC)
—	etomethazene (5-methyl metodesnitazene)	<i>N,N</i> -Diethyl-2-{2-[(4-ethoxyphenyl)methyl]-5-methyl-1 <i>H</i> -benzimidazole-1-yl}ethan-1-amine
—	Fluoro-etonitazene (fluetonitazene, F-etonitazene, F-eto, 2F-eto, 2F-etonitazene)	<i>N,N</i> -Diethyl-2-(2-{[4-(2-fluoroethoxy)phenyl]methyl}-5-nitro-1 <i>H</i> -benzimidazol-1-yl)ethan-1-amine
—	Fluoro-etonitazepyne (fluetonitazepyne, F-etonitazepyne, N-pyrrolidine-fluetonitazene)	2-{[4-(2-Fluoroethoxy)phenyl]methyl}-5-nitro-1-[2-(pyrrolidine-1-yl)ethyl]-1 <i>H</i> -benzimidazole'.

Artikel 2

This Ordinance shall enter into force on the day following its promulgation.

Approved by the Bundesrat.

* Notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241 of 17 September 2015, p. 1).

Justification

A. General part

I. Objective of and need for the provisions

Due to the extent of misuse and the immediate health threat to consumers, on the basis of the authorisation in § 1(2) BtMG Etomethazene, Fluoro-Etonitazene and Fluoro-Etonitazepyne are included in Annex II to the Narcotic Drugs Act (BtMG).

The Experts' Committee pursuant to § 1(2) BtMG was consulted and has endorsed the amendments to the Annex to the BtMG contained in this Ordinance for that reason.

II. Main content of the draft

Article 1 adds three NPS – etomethazene, fluoro-etonitazene and fluoro-etonitazepyne – to Annex II to the BtMG.

III. Alternatives

None.

IV. Regulatory power

The Federal Ministry of Health's power to enact legislation follows from § 1(2) BtMG [Narcotic Drugs Act].

V. Compatibility with European Union law and international treaties

This Ordinance is compatible with European Union law and with international treaties concluded by the Federal Republic of Germany. The changes in Articles 1 were notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241 of 17.9.2015, p. 1).

VI. Impact of the Ordinance

The inclusion of these three NPS in Annex II to the BtMG [Narcotic Drugs Act] results in these substances being treated as marketable but non-prescribable narcotics, as defined by the provisions of the BtMG.

1. Legal and administrative simplification

The Ordinance does not involve the repealing of any provisions or streamlining any administrative procedures.

2. Sustainability aspects

The Regulation takes into account the objectives and principles of the German Sustainable Development Strategy (DNS). In particular, it serves sustainability objective 3 'Ensure a healthy life for all people of all ages and promote their well-being' by limiting the spread and misuse of the NPSs that are hazardous to health and covered by Annex II to the BtMG by updating the substances listed in said Annex. The proposed regulations thus serve to protect the health of individuals and the general public as a whole and thus comply with the guiding principle 3b of the DNS, 'Avoid dangers and unacceptable risks to human health'.

3. Budgetary expenditure exclusive of compliance costs

Any additional material or staffing requirements at federal level are to be offset financially and in terms of positions in the respective section of the budget.

4. Compliance costs

There are no additional compliance costs for citizens.

There are no additional compliance costs for businesses.

For the authorities at federal level, the extended monitoring of narcotics traffic due to the inclusion of further NPS in Annex II of the BtMG will result in a small additional enforcement effort for criminal prosecution by the customs authorities and the Federal Criminal Police Office. The number of checks is the same. For the monitoring and police authorities at state level, the above-mentioned extension to NPS monitoring may result in increased but currently non-quantifiable enforcement costs. Here too, the additional burden is assumed to be very low in individual cases.

5. Other costs

None.

6. Further consequences of the legislation

This Ordinance has no impact on demographic or equal opportunities policies.

VII. Time limit; evaluation

The Ordinance is not intended to have a time limit. The Annexes to the BtMG are subject to ongoing reviews based on the experience gained with their enforcement as well as on the basis of new scientific findings.

B. Specific part

Re Article 1

Annex II BtMG (marketable but non-prescribable narcotics) is supplemented by the addition of three NPS. Etomethazene, fluoro-etomidazone and fluoro-etomidazopyne are three synthetic opioids reported for the first time via the European Early Warning System in 2023 and 2024, respectively. The effects of these three compounds are considered to be comparable to fentanyl and other opioids.

Etomethazene, fluorine-etomidazene and fluorine-etomidazepyne are associated with severe intoxication and deaths in misuse as intoxicants in several federal states and neighbouring European countries.

Through the European early warning system, fluoro-etomidazene first reported in Germany, fluoro-etomidazepyne in four (IT, DE, AT, SI) and etomethazene in eight European countries (SE, FI, SI, DK, EE, DE, PL, FR) for the first time.

Etomethazene, fluoro-etomidazene and fluoro-etomidazepyne have significant chemical-structural similarities with the synthetic opioids etomidazene, etomidazepyne and etazene, which are already listed in the annexes to the BtMG. According to current assessments, the substances are very potent active substances. Due to the molecular structure, it must be assumed that they are highly potent synthetic opioids with an analgesic potency likely to significantly exceed that of morphine. The high potency of new synthetic opioids is associated with an increased risk of overdose and death. There is sufficient evidence that etomethazene, fluoro-etomidazene and fluoro-etomidazepyne are misused and that these substances pose a public health problem. The substances are marketed from Germany through such channels as online shops on the Internet and are easily available. The lack of legal control to date can contribute to a misperception of the hazardous nature of these substances among consumers, so protecting the health of the population is seen as an urgent need for action.

Use of these substances for medicinal purposes, particularly as a finished medicinal product, has not yet been reported for Germany. Therefore, inclusion in Annex III to the BtMG (marketable and prescription narcotic drug) is not necessary.

The use of these substances in scientific research or as reference substances for analysis cannot be ruled out. The inclusion of these substances in Annex II to the BtMG (marketable but non-prescription narcotic drugs) is therefore required. The inclusion in Annex II to the BtMG allows legal trade in these substances for research and industrial purposes subject to authorisation. Furthermore, the comprehensive licence requirement enables uses incompatible with the objectives of the BtMG to be prevented effectively.

Re Article 2

This article governs the Ordinance's entry into force. Since the spread and misuse of this hazardous NPS should be curtailed as quickly as possible in order to protect the health of the individual and the population, the Ordinance should enter into force on the day following its promulgation.