Stakeholder Consultation on the Regulations Amending the Food and Drug Regulations (Opioids)

Reviewer Comments	Reviewer Recommendations
Reviewer 1 The attachment and proposed changes seem appropriate for what HC is suggesting Changes will not really address the issue of "misuse" or "deliberate abuse/misuse", but through this education it may perhaps minimize issues of "accidental misuse" and will increase overall awareness. The use of auxiliary labels is regulated by the provincial pharmacy regulatory authorities, and is not up to each pharmacist as implied in this document.	Define "sponsor", "authorization holder", "sale", "dispense". Clarify whether the legislation applies to services in hospitals or nursing homes. Under what conditions, if any, is the auxiliary label or patient handout to be used? E.g., when medications to be taken while the patient is on leave from the hospital (but still under the care of the hospital), unit-dose packaged opioids, when the patient is in a nursing home. The requirement for the Risk Management Plan needs to apply to older drugs already on the market and not just new drugs. Health Canada should not just restrict use but also limit product availability on the Canadian market. If need be take some duplicate drugs off the market to limit availability.
Reviewer 2 The labelling standard will be helpful and will result in tighter and more closely monitored dispensing of narcotics from emergency departments, for example. It will definitely pose some challenges to smaller hospitals who will need to change processes when dispensing narcotics directly to patients, typically from the emergency department.	Non-prescription (exempted) codeine products should *not* be exempted from the new labelling and handout standard. In most provinces the sale non-prescription codeine must involve pharmacists so this gives them an opportunity to share this important information about codeine, regardless of the dose taken.
Reviewer 3 The revisions are really community pharmacy focused as relate to the selling of narcotics which is not done from a hospital. I would hope the interpretation of the revision would not be that we have to label and provide patient information in the scenario of pass meds or repacking of meds at discharge when there will be a delay in the patient having the prescription filled at the	Clarify the interpretation of "sale". Without that clarification the term is open to interpretation that the revision does not apply to hospital practice but only applies to dispensing that is completed when there is a sale of product. Consider having the prescriber who writes prescription for the opioid provide the patient handout.

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community pharmacy. Also in consideration of this is that not every hospital has an in-house pharmacy service that could do this. I am concerned about the dispensing of opioids in rural communities from hospitals when there is not access to a community pharmacy and a small quantity is dispensed by the prescriber to the patient to get them through until when a community pharmacy is open to have a prescription filled. There is a huge potential for "drug shopping"/abuse when this is permitted. However the patients that really need the drug for pain control and don't require a hospital admission shouldn't suffer because of the actions of others.	
Reviewer 4 The patient handout could be better tailored to patients' literacy level. Also, at first read it seems a bit scary and I am not sure that is the intent of the brochure. ISMP Canada is developing an opioid handout with the aim of preventing unnecessary use/unsafe use that is geared towards patients. Maybe if there were videos targeted to patients, that would help or public announcement commercials. Many people will not read a handout that is so dense with words and so, this message might be thrown out. I like the idea of an auxiliary label that identifies the content of the container as an opioid. Many people don't know they are on an opioid to begin with.	Something along the lines of this video, Question Opioids might also help. https://www.youtube.com/playlist?list=PLvQDf5LHFSkM0I6nMFN9s2-yduDODTC2N
Reviewer 5 The proposed revision to the regulations allowing "the Minister to impose terms and conditions on opioid authorization holders" is reasonable. The intention of the proposed regulatory amendment to "better inform Canadian patients about the safe use of opioids" is reasonable; it	Clarify the situations in which the proposed amendment would apply (e.g., inpatient units, emergency departments, community pharmacies). Consider issuing the handout when the prescriber and patient are deciding whether a prescription for an opioid is in the best interests of the patient. In some instances

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implies an expectation that it will lead to better patient decisions. The background provided in the Regulatory Impact Analysis Statement does not provide sufficient evidence that using the warning sticker or the handout will have at least a good chance of helping Canadians make better decisions about the use of opioids. There may be more effective methods. As the proposed amendment is presently written, the bulk of the work will likely rest with pharmacists. The (extra) resources needed to comply with the regulation will be well spent as long as the handout and the sticker are proven effective. Perhaps the proposed timing of issuing the handout at the time of dispensing could be improved. The handout should never be construed as a substitute for other forms of education (e.g., verbal) given to the patient or better prescribing practices, or other determinants of safe opioid use. According to the Controlled Drugs and Substances Act, "sell includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration". This interpretation implies that the proposed regulatory amendment of using the opioid warning sticker and patient information handout would apply to the hospital setting (including dispensing to inpatients and dispensing by emergency departments), free-standing emergency facilities, clinics, and other similar institutions. The background information does not add that level of clarity. Health Canada is commended for holding internal focus groups with subject-matter experts to ensure the content of the handout is "free of major gaps in serious opioid warnings and precautions, is consistent with the recently updated Canadian Product Monographs for approved opioids, and is written in language that is as clear and plain as	that conversation could occur during preoperative education. (See chapter 11.2, *Provision of written patient information on pain management*, found at https://www.rcoa.ac.uk/system/files/CSQ-ARB-2012_0.pdf). Consider having the patient handout undergo usability testing by a group of patients. Consider conducting a study of the effectiveness of the warning sticker and patient handout within a year that the change in regulation comes into effect. Provide the handout in an electronic format that can be automatically printed whenever a prescription for an opioid is written or dispensed.

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possible" and for conducting patient user testing of the warning sticker. However is there evidence that the handout will result in better informed Canadians and improvements in health behaviour or health status? The Regulatory Impact Analysis Statement does not suggest that the use of the handout has undergone user testing, nor if the handout and warning sticker will be studied by Health Canada to ensure the desired effect is achieved. (Such a process would be akin to studying the efficacy of a drug in a study group, followed a study of the drug's effectiveness in a larger population.) Secondly, even though the content of the handout is factual, it does not appear balanced. This could have unintended consequences such as poor pain management in certain patient populations, which may arise from a fear of addiction, ultimately resulting in poor, prolonged healing.	
Reviewer 6 1. Terminology It is significant to ensure that there is a standardized definition of terms as these will vary by practice setting and also by stakeholder. For example terms such as: " Potency" "Drug in dosage form" "Manufacturer" Need consistent, and agreed upon definitions - a manufacturer in Canada may not be the original manufacturer but rather the whole sale distributor. As well, the terms will have different meaning if in community /hospital/compounding centre/ etc. 2. Application of the proposed regulations There needs to be consultative review of the proposed documentation and labels being suggested by national professional associations who may bring together provincial stakeholder representation so as to ensure agreed upon terminology and clarity, especially including the	Make the regulations less prescriptive. As the amendments currently stand they are too prescriptive and at times anxiety provoking to patients and consumers. The goal is to educate while managing and preventing potential for abuse. The proposed regulations are going to the extreme toward 'fear factor' rather than 'education'. That government hold national stakeholder consultation meetings engaging professional associations, IT vendors, manufacturers, clinicians, and patients/ public representation as well as regulatory colleges, for input.

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patient's voice and patient representation as well as consumer representation. There also needs to be an onus on manufacturers to ensure providing information with their medications so that the pharmacists may readily reference the content in both professional and lay terminology. The regulations cannot be too prescriptive. There needs to be a standard, and agreed upon set of content that the pharmacist may apply their knowledge, skill and judgment to individualize to the patient. For example, the labelling on the medication may scare a patient who has no intention of abusing a medication from thinking that they should not take the medication for fear of addictive potential. We cannot discourage appropriate patient adherence for pain management due to fears over potential for abuse. There are other means for managing the later through the pharmacists' follow-up and monitoring. 3. Cognitive reimbursement for pharmaceutical care plan The time spent with a patient to education, guide decision making, and monitor therapy needs to be recognized by government and reimbursed. Allow pharmacists to monitor a patient's regimen and to reimburse them accordingly. 4. IT vendors There needs to be an onus on IT vendors to incorporate standardized labelling so that the onus is on IT and manufacturers to standardize requirements by Health Canada. The pharmacy practitioners' role is to apply their knowledge, skill and judgment. 5. Warning sticker, patient handout, and risk management plan The proposed amendments to the regulations focus on:	

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- warning stickers - patient information - risk management plan This assumes drugs marketed in Canada. a) Warning sticker. There is agreement that a warning is relevant. However, the currently proposed sticker as currently worded is unlikely to pass the 'grade 6' test that is recommended for any type of consumer information. (In fact, some recommend aiming at a grade 3 level'.) The warning sticker content is concerning as while aiming to cover 'facts' these are not targeted from a consumer's point of view. There needs to be further stakeholder consultation on the warning sticker due to concerns over the type of content, extent of content, and presentation of the content. b) Patient information. To avoid 'administrative burden' on pharmacists' time so as to ensure pharmacists are applying time with patient care and not on creating patient information forms, it is recommended that the manufacturer ensure availability of patient information content through their medical information department. c) Risk management plan. It may be the case that pharmacists are dispensing medications for 'compassionate drug use' and hence, these meds are not yet marketed in Canada. As such, who is accountable for creating the RMP? Again, it is recommended the onus is on the manufacturer, and that government needs to provide a standardized template that the manufacturer would complete. 6. Indication for use A missing factor in the proposed regulations is "indication of use". It will help to monitor therapy and to guide a patient's response to therapy if 'indication of use' may be made mandatory for all prescriptions for opioids.	