Order Amending Schedule V to the Controlled Drugs and Substances Act (R 29676, Spirobrorphine and Spirochlorphine): SOR/2026-71

Canada Gazette, Part II, Volume 160, Number 9

Registration
SOR/2026-71 April 17, 2026

CONTROLLED DRUGS AND SUBSTANCES ACT

Whereas, under paragraph 60.1(1)(a) [a] of the *Controlled Drugs and Substances Act* [b], the Minister of Health has reasonable grounds to believe that the substances referred to in the annexed Order pose a significant risk to public health or safety;

Therefore, the Minister of Health makes the annexed *Order Amending Schedule V to the Controlled Drugs and Substances Act (R 29676, Spirobrorphine and Spirochlorphine)* under paragraph 60.1(1)(a) [a] of the *Controlled Drugs and Substances Act* [b].

Ottawa, April 15, 2026

Marjorie Michel
Minister of Health

Order Amending Schedule V to the Controlled Drugs and Substances Act (R 29676, Spirobrorphine and Spirochlorphine)

Amendments

1 Part 1 of Schedule V to the *Controlled Drugs and Substances Act* [b] is amended by adding the following:

Item	Column 1 Substance	Column 2 Period
1	Spirobrorphine (8-[1-(4-bromophenyl)ethyl]-1-phenyl-1,3,8-triazaspiro[4.5]decan-4-one) and its salts	June 5, 2026 to June 4, 2027
2	Spirochlorphine (8-[1-(4-chlorophenyl)ethyl]-1-phenyl-1,3,8-triazaspiro[4.5]decan-4-one) and its salts	June 5, 2026 to June 4, 2027

2 Table 1 of Part 2 of Schedule V to the Act is amended by adding the following:

Item	Column 1 Substance	Column 2 Period
1	R 29676 (5-chloro-1-(piperidin-4-yl)-1,3-dihydro-2H-benzo[d]imidazol-2-one) and its salts	June 5, 2026 to June 4, 2027

3 Table 3 of Part 2 of Schedule V to the Act is amended by adding the following:

Item	Column 1 Substance	Column 2 Period
1	Any preparation or mixture that contains R 29676 (5-chloro-1-(piperidin-4-yl)-1,3-dihydro-2H-benzo[d]imidazol-2-one) or its salts	June 5, 2026 to June 4, 2027

Coming into Force

4 This Order comes into force on June 5, 2026.

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the orders*.)

Issues

A dangerous and unpredictable illegal drug supply made up of powerful synthetic opioids is driving drug-related deaths and harms and having devastating impacts on individuals and communities across Canada. As part of Canada's Border Plan, the Government of Canada is taking concrete action to further strengthen border security, including by increasing support to law enforcement agencies to detect, intercept, and curb the trade of illegal drugs and precursor chemicals. There is evidence that the chemical R 29676 is being imported into Canada in significant quantities for no legitimate purpose and that it can be used in the illegal production of the benzimidazole class of synthetic opioids. Spirochlorphine and spirobrorphine are synthetic opioids that pose a significant risk to public health and safety due to their potential to be misused or to be sold in the illegal market; neither drug has approved medical uses. Spirochlorphine

has been detected in both the Canadian and international illegal drug markets and has been intercepted at Canada's border. Internationally, it has contributed to both fatal and non-fatal overdoses. Spirobrorphine, which is chemically related to spirochlorphine, has been detected in international illegal drug markets, but not yet in Canada.

Background

Legislative Framework

The *Controlled Drugs and Substances Act* (CDSA) provides a legislative framework for the control of substances that can alter mental processes and may produce harm to health or society when diverted to an illegal market or misused. The CDSA sets out offences and penalties associated with prohibited activities with controlled substances (substances listed in Schedules I to IV or in Part 1 of Schedule V of the CDSA) and precursors (substances in Part 2 of Schedule V or in Schedule VI of the CDSA). Regulations made under the CDSA, such as the *Controlled Substances Regulations* (CSR) and the *Precursor Control Regulations* (PCR), authorize legitimate activities with controlled substances and precursors for medical, scientific or industrial purposes, while minimizing the risk of them being diverted to the illegal market.

Temporary scheduling of substances under the CDSA

To address the emergence of novel synthetic drugs and the precursors used to produce them, the CDSA includes a mechanism to quickly and temporarily schedule a substance of concern.

Subsection 60.1(1) of the CDSA gives the Minister of Health the authority to temporarily add a substance to Schedule V of the CDSA through a Ministerial Order, if the Minister of Health has reasonable grounds to

believe the substance:

(a) poses a significant risk to public health or safety; or

(b) may pose a risk to public health or safety; and

(i) is being imported into Canada with no legitimate purpose; or

(ii) is being distributed in Canada with no legitimate purpose.

Once a substance is added to Schedule V of the CDSA, its importation, exportation, possession for the purposes of exportation, production, and trafficking (including sale), are all prohibited. Anyone seeking to import and conduct otherwise prohibited activities with a substance listed on Schedule V requires appropriate authorizations from Health Canada. Anyone who fails to comply with the law would be subject to the offences and penalties set out in the CDSA.

For temporarily scheduled controlled substances listed in Part 1 of Schedule V to the CDSA, the Minister of Health can, by order, also add those substances to Part III of the Schedule to Part J of the *Food and Drug Regulations* (FDR). On October 1, 2026, the CSR will come into force and Part J of the FDR will be repealed. Temporarily scheduled controlled substances will instead be listed in Part 3 of Schedule 4 to the CSR. Persons wishing to conduct activities with temporarily scheduled controlled substances require a controlled substance licence or other authorization.

Bill C-12, the *Strengthening Canada's Immigration System and Borders Act*, received Royal Assent on March 26th, 2026. Part 2 of the Bill amended the temporary accelerated scheduling pathway in the CDSA to allow the Minister of Health to regulate chemicals listed in Schedule V of the CDSA as precursors. Precursors listed in Part 2, Table 1 of Schedule V are regulated as Class A precursors under the PCR, whereas precursors listed in Part 1, Table 2 of Schedule V are regulated as Class B precursors. Class A

precursors are essential ingredients used in the production of controlled substances, while Class B precursors are common reagents such as solvents, acids, and bases.

Canada's Illegal Drug Market Continues to Evolve

Synthetic opioids, particularly fentanyl and its analogues, remain the main driver of overdose deaths and harms in Canada. Recently, novel synthetic opioids such as nitazenes have also been detected in Canada's illegal drug supply. Newly detected synthetic opioids are often as strong as or stronger than fentanyl, thus increasing the risks of overdose deaths and harms. Health Canada uses a number of different tools to track and report on the type of drugs being found in the illegal drug supply, including its National Wastewater Drug Surveillance initiative and data reported by its Drug Analysis Service. Three new emerging substances of concern – one precursor used to produce synthetic opioids and two synthetic opioids – are the focus of this scheduling action.

R 29676

R 29676 (Chemical Abstracts Service Registry Number: 53786-28-0) is a chemical that can be used to directly synthesize fifteen benzimidazole opioids that are controlled under the CDSA. Tested opioid assays evaluated some of these fifteen substances to be more potent than morphine. Between March 2025 and November 2025, the Canada Border Services Agency (CBSA) intercepted four mislabelled shipments of a significant quantity of R 29676 at the border, suggesting that organized crime groups may have imported this chemical with the intent to start illegally producing one or more of these fifteen novel synthetic opioids. So far, none of these fifteen synthetic opioids have been encountered in intercepted or seized samples.

R 29676 can be used to produce domperidone, a marketed prescription drug that is indicated for the symptomatic treatment of upper gastrointestinal motility disorders and may be used for the prevention of gastrointestinal symptoms associated with certain antiparkinsonian medications. Domperidone is also used off label to increase the production of breast milk.

Spirochlorphine and Spirobrorphine

Spirochlorphine (Chemical Abstracts Service Registry Number: 3222-88-6) is a synthetic opioid that has recently emerged in international illegal drug markets (the United States and Europe) and has also been detected in the illegal drug market in Canada.

Between December 2024 and April 2025, three instances of spirochlorphine were noted in Canada. Health Canada's Drug Analysis Service (DAS) identified spirochlorphine in two separate samples provided by law enforcement. The CBSA intercepted one sample where spirochlorphine was found with a nitazene in small quantities. While spirochlorphine has not yet been reported in overdoses in Canada, it has been identified in at least two fatal overdoses and one non-fatal overdose where it was detected with nitazenes in Europe. It has also been detected in twenty post-mortem cases in the United States.

Spirobrorphine (Chemical Abstracts Service Registry Number: n/a) is a synthetic opioid with a similar chemical structure to spirochlorphine. Spirobrorphine has not yet been detected in the illegal drug market in Canada.

Spirochlorphine and spirobrorphine have no known legitimate uses. However, both spirochlorphine and spirobrorphine have been discussed in online forums, where they were described as having euphoric and sedative

effects. Common routes of administration included smoking and vaping. Based on available data, both spirochlorphine and spirobrorphine may present risks that are similar to those of other known opioids, such as: respiratory depression, sedation, nausea, vomiting, itching, dizziness, mood swings, and coordination disorders.

Objective

The objective of this scheduling action is to temporarily control R 29676, spirochlorphine and spirobrorphine and their salts, for a period of one year, to prevent harms to public health and safety arising from the potential importation and trafficking of these substances. This action gives the CBSA and law enforcement additional tools to take action against any illegal importation, distribution, and use of these three substances.

Description

Pursuant to the Minister of Health's authority under paragraph 60.1(1)(a) of the CDSA, a substance may be temporarily added to Schedule V for a period of up to one year, with the possibility of extending the scheduling for an additional year. Due to their potential to be used in illegal drug production (R 29676) or sold on the illegal market (spirochlorphine and spirobrorphine), the Minister has reasonable grounds to believe R 29676, spirochlorphine and spirobrorphine pose a significant risk to public health and public safety.

Three Ministerial Orders have been made by the Minister of Health to prevent illegal activities involving these substances, while also providing a regulatory pathway through which persons can be authorized to legally conduct activities with these substances for legitimate purposes.

- The first Order adds spirochlorphine and spirobrorphine and its salts to Part 1 of Schedule V of the CDSA (Controlled Substances) and adds R 29676 and its salts to Table 1, Part 2 of Schedule V of the CDSA (Class A Precursors). Listing R 29676 in Part 2, Table 1 of Schedule V allows this chemical to be regulated as a Class A precursor under the PCR during the period of temporary control (up to 1 year).
- The second Order adds spirochlorphine and spirobrorphine and its salts to Part J of the FDR and, when Part J is repealed on October 1, 2026, to the CSR. This ensures that both opioids can be regulated as restricted drugs during the period of temporary control (up to 1 year).
- The third Order adds R 29676 and its salts to the Schedule of the PCR with a maximum quantity of 0 during the period of temporary control (up to 1 year).

Organizations and individuals seeking to conduct activities with R 29676 for legitimate purposes during the period of temporary control will require a Class A precursor licence, whereas those seeking to conduct activities with spirobrorphine and spirochlorphine will require a controlled substances licence. Licences are available through an application process with Health Canada.

Regulatory development

Consultation

A targeted stakeholder survey was used to gather input on the proposed temporary scheduling of R 29676, spirochlorphine, and spirobrorphine. This outreach sought to determine whether these substances were being used

for legitimate purposes in Canada, and to identify any potential impacts associated with their control. Over the 10-day consultation period, 94 responses were received, representing 86 unique stakeholders.

Survey findings

Respondents reported that R 29676 is used exclusively as an impurity reference standard in Canada, with annual import quantities well below one gram. One stakeholder indicated that the substance is used for impurity testing of domperidone drug products. No additional commercial applications were identified.

Most respondents indicated that spirochlorphine and spirobrorphine are not being used for commercial or research purposes in Canada, other than as reference standards. One respondent reported synthesizing reference standards containing these substances domestically in small quantities; however, no broader ongoing or planned uses were identified.

Stakeholders generally anticipated that any impacts associated with the temporary scheduling would be limited in scope. Feedback focused primarily on administrative considerations, such as the need to obtain import or export permits for small quantities of analytical standards, rather than on financial or operational impacts. Forensic laboratories indicated that continued access to reference standards would be required to support analytical activities.

Overall, the feedback received suggests that the temporary scheduling of R 29676, spirobrorphine, and spirochlorphine is not expected to adversely impact legitimate industry activities. Any impacts identified were characterized as low in magnitude and largely administrative in nature.

Indigenous engagement, consultation and modern treaty obligations

As required by the Cabinet Directive on the Federal Approach to Modern Treaty Implementation, an assessment of modern treaty implications was conducted on the proposal. The assessment did not identify any modern treaty implications or obligations.

Instrument choice

Controlling these substances by adding them to Schedule V provides the CBSA and law enforcement with the authority to take legal action in relation to activities with R 29676, spirochlorphine and spirobrorphine that contravene the CDSA.

Health Canada considered whether these substances should be scheduled using the Governor in Council's authority to schedule substances under the CDSA following the standard regulatory development process. It was determined that, given the significant risk these substances pose to public health and safety, the accelerated scheduling pathway provided for under subsection 60.1(1) of the CDSA was the most appropriate mechanism for the Minister to use in the short term, as it allowed for rapid action to be taken to control these substances and for additional time to gather information to inform possible longer-term scheduling.

Regulatory analysis

Benefits and costs

Baseline scenario

The three substances – R 29676, spirochlorphine and spirobrorphine (and their salts) – are not controlled under the CDSA. Any activities (e.g., production, importation/exportation, or sale/provision) involving them can be carried out without the need for an authorization under the CDSA.

Regulatory scenario

R 29676

The precursor R 29676 is temporarily controlled under the CDSA for one year and regulated under the PCR as a Class A precursor. During this period, entities who conduct regulated activities such as producing, selling or providing, exporting or importing will need a Class A precursor licence. Licence holders must meet all PCR obligations for Class A precursors, including obtaining import/export permits and complying with reporting requirements. Researchers who obtain R 29676 must submit a signed and dated end-use declaration when ordering the substance from a licensed company.

Spirochlorphine and spirobrorphine

The two synthetic opioids, spirochlorphine and spirobrorphine, are temporarily controlled under the CDSA for a period of one year and regulated as restricted drugs. Entities seeking to conduct regulated activities such as production, importation, or sale/provision must hold a controlled substances licence. Researchers wishing to use these substances should apply using the Application form for an exemption to use a controlled substance for scientific purposes. Entities must meet the applicable or specified requirements, including record-keeping, reporting, and obtaining permits before importing or exporting these substances.

Benefits

The temporary control of the three substances will help reduce the negative public health and public safety outcomes associated with illegal synthetic opioid production and trafficking. By adding the three substances to Schedule V to the CDSA, the CBSA and law enforcement will be able to take action to prevent R 29676, spirochlorphine, and spirobrorphine from entering the illegal drug market. In addition, adding spirochlorphine and spirobrorphine to the schedule to Part J of the FDR (and the CSR when it

comes into force) and regulating R 29676 as a Class A precursor under the PCR enable potential research activities and other legitimate activities while maintaining strict controls. Further, the temporary scheduling of these substances provides Health Canada with the opportunity to collect additional information to inform decisions on longer-term control.

Costs

The temporary scheduling of R 29676, spirochlorphine, and spirobrorphine is expected to have minor impacts on industry. Researchers could be affected if they conduct activities with any of the three substances, though associated costs are expected to be minor. A small number of government organizations will also be impacted. Overall costs across all affected entities are expected to be limited.

Costs to industry

Results from the industry survey conducted by Health Canada indicate that two companies are expected to be affected by the temporary control. One company, an existing controlled substance and PCR Class A precursor licence holder, is currently engaged in activities involving all three substances. To comply with the temporary control of the three substances, this company will incur costs associated with amending its controlled substance and Class A precursor licences.

The other company, which is conducting activities with R 29676 only, will face costs related to completing an initial PCR Class A precursor licence application, obtaining criminal record checks for responsible personnel (senior person in charge, responsible person in charge, and alternate responsible person in charge) as part of the initial licence application, and implementing necessary physical security measures.

Both companies will also incur costs for obtaining permits prior to importing or exporting these substances, as well as for meeting record-keeping and reporting obligations.

Based on previous feedback from industry, the following assumptions are used to estimate the associated administrative costs, using an hourly wage of $43.63 (alternate/responsible person in charge) [1] and $75.14 (senior person in charge) [2] in 2025 Canadian dollars:

- Preparing and submitting a licence amendment - approximately half an hour;
- Preparing and submitting a PCR Class A precursor licence application - approximately four hours;
- Preparing criminal record check applications for PCR licence applicants (four employees: three responsible people in charge and one senior person in charge) – approximately two hours per employee;
- Applying for import and export permits – approximately half an hour per permit; and
- Undertaking record-keeping and reporting activities - approximately one hour annually.

In addition to the above administrative costs, the affected company that does not currently hold a PCR licence will also incur a cost of $70.00 per employee (four employees total) to conduct criminal record checks.

With respect to implementing physical security measures, while Health Canada acknowledges the financial impact on the affected company, it is not possible to monetize this cost due to a lack of information on the extent of security measures that will be implemented.

Costs to researchers

Health Canada's assessment indicates that the likelihood of spirochlorphine and spirobrorphine being imported into Canada for research purposes is low. In the unlikely event that research activities associated with spirochlorphine or spirobrorphine are undertaken, entities would need to be authorized.

Health Canada estimates that preparing and submitting an application to use a controlled substance for scientific purposes would require approximately 75 minutes. Using an hourly wage of $61.35 [3] (in 2025 Canadian dollars), the administrative cost per application would be minimal. Although Health Canada does not have information to be able to estimate how frequently this activity could occur, given the limited administrative efforts per application, the overall costs for this group of stakeholders are expected to be minimal.

Researchers possessing R 29676 and not conducting any prohibited activities with this substance do not require any authorization from Health Canada; however, an end-use declaration must be signed and submitted to the licensed dealer from whom the researcher would order this precursor.

Costs to government

A small number of federal or provincial government organizations may incur costs associated with applying for licence amendments and permits before importing reference standards containing the three temporarily controlled substances. Health Canada will also incur costs to process licence and import and export permit applications. Incremental costs related to implementation and compliance and enforcement activities will be incurred by Health Canada and federal government partners. They include preparing compliance promotion materials and responding to enquiries from stakeholders. These costs are expected to be minimal.

Small business lens

Analysis under the small business lens concluded that this temporary scheduling action will not have any impacts on small businesses. Thus, the small business lens does not apply.

One-for-one rule

The one-for-one rule applies since there will be an incremental increase in administrative burden on businesses. The Ministerial Orders are considered an IN under the rule.

The affected businesses are expected to incur administrative costs as outlined in the Benefits and Costs section. The assessment of administrative impacts under the one-for-one rule was conducted for ten years (2026-2035). All values listed in this section are presented in 2012 dollars and discounted to 2012 at a rate of 7%.

The time spent by responsible employees on fulfilling administrative activities was monetized using an hourly wage of $32.34. This includes time spent applying for a licence, applying for criminal record checks (not including payment of fees), requesting a licence amendment, applying for import/export permits, and meeting record-keeping or reporting requirements. For the senior person in charge, the time spent applying for a criminal record check was monetized using an hourly wage of $55.69. Based on these estimates, the total incremental administrative burden to both affected businesses is estimated to be $256.4 in present value (PV) or $36.5 in annualized value.

Regulatory cooperation and alignment

International obligations

R 29676 is not listed under the *United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances* (1988), to which Canada is a party.

Additionally, spirochlorphine and spirobrorphine are not listed under the *Single Convention on Narcotic Drugs, 1961* or the *UN Convention on Psychotropic Substances, 1971*. In 2025, the European Commission received notice that spirochlorphine would be scheduled under domestic legislation in the Czech Republic, Hungary, Germany, Latvia, and Sweden.

Concerns relating to the illegal production, trafficking, distribution and use of illegal synthetic drugs are global. As a result, the control of substances used in the illegal production of synthetic opioids helps to address domestic and international illicit drug trafficking concerns.

Controlling these substances is in line with Canada's plan to detect and disrupt the illegal drug trade as part of Canada's Border Plan. It also aligns with Canada's commitment to strengthen the coordinated global response to the international public health and public safety challenges posed by synthetic drugs, as outlined in the Ministerial Declaration on Accelerating and Strengthening the Global Response to Synthetic Drugs.

Effects on the environment

In accordance with the *Cabinet Directive on Strategic Environmental and Economic Assessment*, a preliminary scan concluded that a strategic environment and economic assessment is not required.

Gender-based analysis plus

Canada continues to face an unprecedented toxic drug crisis affecting individuals of all walks of life regardless of sex/gender, geography or socioeconomic status. Opioid-related harms are distributed unevenly

among subgroups of affected people living in Canada based on sex/gender or other factors. For example:

- In Canada, there was a total of 53,308 apparent opioid toxicity deaths between January 2016 and June 2025. [4]
- Of all apparent opioid toxicity deaths between January 2025 and June 2025, 83% involved opioids that were non-pharmaceutical.
- Most opioid-related poisoning hospitalizations occurred among males (58%) and among individuals aged 60 years or older (27%) between January 2025 and June 2025.
- About 78% of the accidental apparent opioid toxicity deaths which occurred from January 2025 to June 2025 were in British Columbia (B.C.), Alberta, and Ontario.
- Across all genders, individuals aged between 30 to 39 years old represented the majority of deaths associated with opioids from January 2025 to June 2025.
- Indigenous people have been and continue to be disproportionately impacted by the toxic drug crisis. For example, First Nations people in B.C. died of an overdose at six times the rate of other B.C. residents in 2024 [5] and in Alberta, First Nations people died of an accidental opioid overdose at eight times the rate of other residents in 2021 and 2022. [6]

Actions to disrupt the illegal importation and use of synthetic opioids and precursors in Canada are expected to benefit groups affected by the illegal drug crisis. These benefits are expected to be experienced by all potentially impacted groups or subgroups. Although there are sex/gender differences in adverse health outcomes associated with the consumption of opioids,

there is no evidence indicating that the Orders will result in any potential for disproportionate impacts to any affected groups or subgroups based on sex/gender, socioeconomic, or any other such characteristics.

Implementation, compliance and enforcement, and service standards

Implementation

The Orders controlling R 29676, spirochlorphine and spirobrorphine come into force on June 5, 2026, and will be in effect for one year, until June 4, 2027.

Health Canada will contact all potentially impacted stakeholders by email to ensure they are aware of the Orders and their implications. This notification will also include contact information, and instructions on how to apply for or amend a controlled substance or Class A precursor licence.

Compliance and enforcement

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

The CBSA 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. Under the CDSA, a range of penalties apply to the offences associated with the substances covered by these amendments. The offences set out in the CDSA involving Schedule V substances (trafficking, possession for the purpose of trafficking, importing, exporting, possession for the purpose of exporting, production)

carry a maximum penalty of up to 10 years of imprisonment if the offence is prosecuted by indictment or of up to 18 months of imprisonment if the offence is prosecuted by summary conviction.

The criminal prohibition on possession of controlled substances under subsection 4(1) of the CDSA does not apply to substances listed in Schedule V.

Contact

For enquiries or for more information, please contact the Office of Legislative and Regulatory Affairs in Health Canada's Controlled Substances and Overdose Response Directorate at csd.regulatory.policy-politique.reglementaire.dsc@hc-sc.gc.ca.

Footnotes

a S.C. 2017, c. 7, s. 45

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. Sourced from Statistics Canada Table 14-10-0417-01, Employee wages by occupation, annual.

2 Hourly wage for management occupations, adjusted for overhead. Sourced from Statistics Canada Table 14-10-0417-01 Employee wages by occupation, annual.

3 Hourly wage for natural and applied sciences and related occupations, except management, adjusted for overhead. Sourced from Statistics Canada Table 14-10-0417-01 Employee wages by occupation, annual.

4 Opioid- and Stimulant-related Harms in Canada

5 First Nations and the Toxic Drug Poisoning Crisis in B.C. (PDF)

6 Alberta Opioid Response Surveillance Report: First Nations Peoples in Alberta (PDF)