Frequently Asked Questions (FAQ) Document:
Regulatory Enrolment Process (REP) for Human Drugs, Veterinary Drugs and Disinfectants

The majority of the responses to the questions included on this document can be obtained from the REP guidance document or the instructions on the REP templates. We advise sponsors to read these documents as they provide detailed information in each subject where our responses below may have limited information. We also have video tutorials on the REP templates page, which provide a good overview of the process that sponsors may use for understanding the REP. Furthermore, inquiries can be sent via email to hc.ereview.sc@canada.ca.

Acronyms

REP Regulatory Enrolment Process
RT Regulatory Transaction
PI Product Information
CO Company
DO Dossier
CESG Common Electronic Submissions Gateway
eCTD electronic Common Technical Document
ID Identifier

Questions and Responses

A. General

1. The REP Guidance Document is only available upon request via email, how do I know if I have the most recent version?

Response: Each time the REP Guidance Document is modified, the date beside the link on the REP information page will be revised to reflect the last update. A notification will also be sent via the RSS (Really Simple Syndication) feed indicating that the guidance has been updated. Please refer to the website often to check for updates and register for the RSS Feed so that you can receive these notifications. Please refer to the link on the REP information page. The REP Guidance Document and supporting documents are sent within a few minutes upon request.

2. What do I need to do in preparation for the REP?

Response Companies should familiarize themselves with the REP (i.e. review the guidance document, templates, video tutorials, etc.). Preparation for the REP will include setting up a CESG account, obtaining your company and dossier IDs and completing the PI files for your dossiers. If

additional assistance is required, please refer to “Appendix A: Contacts” of the REP guidance document.

3. How do I ensure I am using the most up to date templates?

Response: You should delete your browser cache frequently and refresh the RT template link prior to every use to ensure your browser is loading the up to date template.

4. What changes are made with each release of to the Regulatory Enrolment Process (REP) templates?

Response: A summary of the changes to the REP templates can be found in the REP Template Version History page, which is on the REP Templates & Form Links page of the Health Canada website.

5. Can I rename the REP XML files?

Response: No, the filenames are auto-generated by the templates and must not be modified. Revisions to the filenames may result in processing delays and may be rejected.

6. What is in and out of scope for the REP?

Response: Please refer to the REP information page and REP guidance documents to obtain the most up-to-date information for what is in scope of the REP.

Any product lines or regulatory activity types that are not included in the summary table on the information page or indicated in the REP guidance documents are out of scope for REP. For example: Adverse effect reports, master files, establishment licences, licence applications for Natural Health Products **are not** in scope of the REP.

B. CESG

1. How do I use the CESG?

Response: Refer to the CESG Health Canada Reference Guide (sent as a separate attachment when the REP guidance document is requested from the webpage) for information on: setting up a CESG account, sending a draft CO file to Health Canada, retrieving the final CO sent by Health Canada, and sending a regulatory transaction to Health Canada for review.

2. Where do we include the private key certificate in the transaction?

Response: The private key certificate is only required for setting up a CESG account, it must not be included in a transaction sent to Health Canada.

3. What is two-way communication? When will it be available for use?

Response: Two-way communication allows Health Canada to send correspondences to sponsors using the CESG during the processing and review of a drug. A date has not yet been determined for the implementation of two-way communication. Health Canada is still conducting testing and developing processes. Several months prior to the implementation of two-way communication, Health Canada will publish detailed instructions for sponsors. In the interim, Health Canada will continue to collect routing IDs on a voluntary basis, in preparation.

4. Why do we have to register with FDA?

Response: Health Canada has collaborated with its United States regulatory counterpart, the Food & Drug Administration (FDA), to reduce regulatory burden for health products as part of the Canada-U.S. Regulatory Cooperation Council (RCC) Action Plan. Since the common electronic submissions gateway (CESG) is owned by the FDA, the initial steps for setting up an account must be with the FDA. Once completed, further interactions related with CESG will be with Health Canada.

5. Does each sponsor or third party need a CESG account?

Response: It is recommended that each company obtain their own CESG account for sending transactions to Health Canada.

6. What is the delivery time for the three acknowledgement receipts for files under 10 GB submitted through the CESG?

Response: The first two acknowledgment receipts should be received within 30 minutes of sending the transaction. The timing for the third receipt depends on the size of the transaction, and can take minutes to hours. If you have not received the third acknowledgement within 24 hours, please send an email to hc_cesg_pcde_sc@hc-sc.gc.ca including the initial acknowledgement receipt as an attachment. Please **do not** send the transaction again until you are certain it has not been sent successfully, as receiving the same transaction twice will cause complexities and delays.

Note: Health Canada recommends that transactions between 5GB and 10GB in size be sent after 4:30PM EST.

7. How can we send regulatory transactions in non-eCTD format through CESG?

Response: The steps on how to send a REP CO transaction and a regulatory transaction in non-eCTD format submitted for review through the CESG are described in the *CESG Health Canada Reference Guide.*

8. Can I subscribe to e-billing using the CO template?

Response: No, a separate e-billing form must be completed to subscribe to electronic billing. If you have not already enrolled in the e-billing program please contact the Client information Unit by email at hc.client.information.sc@canada.ca to obtain an e-billing form. The e-billing form will also be sent out with the ADNF package in June.

Furthermore, if changes need to be made such as company address or contact information, the REP CO enrolment/amendment process must be used to make the change.

C. Consultant/Third party

1. How can an authorized third party prepare the REP files on behalf of a sponsor, when they do not have some of the mandatory information?

Response: It is the responsibility of the sponsor/manufacturer to ensure that the third party they have authorized to prepare the REP files on their behalf, have the necessary information to complete each REP template.

2. Can a third party send a draft CO file to Health Canada on behalf of a sponsor?

Response: If the company enrolment/amendment process is being handled by an authorized third party company on behalf of a sponsor, the third party company will need a CESG account and will be responsible for receiving and managing the final CO file sent by Health Canada. The authorized third party may also want to be identified as the "Regulatory Enrolment Process contact" role under the "Company Representative Information" section of the company template.

3. How can a third party file regulatory activities and transactions on behalf of a sponsor?

Response: If the regulatory activity and regulatory transactions are being managed by an authorized third party, they must have a CESG account and will need to provide a *Third Party Authorization Letter* signed by the sponsor/manufacturer within the initial transaction of specified regulatory activities.

A Third Party Authorization letter is required within a regulatory transaction, for a REP dossier, when:

- The regulatory contact for THAT regulatory activity, indicated on the RT file, is a third party acting on behalf of the manufacturer/sponsor; and
- The regulatory activity type is one of the following (including administrative submissions): COV19, COV19A, NDS, NDS CV, SNDS, ANDS, SANDS, SNDS-C, SANDS-C, NC, EUNDS, EUSNDS, EUANDS, EUSANDS, DINA, DINB, DIND, DINF, PDC, PDC-B.

When provided, a separate PDF authorization letter is required for each regulatory activity. The authorization letter is only required once per regulatory activity unless the third party has changed, in which case a new authorization letter will be required.

Even if an authorization letter from a previous regulatory activity is still valid (same contact), it needs to be provided again within the initial transaction of the new regulatory activity.

D. Company (CO) Enrolment/Amendment

1. Where can I find the sponsor company ID?

Response: Your company ID can be found on the latest Annual Drug Notification Form (ADNF) sent by Health Canada, as the "company code".
If your company ID is less than 5 digit, add leading zeros when entering the ID on the RT and PI templates (e.g. 01234).

NOTE: The company ID is not the same as your CRA issued business number, or company codes assigned for other product lines (i.e. NHPs).

2. If I already have a company ID, can I skip the company enrolment step?

Response: Yes, if you have the sponsor's company ID and the company name, address, or contact information has not changed since you last provided it to Health Canada, you may skip the CO enrolment step. Should any information need updating anytime in the future, a *draft CO XML* file must be sent to Health Canada using the Company Enrolment/Amendment Process described on the REP Guidance Document.

3. Do I need to enrol/amend my company template if the only thing that has changed is the REP contact?

Response: No, the REP contact collected on the CO template is only used to facilitate the CO enrolment/amendment process. Once the final CO XML has been returned, the REP contact will not be used for future correspondences.

4. The regulatory contact may change with each submission (regulatory activity); does the company file need to be updated every time to account for this?

Response: The regulatory transaction (RT) template collects information on the regulatory contact for THAT regulatory activity. The RT XML file must be sent with **each** transaction for a REP dossier, therefore this contact information can be updated with every transaction sent.

If any of the contact information collected using the company template (with the exception of the REP contact) has changed, you must send a draft CO XML file or amend your *final CO XML* file and

send it to Health Canada. The “Regulatory Mailing” contact role is used by Health Canada to assign the contact who will be responsible for receiving and returning the Annual Drug Notification Form (ADNF) each year, and is not equivalent to the regulatory contact for a specific submission (regulatory activity).

5. **Do I need to fill out the CO template using a blank template each time, or can I import data from a previously completed file? When is the field “Select a file to load” used?**

   Response: If you are updating information that has previously been provided using the company template, you must upload the most recent final CO file into a blank CO template and all the fields will be prepopulated. You can revise any of the fields before generating a new draft CO file for sending to Health Canada. You must use the field “Select a file to load**”** in cases where you have already received a final CO, sponsors must load the previous final CO XML issued by Health Canada to make amendments.

6. **How do I change my company name using the CO enrolment/amendment process if I do not have a final CO XML to amend?**

   Response: When creating the initial draft CO XML, be sure to include your existing company ID and the changes that are being made in the “Reason for Filing” field.

7. **What do I do if my company information has changed due to buyouts, mergers, company name change?**

   Response: If your company information has changed (i.e. buyouts, mergers, company name change) and a regulatory transaction will need to be filed under the administrative pathway, please ensure that the company enrolment/amendment process is complete prior to filing the administrative regulatory activity as a new company ID may need to be assigned. Depending on the type of administrative change, a new company ID and/or new dossier ID(s) may be required. Please refer to the question “Is this regulatory activity an Administrative Submission or does this regulatory activity contain an administrative component?” on the RT template. If you select “Yes”, a picklist will be displayed for *Reason for Administrative Submission or administrative component*. Depending on your selection, a description will appear along with an information note highlighted in blue. Please refer to the note to verify if a new dossier ID is required and what company ID you should use on this RT and associated PI template.

   If a new company ID is required, you must first obtain the company ID (via the CO enrolment/amendment process) prior to filing the administrative submission as you will need to identify the new company ID on the RT and the PI templates.

   If a new dossier ID is required, you must first obtain the new dossier ID (using the dossier ID request form) prior to filing the administrative submission as you will need to identify the new dossier ID on the RT and the PI templates.

8. What happened to the Importer Company ID?

Response: Importer company ID will no longer be assigned, as a result, importer information will not be collected during the company enrolment/amendment process. You will instead provide the importer information when you fill out your Product Information (PI) Template.

E. Dossier ID

1. What is dossier ID? When do it need it?

Response: A dossier is a collection of all regulatory activities throughout the life cycle of a product or products (with the same medicinal ingredient(s)) for a sponsor. The dossier ID is the code created by Health Canada to uniquely identify the dossier. A dossier ID is required regardless if you are filing in eCTD or non-eCTD formats. The dossier ID is required to complete the RT and PI templates as well as for the top-level folder name to structure a regulatory transaction for filing.

2. For new dossier IDs that have been requested and have not been used (i.e. no regulatory transactions filed), is there an easier way to check if the dossier ID is still valid? Should we request a new one through the Dossier ID request form or confirm via email?

Response: Sponsors may check DSTS-IA, by querying the status field for “eCTD hold” or “non-eCTD hold”, to find the dossier ID for a product. Otherwise, the appropriate dossier ID request form must be completed via the link on REP webpage and Health Canada will provide a new dossier ID in an email response.

Sponsors can request their dossier IDs up to two months in advance of the regulatory transaction intended filing date.

3. Can sponsors use a generic or random Top-level folder name, dxxxxxx, when filing non-eCTD transaction with REP?

Response: The top-level folder name **must always** be the dossier ID assigned by Health Canada (consisting of a lowercase letter, followed by 6 numeric digits) regardless of the format of the transaction (eCTD or Non-eCTD). Dossier IDs for division 1 transactions in Non-eCTD format (human drugs) begin with a lowercase ‘d’, dossier IDs for veterinary drugs begin with a lowercase ‘v’ and dossier IDs for transaction in eCTD format (human drugs) begin with a lowercase ‘e’.

F. Filing transactions with REP

1. How can I prevent the delays during processing?

Response: You can prevent delays by ensure the information provided in the RT template matches with the content of the cover letter and ensure all field entered in the RT are accurate such as dossier type and Dossier ID. When Health Canada identifies inaccuracies, it causes delays, as Health Canada needs to confirm the intent of the transaction in order to process it accurately and route it to the appropriate review bureau.

2. Do I need to fill out each template from blank each time or can I import data from a previous file?

Response: Previously completed files may be uploaded into a blank template and modifications can be made at this point to update the information.

RT template - If you are filing a subsequent regulatory transaction and want to pre-populate the RT template, you can upload a working RT .hcsc file or a final RT XML file and all the fields will be auto-populated. However, please ensure you update the appropriate fields accordingly and check that the regulatory activity contact information and other pre-populated fields are still valid before generating a new final RT XML file. Erroneous information will result in delays in the processing and review of the transaction.

PI template - If you are filing a new regulatory activity and want to pre-populate the PI template, you can upload a working PI .hcsc file or final PI XML file and all the fields (e.g. active ingredients, excipients, formulations, etc....) will be auto-populated. However, please note all the information in the PI should be related to one regulatory activity **only**. You may proceed to add, delete or modify information to generate an updated final PI XML file for the new regulatory activity.

3. How do I determine the appropriate Dossier Type?

Response: Refer to the instruction for dossier type on the RT template. For example, radiopharmaceutical products are filed under the "Biologic" dossier type. It is important to select the correct dossier type as certain selections (i.e. Regulatory Activity Lead, Regulatory Activity Types and associated transaction descriptions) may not be visible in subsequent fields.

4. What is the Company Identifier (ID) (5-digit)?

Response: The Company ID refers to the Manufacturer/sponsor/DIN holder. The Company ID can be found in the final CO XML received from Health Canada or from your latest Annual Drug Notification Form (ADNF). Add a leading zero if your company has a four digit Company ID (e.g. 01234). If you have submitted a new draft CO with amendment, please wait until you receive your final CO XML from Health Canada prior to filing your regulatory transaction.

5. How do I determine the appropriate Dossier Identifier (ID)?

Response: The dossier is the collection of regulatory activities and transactions associated with a product (or a group of products with the same medicinal ingredient, brand name, etc.). You can find your Dossier ID in DSTS-IA by searching for a recently filed control number. Alternatively, you can use the Dossier ID request form to confirm a Dossier ID or request a new one for a new product.

6. How do I determine the appropriate reason for administration submission or administrative component?

Response: Refer to the Guidance Document: Administrative Processing of Submissions and Applications Involving Human or Disinfectant Drugs. Please ensure you review the "note" in blue to verify which Company ID, Dossier ID to use on the RT template.

7. What is the Control Number?

Response: The control number is a six-digit number associated with their regulatory activity.
You can enter "000000" as the control number for the first transaction of a new regulatory activity (if control number has not yet been assigned)
You MUST enter the control number identified in the correspondence issued by Health Canada for all responses (e.g. response to clarification request).
You can enter "000000" as the Control Number for regulatory transactions that do not require a control number (e.g. Level III - Post-NOC Changes, UDRA – DIN cancellations, UDRA - Notification Interruption of sale, UDRA - eCTD Dossier Clean-up).
You should file the Drug Notification Form(s) (DNF) under the same control number it has been issued for the product(s) that are now being sold on the market.
In some cases, the pre-assigned control number for the first transaction of a new regulatory activity that was communicated by Health Canada (e.g. via an Advisement Letter sent by Marketed Health Products Directorate) in which case use the number provided.

Common mistake: Sponsor not using "000000" for a new regulatory activity. Sponsor using 000000 for subsequent transactions after a control number is assigned (in clarification request or advisement letter), sponsor using a control number associated with another regulatory activity, sponsor pre-populated from loading a previously generated RT and not updating as needed and sponsors referencing a control number on the RT that does not match the cover letter.

8. How do I determine the Regulatory Activity Lead?

Response: Refer to the definitions of each regulatory activity lead.

Biological: Includes all regulatory activities and transactions under the Biologics and Radiopharmaceutical Drugs Directorate (BRDD) mandate (biologics/radiopharmaceuticals).

Consumer Health Products: Includes all regulatory activities and transactions for non-prescription pharmaceuticals and disinfectants under the Natural and Non-Prescription Health Products Directorate (NNHPD) mandate.

Pharmaceutical: Includes all regulatory activities and transactions for prescription pharmaceuticals and ethical products under the Therapeutic Products Directorate (TPD) mandate.

Post-Market Vigilance: Includes all regulatory activities and transactions under the Marketed Health Products Directorate (MHPD) mandate (prescription and non-prescription pharmaceuticals for human use, biologics, radiopharmaceuticals).

9. How do I determine the appropriate Regulatory Activity Type?

Response: Refer to the Guidance Document: Management of Drug Submission and Application, Post NOC Change Guidance Document, Post DIN Change Guidance Document or contact the appropriate review bureau for your product in advance to confirm the correct Regulatory Activity Type prior to filing.

Common mistake: Sponsor filing a post-DIN change as a PDC while it should be a DINA as per the Post DIN Change Guidance Document; sponsor using a Regulatory Activity Type on the RT that does not match the cover letter.

10. How do I determine the appropriate Regulatory Transaction Description?

Response: You can make the appropriate selection in the Regulatory Transaction Description by carefully reviewing the list of transaction descriptions available and select the appropriate one. Definitions of some transaction descriptions will be displayed when selected.

Common mistake: "Administrative" is only to be used for initial transactions for regulatory activity for an administrative change as per the Administrative Guidance Document (i.e. change in company name, merger, etc.). Do not use "Administrative" as a 'catch-all' description.

Common mistake: "Response to email request" is only to be used when the RT is responding to an email request. Determine the type of clarification request and use the appropriate transaction description (i.e. Response to quality clarification, response to clinical clarification, response to processing clarification, etc.).

11. How do I indicate the appropriate "Requester of Solicited Information"?

Response: Use the name of the solicitor as indicated in the document requesting the information. When you provide the accurate name, it ensures the transaction Health Canada receives is sent quickly and accurately to the solicitor in the review bureau.

Common mistakes: Sponsor omits the field when necessary, sponsor indicates an incorrect name (often their own or the requester of a previous clarification request).

12. Can more than one formulation/strength be listed on a PI template?

Response: Yes, the PI template is capable of capturing product information for more than one formulation/strength. After creating one formulation record, simply use the copy formulation button and modify the record accordingly. Please ensure to name each formulation that is identified on the PI template. Only include information that is pertinent to the regulatory activity (i.e. if the dossier has 5 dosage forms, but this regulatory activity only applies to 1, only list the formulation for that 1 dosage form in this version of the product information XML file). Refer to section 5 "*Important Considerations*" of the REP Guidance Document for more instructions.

For ease of managing product information for a dossier with multiple formations and strengths, a PI file can be prepared with all the formulations/products under the dossier. In anticipation of a filing, you can create a copy of the PI file and remove all the formulations/products that are not applicable for the specified regulatory activity.

13. For the Animal Tissue section of the Product Information (PI) template, is it possible to include age descriptor? For example, not less than 5 years old.

Response: On the PI template, if you do not know the exact age, you may indicate that it is not known, otherwise if you indicate yes, you will be required to provide the age of the animal in months. We do not have any plans to change the way this information is captured for the time being.

14. How can we fill out the PI template for kits or co-packaged products?

Response: Please contact the applicable review bureaux for more instructions as the approach may differ depending on the composition of the final products.

15. Can I use the same PI file in multiple regulatory activities?

Response: Yes, if the same formulations/products apply to more than **one** regulatory activity and all the information on the PI file is identical, the same PI file can be included in the initial transaction for the new regulatory activity type.

Transactions in eCTD format only (not applicable for non-eCTD): the operation attribute for the PI XML file is "**new**" when provided for each new regulatory activity and "**replace**" when an updated PI

file is provided within a subsequent transaction for the same regulatory activity. If the PI XML file from a previous transaction still applies, a new PI XML does not need to be generated. File "re-use" can be used in the eCTD dossier.

16. Can the first-ever regulatory transaction with REP be a Level III notification?

Response: Yes, this regulatory transaction would include the Level III notification form and accompanied by the RT XML file.

17. How do you indicate that the non-medicinal ingredients contain proprietary information?

Response: For non-medicinal ingredients with proprietary information, select the checkbox for "proprietary information" and provide the known information. The remaining mandatory fields in the ingredient section will now be optional. The identification of where the proprietary information can be found is required. Please note the review bureau may request complete ingredient details if the referenced source is insufficient.

18. How do I view all the information in an XML file?

Response: The best way to view XML files is to use the stylesheet package provided on the REP information page. The stylesheet will enable you to open the fully completed template in a more viewable and printable format. Refer to the stylesheet instructions provided as a separate document in response to a request for the REP Guidance Document from the REP information page.

Alternatively, you can upload the XML file back into the appropriate blank template and the fields will be auto populated for viewing.

19. Once I save a working file for a PI or RT template, can I use the same file in the future for a new transaction or product by adding the required changes?

Response: The working and final PI or RT files can be used to pre-populate the fields by uploading into the appropriate blank template. However, please be cautious when pre-populating with previously generated files, the information must be appropriately revised to reflect the new product or new regulatory transaction. Errors will result in delays during the processing of the transaction.

20. Is it acceptable to include the draft CO XML file or final CO XML file in a regulatory transaction filed for review?

Response: No, as per section 2.3 of the REP Guidance Document, the Company (CO) template is managed independent of the regulatory transactions filed for review. The CO enrolment and amendment process allows the sponsor to obtain their company ID and amend company information respectively. Once you have the company ID from the final CO XML file, you may proceed with using the 'company ID' on the Regulatory Transaction (RT) template and Product

Information (PI) template. The **only** REP files you would ever include in a regulatory transaction filed for review would be the RT and the PI files.

21. Do transactions with REP files need to be validated?

Response: Yes, all regulatory transactions in eCTD or non-eCTD format must be validated according to the validation rules posted on the filing submissions electronically and the REP webpages prior to filing. Transactions that fail validation will not be accepted. In order to assist sponsors Health Canada has published three separate validation rules:

- Validation Rules for Transaction Containing the Regulatory Enrolment Process (REP) Company XML File
- Validation Rules for Regulatory Transactions Filed in eCTD Format
- Validation Rules for Regulatory Transaction Filed in Non-eCTD Format

22. What do I do if my working copy or final XML file is not saving all the data I have entered correctly?

Response: In the sections of the templates where data is summarized in tables, the record must be saved before generating the working copy or finalizing the XML. If you have not 'saved' the content of each section the information may be lost.

For example: the ingredients section, formulation section, human/animal sourced ingredient/material section.

G. Human Drugs

1. Transition to mandatory REP: If I have a human drug submission currently under review, how do I transition to REP? Do I need to refile with the appropriate REP files?

Response: No, if the CR date of the regulatory activities is before October 1, 2020, you do not need to refile any transactions already received by Health Canada. However, all subsequent regulatory activities and transactions will require the REP files. A REP PI file is required only if Health Canada requests an update or if the information on the PI (which was previously on the HC3011) has changed.

2. Can the HC-SC3011 and Fee forms be included in a human drug regulatory transaction filed to Health Canada?

Response: No, the HC-SC3011 and the Fee forms **must not** be included in any transactions filed that are using the REP. The information from the HC-SC3011 and Fee forms can be found integrated into the RT and PI files. Providing copies of the HC-SC3011 and Fee forms may result in conflicting

information when compared to the RT and PI, which will result in a delay in processing the transaction.

3. **For eCTD format, once we include the PI and RT XML under 1.2.1, is it recommended that we delete the HC-SC3011 form and the Fee form that were submitted in prior transaction(s)?**

Response: You do not need to revise transactions that were filed prior to Oct 1, 2020 in order to meet the mandatory REP requirements. However, if after Oct. 1, 2020, the HC-SC3011 or the Fee form was included in a transaction erroneously, we recommend that you use the 'delete' operation attribute for the HC-SC3011 form or the fee form in the subsequent transaction.

4. **How do I make the correct selection for "Are new or revised fees associated with this transaction?"**

Response: Please refer to the fees guidance document to determine the regulatory activity types that are subject to fees and select the correct fee class. You must complete the fee section when applying for fee mitigation measures (i.e. small business, government organization, publicly funded health care institution).

Common mistakes: "No" is often selected for regulatory activities that are subject to fees, NC and PDC submissions will also periodically have fees indicated erroneously. "No" is selected when applying for small business. "Yes" is selected for a subsequent transaction, but fees have not changed.

5. **How do I apply for the small business fee mitigation measure?**

Response: You need to register with the small business registry prior to filing your regulatory activity/transactions. You need to enrol your company using the REP Company (CO) template to get your company ID (unique identifier). Using this unique identifier, sponsors can apply for the small business status. For more information please refer to the "how to apply" information page to apply for the small business fee mitigation measure. If you are applying for the small business fee mitigation measure for Drugs Establishment Licences (DEL) purposes only, please contact hc.client.information.sc@canada.ca. Please note DEL are not within the scope of REP

H. Veterinary Drugs

1. **Where are the REP templates for veterinary drugs?**

Response: The links to all the REP templates, stylesheets and the video tutorials are accessible from the REP information page. Please refer to this page often to check for updates and register for the RSS Feed. If you bookmark/favourite the REP templates to your local computer, be sure to refresh

the page before each use and delete your cache frequently, as newer versions of the templates may not automatically be loaded.

2. **Can the HC-SC3011 form be included in a veterinary drugs regulatory transaction filed to Health Canada?**

   Response: No, the HC-SC3011 form must not be included in any transactions filed that are using the REP. The information from the HC-SC3011 form can be found integrated into the RT and PI files. Providing copies of the HC-SC3011 form may result in conflicting information when compared to the RT and PI, which will result in a delay in processing the transaction.

3. **Should the fee form be included for veterinary products?**

   Response: Yes, the fee form continues to be required similar to process when filling without REP.

4. **Transition to voluntary REP for veterinary drugs: If I have a submission currently under processing, screening or review, do I need to refile with the appropriate REP files?**

   Response: No, you do not need to refile any transactions using REP via CESG. You are encouraged to start including REP XML files in your transactions and filing via CESG for future transactions. Once you start filing a submission with REP, you must continuing filing with REP for that dossier.

I. Disinfectants

1. **Should I select "Yes" for "*Was this regulatory activity approved for priority review?*" on the RT template if the application is COVID-19 related disinfectant drug and I am requesting an expedited review?**

   Response: No, the expedited review of a COVID-19 related application is not related to the Priority Review of Drug Submissions and/or Priority Review status. Please refer to the Guidance for Industry – Priority Review for more information regarding the criteria and scope of this policy. For information related to the expedited review of COVID-19 related disinfectant drug applications, please consult the following document: Applying for a Drug Identification Number (DIN) for a disinfectant drug during the COVID-19 pandemic.

2. **If my disinfectant drug application is COVID-19 related, should I select "Urgent Public Health Need" under "Mitigation measures" on the REP RT template?**

Response: No, the expedited review of a COVID-19 related application is not related to the List of Drugs for an Urgent Public Health Need as per the *Access to Drugs in Exceptional Circumstances Regulations* and associated requirements.

3. What Dossier Type should I select on the REP PI/RT templates for a disinfectant drug application?

Response: "Pharmaceutical" should be selected. Pharmaceutical dossier applies to all pharmaceutical products for human use, non-prescription and ethical products, disinfectants.

4. What Schedule and Prescription status should I select for a disinfectant drug?

Response: The Schedule and Prescription status selected for a disinfectant drug is "a non-prescription drug".

5. What do I declare for the Route of Administration in field F of the REP PI template for a disinfectant drug?

Response: The Route of Administration field should indicate the proposed drug use areas for the disinfectant drug, consistent with those selected within the "Disinfectant Type" field of the REP PI template. These include the following: DISINFECTANT (Barn), DISINFECTANT (Food Premises), DISINFECTANT (Domestic), DISINFECTANT (Hospital/HC Facilities) and DISINFECTANT (Institutional/Industrial).

6. When should I select "Solution" vs. "Spray" vs. "Solution, Spray" for the dosage form on the PI template for a disinfectant drug?

Response: Please take note of the following scenarios and applicable dosage form:

a) If the proposed disinfectant is available in regular bottles/refills bottles only (e.g., regular cap bottles, jugs, pails, drums, etc.), the dosage form should be "Solution";
b) If the proposed disinfectant is available in spray bottles only (i.e., ready-to-use), the dosage form should be "Spray"; and
c) If the proposed disinfectant is available in both spray bottles, and regular bottles/refill containers (e.g., regular cap bottles, jugs, pails, drums, etc.), the dosage form should be "Other" and "Solution, Spray" should be entered into the free text box "Dosage Form Other Details".
d) Products that are dilutable concentrates should generally be declared as "Solution" only.

7. What should I indicate in field 10 "Proposed Indication/Use/Dosage" on the PI template for a disinfectant drug?

Response: For disinfectants that are ready-to-use (RTU), you may indicate "Hard Surface Disinfectant, Ready-to-Use". For disinfectants that are dilutable concentrates, you may indicate

"Hard Surface Disinfectant, Dilutable Concentrate:" and list the appropriate use-dilutions for the product (i.e., the use-dilutions must correspond with those listed on the proposed label). Please note that certain variations may be acceptable, for example the indication of "Hard Surface Disinfectant-Sanitizer, Ready-to-Use" would be acceptable if the product has efficacy claims as both a surface disinfectant and sanitizer.

8. Am I required to declare the Shelf Life and Other Shelf Life Considerations on the PI template for a disinfectant drug?

Response: Yes, the shelf life duration and temperature range are essential in order to verify the continued efficacy and quality of the product, when stored in accordance with the declared shelf life, and with the specific storage information provided as appropriate on the label. Please note that the field "Other Shelf Life Considerations" can be completed only as needed, however the shelf life duration and temperature range must always be declared.

9. Am I required to declare the Chemical Abstracts Service (CAS) numbers for the formulation ingredients on the REP PI template for a disinfectant drug?

Response: Yes, CAS numbers for the active and non-medicinal ingredients are essential in order to verify the efficacy, safety and quality of a disinfectant product formulation. While it is acknowledged that CAS numbers may not be available for certain proprietary blends such as fragrance or colorant ingredients, CAS number must be declared for all other ingredients in the product formulation. If you do not have access to certain CAS numbers within your formulation (e.g., due to proprietary information exclusive to the supplier/manufacturer), please contact the Disinfectants Division for further information on a case-by-case basis at: hc.nded-demvso.sc@canada.ca.

10. How do I enter multiple Chemical Abstracts Service (CAS) numbers and/or components for the same ingredient (i.e., blend) on the REP PI template for a disinfectant drug?

Response: The Disinfectants Division has been providing specific guidance on a case-by-case basis for ingredients and/or blends with multiple CAS numbers and component ingredients. In some cases where space is limited on the REP PI template, it may be appropriate to submit a stand-alone document detailing all of the product's ingredients and CAS numbers, to expand on the formulation declared on the REP PI template. Please contact the Disinfectants Division for further information on how to capture your formulation in the REP PI template at: hc.nded-demvso.sc@canada.ca.

J. Revision History

May 3, 2021 release

Heading	Change

A. General	• Question 1 revised for clarity • Moved questions to section G. Human Drugs • Moved questions from section F. Filing transactions with REP • Moved question from the removed Out of Scope section
B. CESG	• CESG Instruction document was revised to CESG Health Canada Reference Guide
C. Consultant/Third party	• Question 3 added NDS CV to the list of regulatory activity types • Added question 8
D. Company (CO) Enrolment/Amendment	• Questions 1, 2, 5, 6 and 7 revised for clarity • Added Question 8
E. Dossier ID	• Question 2 revised for clarity
F. Filling transaction with REP	• Moved questions to A. General • Added questions 1, 3 to 12 • Revised question 17 for clarity • Removal of questions regarding Lifecycle Management Tables (LCM) and a fixed bug
G. Human Drugs	• Created new section and added questions 4 to 5 • Moved question from A. General • Moved question from F. Filing transactions with REP
I. Veterinary Drugs	• Created new section and added questions 1 to 4
H. Disinfectants	• Created new section and added questions 1 to 10