Order Amending Schedule IV to the Controlled Drugs and Substances Act (Carisoprodol): SOR/2025-221

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CONTROLLED DRUGS AND SUBSTANCES ACT

P.C. 2025-745 October 30, 2025

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, considering that it is necessary in the public interest, makes the annexed *Order Amending Schedule IV to the Controlled Drugs and Substances Act (Carisoprodol)* under section 60 [a] of the *Controlled Drugs and Substances Act* [b].

Order Amending Schedule IV to the Controlled Drugs and Substances Act (Carisoprodol)

Amendment

1 Schedule IV to the *Controlled Drugs and Substances Act* [b] is amended by adding the following after item 27:

28 Carisoprodol (2-((carbamoyloxy)methyl)-2methylpentyl isopropylcarbamate)

Coming into Force

2 This Order comes into force on the 30th day after the day on which it is published in the *Canada Gazette*, Part II.

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Order or the Regulations*.)

Issues

On February 28, 2025, the then-Minister of Mental Health and Addictions and Associate Minister of Health issued a ministerial order under the *Controlled Drugs and Substances Act* (CDSA) to temporarily control the sedative drug carisoprodol, recognizing the significant risk it could pose to public health and safety. Subsequently, on March 12, 2025, the United Nations (UN) Commission on Narcotic Drugs voted in favour of scheduling carisoprodol under the *Convention on Psychotropic Substances, 1971)*, one of three international drug conventions to which Canada is a party. Because the *Order Amending Schedule V to the Controlled Drugs and Substances Act (Fentanyl Precursors and Carisoprodol)* [the Ministerial Order] is set to expire on April 13, 2026, Canada must take steps to schedule carisoprodol on a longer-term basis under the CDSA for controls to continue. These controls are needed for Canada to continue to meet its international obligations as a party to the UN's drug conventions after the Ministerial Order expires.

Without these controls in place, border and law enforcement would have fewer tools available to them to prevent the drug's illegal importation, distribution, and use.

Background

Carisoprodol is a sedative drug used in some countries as a muscle relaxant indicated for the relief of acute, painful musculoskeletal conditions. It produces effects similar to central nervous system depressants, such as benzodiazepines. In October 2024, the World Health Organization (WHO) Expert Committee on Drug Dependence published a Critical review report on carisoprodol (PDF), in which it summarized evidence of the drug's misuse and diversion to illegal drug markets in a number of countries around the world. Based on the findings of the report, the Director General of the WHO recommended to the UN Commission on Narcotic Drugs that carisoprodol be considered for international control under the UN's drug control conventions.

Health Canada also conducted a scientific assessment of carisoprodol. At the time of the assessment, based on available information, no known medical, commercial, or industrial uses of carisoprodol were identified in Canada. There was also little evidence of its non-medical use in Canada and, between 2021 and early 2025, carisoprodol had not been identified in seized samples from Canadian law enforcement agencies or the Canada Border Services Agency. While carisoprodol is sold as a prescription drug in the United States and in several other countries, it is not currently authorized for sale in Canada.

Recognizing carisoprodol's significant potential for diversion and misuse, the then-Minister of Mental Health and Addictions and Associate Minister of Health made a temporary Ministerial Order under paragraph 60.1(1)(a)

of the CDSA to schedule carisoprodol for a period of one year to protect public health and safety. The Ministerial Order adding carisoprodol to Schedule V of the CDSA — the temporary accelerated scheduling pathway — came into force on April 14, 2025. The Ministerial Order temporarily prohibited the importation, exportation, production, trafficking, and possession for the purposes of trafficking of carisoprodol, and allowed law and border enforcement officials to take action against its illegal use. A second Ministerial Order was also made to add carisoprodol to Part III of the schedule to Part J of the *Food and Drug Regulations* (FDR) to facilitate research and clinical testing with the drug while it was temporarily controlled. Since the Ministerial Order to temporarily control carisoprodol was made, the Canada Border Services Agency has intercepted illegal shipments of carisoprodol at the border.

Following carisoprodol's temporary control, Health Canada learned that only a small number of stakeholders are conducting activities with carisoprodol in Canada. These activities include using carisoprodol as a reference standard for drug analysis or for scientific studies, destruction, or selling to compounding pharmacies. These stakeholders, all of whom already hold controlled substance licences, have since applied to Health Canada for authorization to conduct these activities with carisoprodol while it is temporarily controlled. Health Canada subsequently authorized these applicants to conduct limited activities with carisoprodol by amending their licences to list the drug. Should carisoprodol be controlled on a longer-term basis under the CDSA, these licence holders do not need additional licence amendments to continue conducting these activities with carisoprodol.

On March 12, 2025, the United Nations Commission on Narcotic Drugs voted to place the drug under international control by adding it to Schedule IV of the *Convention on Psychotropic Substances, 1971*. Parties to the Convention, including Canada, are expected to control carisoprodol

domestically to realize their obligations under the convention. For Canada's controls on carisoprodol to continue after the expiry of the Ministerial Order on April 13, 2026, the Ministerial Order must be renewed for another year, or the drug must be moved from Schedule V to another schedule of the CDSA.

Because carisoprodol is structurally similar and has a similar mechanism of action to meprobamate, a substance currently controlled under Schedule IV to the CDSA, it is recommended that carisoprodol be controlled on a long-term basis by listing it on Schedule IV. Substances listed on Schedule IV of the CDSA may have therapeutic uses, but also the potential for misuse or diversion. Any unauthorized activities with substances listed on Schedule IV, such as import or export, sale, production, and trafficking, are prohibited and subject to criminal penalties. Possession of a substance on Schedule IV is not prohibited. When a substance is scheduled under Schedule IV of the CDSA, it is simultaneously scheduled under the CDSA's regulations to permit certain legitimate uses.

It is recommended that carisoprodol also be added to the schedules to the *Benzodiazepines and Other Targeted Substances Regulations* (BOTSR), similar to how meprobamate is scheduled. The BOTSR describe the circumstances and requirements in which persons, producers, distributors, importers, exporters, pharmacists, practitioners and hospitals may conduct regulated activities, including possession, sale, distribution, importation and exportation, and production, with benzodiazepines and other targeted substances.

Objective

The objective of the *Order Amending Schedule IV to the Controlled Drugs and Substances Act (Carisoprodol)* and the *Regulations Amending the Benzodiazepines and Other Targeted Substances Regulations (Carisoprodol)* [the amendments] is to protect public health and safety by strictly controlling activities with carisoprodol on a longer-term basis under the CDSA. Controlling carisoprodol as a controlled substance and targeted substance under the CDSA and BOTSR, respectively, provides strict federal oversight of legitimate activities with carisoprodol. It also allows law and border enforcement to continue to take action, following the expiry of the temporary Ministerial Order, against any illegal importation, distribution, and use of this substance.

Description

To ensure that carisoprodol remains controlled under the CDSA on a long-term basis, the Government of Canada is adding carisoprodol to Schedule IV of the CDSA and to the Schedules to the BOTSR. With these amendments, any person not authorized to conduct regulated activities with carisoprodol will be subject to the offences and penalties set out in the CDSA.

Regulatory development

Consultation

In advance of the temporary scheduling of carisoprodol, Health Canada published a Notice of Intent (NOI) to inform the public and Canadian industry of the proposal to temporarily control the substance. Targeted emails were also sent to key stakeholders who might be impacted, including controlled substance licence holders, precursor licence and

registration holders, and drug establishment licence holders. Health Canada also held a technical briefing on the proposal that was attended by industry representatives. In response to this consultation, Health Canada heard from one company which manufactures and sells carisoprodol in Canada who indicated that controls on carisoprodol could impact turnaround times to process orders.

When the Ministerial Order was made on February 28, 2025, the Regulatory Impact Analysis Statement that was published in the *Canada Gazette*, Part II, indicated that Health Canada planned to advance a regulatory package for carisoprodol's longer-term control. Further, after the Ministerial Order was issued, Health Canada published a notice of consultation to solicit feedback on the removal of carisoprodol from the Prescription Drug List. No feedback was received in response to these actions. Carisoprodol was removed from the Prescription Drug List on April 14, 2025.

Indigenous engagement, consultation and modern treaty obligations

Health Canada examined the geographical scope and subject matter of the initiative in relation to modern treaties in effect and did not identify any potential modern treaty implications.

Instrument choice

Controlling carisoprodol on a longer-term basis under the CDSA provides law enforcement with the authority to continue to take action in relation to activities with the drug that contravene the CDSA. Without these amendments, the Ministerial Order would expire and there would be a lapse in control of carisoprodol, and law and border enforcement would have fewer tools to take action to halt the illegal importation, distribution, and use of this potentially harmful substance. Controlling carisoprodol under the CDSA is also the only means by which Canada can realize its

obligations to control the drug domestically as a party to the UN *Convention on Psychotropic Substances, 1971*. As a result, controlling carisoprodol on a longer-term basis under the CDSA is the recommended option.

Regulatory analysis

Benefits and costs

Baseline scenario

Carisoprodol is temporarily controlled under the CDSA through a Ministerial Order that expires on April 13, 2026. Under the Ministerial Order, any activities involving carisoprodol, such as possession, production, sale or provision, distribution, importation/exportation, transportation or research, require authorization from Health Canada. During the period in which the Ministerial Order has been in force, fewer than 15 licence holders submitted applications to amend their existing licences, no new licence application specifically for carisoprodol was submitted, and only one company applied for importation permits. Going forward, once the Ministerial Order expires, authorization under the CDSA would no longer be needed to conduct these activities, as carisoprodol would no longer be controlled under the CDSA. As a result, any entities that did not obtain or amend licences during the period in which the Order was in effect could conduct activities with carisoprodol without violating the CDSA.

Regulatory scenario

Under the regulatory scenario, carisoprodol will be controlled on a long-term basis under the CDSA and regulated under the BOTSR. Authorization under the CDSA will be required for any activities involving carisoprodol. Authorizations needed may include obtaining a licence, amending an existing licence to include carisoprodol, securing an import/export permit, or applying for a subsection 56(1) exemption. Licensed dealers that

amended their licences under the baseline scenario will not be affected by the long-term control of carisoprodol. It is also anticipated that no entity will apply for a new licence solely for the purpose of conducting activities with carisoprodol.

Benefits

The amendments will allow Canada to continue to meet its international obligations under the UN *Convention on Psychotropic Substances, 1971*. The amendments will also ensure strict federal oversight of legitimate activities with the drug. It also serves as a precautionary measure to prevent carisoprodol from being diverted to illicit markets and use, thereby protecting public health and safety.

Costs

Licensed dealers

Costs associated with licence amendments

Based on Health Canada's scientific assessment and because only one company responded during the consultation period to indicate that it conducts activities with carisoprodol, Health Canada anticipates that the number of businesses impacted by this amendment will not be significant. Furthermore, fewer than 15 licence holders amended their licences to include carisoprodol during the period in which the Ministerial Order was in effect. Given that entities interested in conducting activities with carisoprodol would likely have taken the opportunity to amend their existing licences during that time, and many already have, Health Canada assumes that 2 more licence holders in total over the next 10 periods of 12 months will submit licence amendment applications. Based on industry feedback, preparing and submitting an amendment application takes

approximately 30 minutes. Thus, applying an hourly wage of $41.52, [1] it will cost an affected licence holder $20.76 (in 2024 dollars) to apply for a licence amendment.

Costs associated with becoming licensed

Since impacted businesses would have already applied for a licence during the period in which the Ministerial Order was in effect to maintain business continuity, and because Health Canada's internal administrative data indicates that it is very rare for an applicant to request a licence only to conduct activities with a single substance, it is highly unlikely that new licence applications will be submitted solely for the purpose of conducting activities with carisoprodol. Nevertheless, Health Canada acknowledges that there are costs associated with submitting an application to become licensed.

The licensing application process requires a company to complete a licence application form, implement required physical security measures, and conduct criminal record checks for responsible personnel (senior person in charge, qualified person in charge, and alternate qualified person in charge). Additionally, a new licence holder will incur incremental costs associated with applying for licence renewals every three years, paying licensing fees and meeting regulatory requirements (e.g. submitting monthly reports and reporting losses or thefts). The related administrative costs can be estimated using the following:

Activities	Time	Hourly wage (2024 dollars)
Preparing form for a criminal record check	Two hours per affected person [1]	$41.52 (qualified person in charge, alternate qualified person in charge) $75.65 (senior person in charge)
Preparing and submitting licence application	Eight hours (one-time)	$41.52 (qualified person in charge, alternate qualified person in charge)
Preparing and submitting licence renewal form (every three years)	One hour	$41.52 (qualified person in charge, alternate qualified person in charge)
Preparing and submitting monthly reports	Eight hours annually	$41.52 (qualified person in charge, alternate qualified person in charge)

[1] Each licence holder will need to request a criminal record check for one senior person in charge, one qualified person in charge and two alternate qualified persons in charge.

Additional expenses include government fees for obtaining criminal record checks for the senior person in charge, qualified person in charge, and alternate qualified person in charge both during initial application and renewal. Furthermore, applicants must invest in physical security measures, which vary based on the quantity of carisoprodol stored and the location of the licensed site.

Costs associated with import/export permits applications

With the amendments, licence holders will need to obtain a permit before importing or exporting carisoprodol. During the period in which the Ministerial Order was in effect, less than 5 import/export permit applications were received by Health Canada. Drawing on feedback received during the consultation period and internal administrative data, Health Canada assumes that it will receive, from medium or large companies, around 20 import permit and 2 export permit applications over the next 10 periods of 12 months. Industry response to a previous survey indicates it takes approximately 30 minutes for a company to prepare and submit a permit application. It is estimated that it will cost an affected licence holder $20.76 (in 2024 dollars) to apply for such a permit using an hourly wage of $41.52.

Researchers and individuals

With these amendments, researchers will need to apply for an exemption under subsection 56(1) of the CDSA in order to conduct research activities with carisoprodol. Health Canada estimates that preparing and submitting the exemption application requires approximately 45 minutes at an hourly wage of $64.68. [2] It is not possible to predict how many exemption applications for research, if any, Health Canada could receive in the future. However, the cost to a researcher to submit a single application is approximately $48.51.

Individuals entering or leaving Canada will need to apply for an exemption under subsection 56(1) if carrying a drug product containing carisoprodol in excess of a 90-day supply. Health Canada estimates that it takes an individual approximately 10 minutes to send a request (e.g. an email) for an exemption. Health Canada assumes that the number of such requests from individuals, if any, will be limited. Therefore, the associated costs are expected to be minimal.

Government

Health Canada will incur costs to undertake compliance promotion and enforcement activities to ensure that only authorized activities are conducted with carisoprodol. These costs can primarily be attributed to the need to respond to any inquiries.

Health Canada will also incur costs to process new licence applications or licence amendments, import and export permits, subsection 56(1) exemption requests from researchers, and a very limited number of individual exemption requests.

Small business lens

Analysis under the small business lens concluded that these amendments will impact small businesses. Of the potentially five affected companies, three meet the definition of small businesses. The costs to impacted small businesses relate to administrative burden and are described in the "Benefits and costs" section above. These costs will be related to applying for a licence amendment or import/export permits.

Overall, the costs to these businesses will be minimal. Undertaking these administrative actions is necessary to obtain authorizations to conduct activities with carisoprodol and meet existing regulatory requirements. Therefore, providing flexibility to small businesses is not feasible.

One-for-one rule

Order Amending Schedule IV to the Controlled Drugs and Substances Act (Carisoprodol) and *Regulations Amending the Benzodiazepines and Other Targeted Substances Regulations (Carisoprodol)*

The one-for-one rule applies, since there is an incremental increase in administrative burden on business, and the amendments are considered burden IN under the one-for-one rule.

A very limited number of businesses are expected to incur administrative costs, as outlined in the "Benefits and costs" section above. Administrative costs to businesses are estimated over 10 periods of 12 months (2025 to 2034) and discounted to 2012 using a 7% real discount rate.

Health Canada anticipates that, over the next 10 years, only 2 licence amendments and 22 import/export permit applications related to carisoprodol will be submitted. Industry feedback indicates that each submission, whether for a licence amendment or an import/export permit, requires approximately 30 minutes to complete. Applying an hourly wage of $31.41 to monetize the time spent, the total costs of these activities are estimated at $115 (present value [PV]) over 10 years, or $16 in annualized value.

Order Amending Schedule V to the Controlled Drugs and Substances Act (Fentanyl Precursors and Carisoprodol)

In the Regulatory Impact Analysis Statement that accompanied the Ministerial Order that temporarily controlled carisoprodol under the CDSA, Health Canada indicated that the Order would impose an administrative burden on affected stakeholders should they need to apply for licence amendments, new licences or import/export permits. Health Canada acknowledged that the Ministerial Order was an IN under the one-for-one rule. However, an estimate of the administrative burden was not conducted at the time. Since the publication of the Ministerial Order, 10 licence amendments and 2 import permit applications were submitted to Health Canada. Using the same assumptions outlined in the previous paragraph, the total administrative costs to implicated licence holders related to these activities are estimated at $73 (PV) in 2012 dollars or $10 in annualized value.

Regulatory cooperation and alignment

Other countries, including the United States, Mexico, Sweden, and Norway, already have controls in place for carisoprodol (PDF). Since carisoprodol was recently scheduled under the UN *Convention on Psychotropic Substances, 1971*, it is expected that all countries that are parties to the Convention that have not yet controlled the drug will take steps to schedule the drug domestically.

Controlling carisoprodol on a long-term basis allows Canada to realize its international obligations and aligns with the actions taken by other countries to schedule this substance.

International obligations

Canada, as a party to the UN *Convention on Psychotropic Substances, 1971*, is expected to take action to control carisoprodol domestically. The long-term controls will ensure there is no lapse in control of carisoprodol when the Ministerial Order expires on April 13, 2026.

Effects on the environment

In accordance with the *Cabinet Directive on Strategic Environmental and Economic Assessment*, a preliminary scan concluded that a strategic environmental and economic assessment is not required. There are no anticipated effects on the environment, positive or negative, as a result of the amendments.

Gender-based analysis plus

The objective of the amendments is to control carisoprodol on a long-term basis to prevent harms to health and safety arising from the potential misuse and diversion of the substance, and to allow Canada to realize its obligations under the UN *Convention on Psychotropic Substances, 1971* to which it is a party. These amendments are not expected to impact

individuals, given that there are no approved therapeutic products containing carisoprodol on the market in Canada, and it has not been identified in the illegal drug market in Canada since 2021. As a result, the amendments will not have any disproportionate impacts on groups of people in Canada or any disproportionate impacts on subgroups of people in Canada based on sex, gender, socioeconomic status, or other gender-based analysis plus (GBA+) factors.

Implementation, compliance and enforcement, and service standards

Implementation

These amendments will come into force 30 days after their publication in the *Canada Gazette*, Part II. The delayed coming into force gives anyone wanting to conduct legitimate activities with carisoprodol time to apply to Health Canada for authorization. Health Canada will send notification emails to potentially impacted stakeholders on the date the amendments are published to ensure they are aware of the amendments and their implications.

Compliance and enforcement

Health Canada is responsible for authorizing (through licences, permits, and exemptions) legitimate activities with substances scheduled under the CDSA and its regulations and for monitoring compliance with regulatory requirements.

The Canada Border Services Agency supports compliance monitoring for controlled substances and precursors at the border. Federal, provincial and local law enforcement are responsible for taking enforcement action in response to contraventions of the CDSA and its regulations.

Contact

Office of Legislative and Regulatory Affairs
Controlled Substances and Overdose Response Directorate
Health Canada
Email: csd.regulatory.policy-politique.reglementaire.dsc@hc-sc.gc.ca

Footnotes

a S.C. 2018, c. 16, s. 206(6)

b S.C. 1996, c. 19

1 The wage is derived based on wages of four occupational groups (technical occupations in health, technical roles in natural and applied sciences, service representatives and other customer and personal service positions, as well as technical trades and transportation officers and controllers), and adjusted for overhead in 2024 dollars. These wage figures are sourced from Statistics Canada Table 14-10-0417-01, Employee wages by occupation, annual.

2 Hourly wage for professional occupations in natural and applied science, adjusted for overhead in 2024 dollars. Sourced from Statistics Canada Table 14-10-0417-01, Employee wages by occupation, annual.