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Common Electronic Submissions Gateway (CESG)

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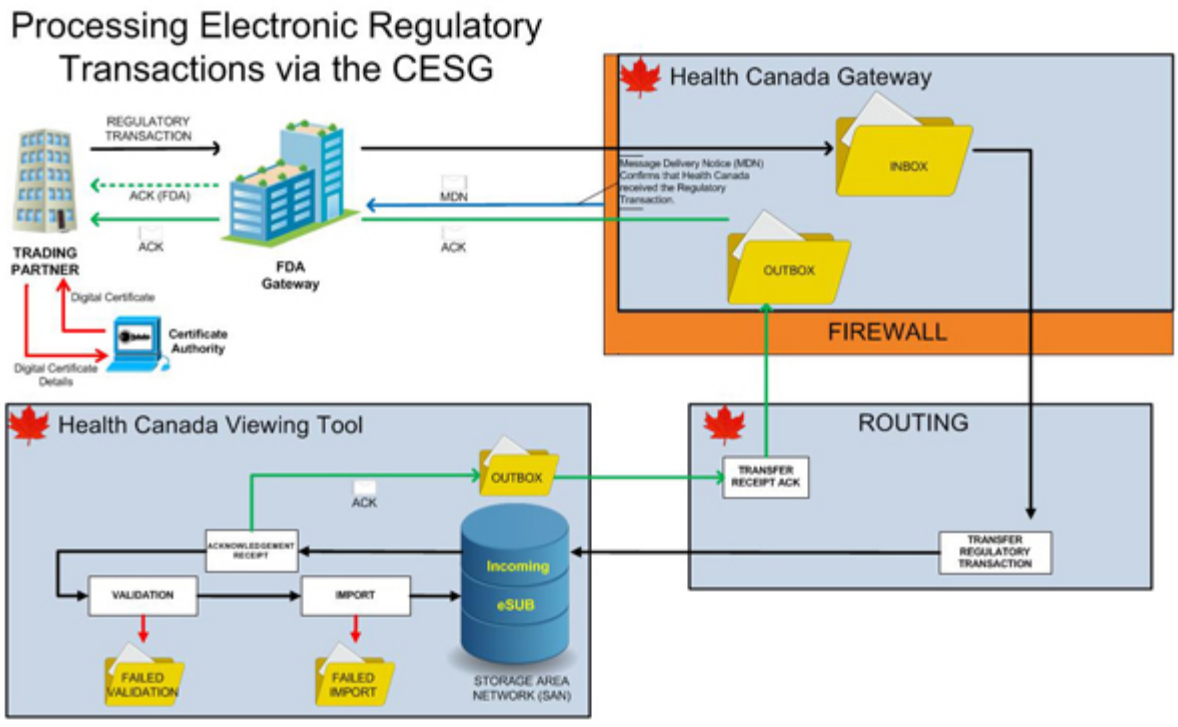
Frequently Asked Questions – Common Electronic Submissions Gateway

1. How does the Common Electronic Submissions Gateway (CESG) work?

The CESG allows Trading Partners provide regulatory transactions to Health Canada electronically, i.e. an "electronic" courier. The CESG is a service of convenience and is an optional method of providing regulatory transactions, taking the place of traditional courier methods and/or submitting on CD/DVD.

See Figure 1 for an illustration of the CESG High Level Architecture:

Figure 1: Common Electronic Submissions Gateway (CESG) High Level Architecture



2. How do I become a Trading Partner to use the CESG?

Please refer to the Food and Drug Administration (FDA) User guide for registration process information.

3. I am already registered as a Trading Partner with the Food and Drug Administration (FDA), do I need a Health Canada specific account?

If you are already registered with the FDA as a Trading Partner and now wish to do business with Health Canada via the CESG, you do **not** need to create a new account. You can use your existing account and simply select "HC" as the Review Centre

4. What do the FDA Message Disposition Notification (MDN) and the Health Canada Acknowledgement Receipt mean?

When using the CESG to submit to the "HC" Centre, you will receive two messages. The first message (MDN) will be issued by the FDA, indicating that the FDA portion of the gateway has successfully received your regulatory transaction. The second message (Health Canada Acknowledgement Receipt) will be issued by Health Canada, indicating that your regulatory transaction has been successfully received by Health Canada portion of the gateway.

Figure 2 illustrates how the MDN and Health Canada Acknowledgment receipt appears in the Inbox of the WebTrader:

Figure 2: MDN and Health Canada Acknowledgement Receipt

5. Where can I find the time stamp that Health Canada received the regulatory transaction?

The time stamp that Health Canada uses as the receipt date/time can be found in the Health Canada Acknowledgement Receipt and is highlighted in Figure 3:

Figure 3: Health Canada Acknowledgement Receipt

This message confirms receipt of the transaction identified below
by Health Products and Food Branch, Office of Submissions and Intellectual Property.
If applicable, a letter of acknowledgement will be issued when a Regulatory Activity is
considered administratively complete.

For status information please consult the Drug Submission Tracking System - Industry Access
(DSTS-IA). This message has been generated using the information from the schema file
provided in this transaction.

Core ID:	ci1111111111111.1111@fdsu10000_te1
Date & Time - Date & Heure:	12202013094914
Dossier ID:	e1xxxxx
Sequence Number - Numéro de Séquence:	0001
Company Name - Nom de Compagnie:	Example Company
Product Name - Nom du Produit:	Example Product

Par le présent message, le Bureau des présentations et de la propriété intellectuelle de la
Direction générale des produits de santé et des aliments accuse réception de la transaction mentionnée ci-dessus.
Le cas échéant un accusé de réception vous sera envoyé lorsque l'activité de réglementation sera considérée complète sur le plan administratif.

Pour connaître l'état d'avancement de la présentation, consultez le Système de suivi des présentations de drogues - Accès de l'industrie
(SSPD-AI). Ce message a été généré à l'aide des renseignements du fichier schéma fourni avec la présente transaction.

The time stamp "12122013094914" can be read as "Month/Day/Year/Hour/Minute/Second" or "December 12, 2013 at 09:49:14 AM".

6. How are transactions received after end of business, on the weekend, or on a Statutory Holiday handled by Health Canada?

These transactions are handled in a manner that is consistent with current practices. Any regulatory transaction received after 5:00 pm Eastern Standard Time, on a weekend, or on a Statutory Holiday is considered received on the next Health Canada business day.

7. What format of regulatory transactions can be sent via CESG?

At this time Health Canada is **only** accepting regulatory transactions in **eCTD** format via CESG.

8. What types of regulatory transactions can be sent via CESG?

(Updated 2014-05-23)

Health Canada is **only** accepting the following regulatory transaction types via CESG at this time:

- Additional information;
    - Solicited Information such as Response to a Clarification Request; Response to Telephone Request, Response to email Request, Response to Screening Acceptance Letter
    - Unsolicited information such as safety information and changes in the name of the sponsor or product during review
      Note: For more details about solicited and unsolicited information, see Section 5.5, "Evaluation of Submissions" in Health Canada's *Guidance for Industry: Management of Drug Submissions*
- Periodic Safety Update Report (PSUR) or Periodic Benefit-Risk Evaluation Report (PBRER) requested during the pre-market review process by Therapeutic Products Directorate (TPD) and Biologics and Genetic Therapies Directorate (BGTD);
- Comments to the Summary Basis of Decision;
- Pristine Product Monograph;
- Second Language Product Monograph;
- Drug Notification Form (DNF);
- Post Clearance Data;
- Minutes of Meeting (pre-submission meeting, NON meeting, NOD meeting etc.) and,
- Cancellation Letter.

Note: The above listed regulatory transactions are applicable to any regulatory activity (submission) types that are eligible for filing in eCTD format as per the Draft Guidance document: Preparation of Regulatory Activities in eCTD format.

If you need to submit a regulatory transaction that does not appear on this list, please use an alternate method of Submissions.

Health Canada will be expanding this list to include additional regulatory transactions in the future.

9. Can I send Post-Notice of Compliance (NOC) Changes: Level III via CESG?

Yes.

10. What folder structure should be used when sending regulatory transactions via CESG?

Health Canada requires that the Trading Partner includes the top level folder when sending the eCTD sequence via CESG. For an illustration of the acceptable folder structure, see Figure 4.

Figure 4: Folder Structure

11. Can the revised sequence for an eCTD sequence that failed validation be resent via CESG?

Health Canada will accept the revised eCTD sequence that failed validation only for

regulatory transaction types listed in FAQs # 8 and 9.

12. What should be done if the Health Canada Acknowledgement Receipt is not received?

The Trading Partner should notify Health Canada via email at hc_cesg_pcde_sc@hc-sc.gc.ca

13. What should be done if the Health Canada Acknowledgement Receipt is received with missing information?

The Trading Partner should provide the Acknowledgment to Health Canada via email at hc_cesg_pcde_sc@hc-sc.gc.ca.

14. If the Health Canada Acknowledgement Receipt was not received should the eCTD sequence be resent?

Please do not resend an eCTD sequence if the Health Canada Acknowledgement is not received right away. Depending on the file size, it may take one hour or more to receive an Acknowledgement Receipt. Trading Partners should not resend eCTD sequences unless it is requested by Health Canada. If you would like to confirm whether your sequence has been received, please contact hc_cesg_pcde_sc@hc-sc.gc.ca.

15. Are electronic Signatures (e-Signatures) accepted by the Health Products and Food Branch (HPFB) and can they be used when submitting to the CESG?

Yes, e-signatures are accepted at HPFB in accordance with the Health Products and Food Branch Electronic Signatures Policy. They are coordinated with the directorates and handled on a case-by-case basis. The Policy, which was co-authored with industry, is provided upon request by emailing hc_cesg_pcde_sc@hc-sc.gc.ca.

16. What are some of the CESG terminology differences between the FDA and Health Canada?

When using the CESG you will notice differences in the terminology used by the FDA and Health Canada. Table 1 provides a comparison of similar terms used by FDA and Health Canada.

Table 1: Comparison of Similar Terms used by FDA and Health Canada

FDA Term	Health Canada Term
FDA ESG (FDA Electronic Submissions Gateway)	CESG (Common Electronic Submissions Gateway)
Transaction Partner	Trading Partner
Submissions	Regulatory Transaction

Please note that, in some cases, these terms may be used interchangeably when corresponding with Health Canada and/or the FDA.

17. Who do I contact for more information on the Common Electronic Submissions Gateway (CESG)?

Please refer to Inquiries and Support for details on where to direct your questions.

18. Is it acceptable that the second language Product Monograph be sent via CESG exclusively?

Yes, the second language product monograph can be sent exclusively via CESG. There is no need to provide the second language product monograph separately via email to SIPD-DIN@HC-SC.GC.CA. Health Canada will internally route this transaction to the appropriate bureau.

19. Is it acceptable that the Drug Notification Form be sent via CESG exclusively?

Yes, the Drug Notification Form can be sent exclusively via CESG. There is no need to provide the Drug Notification Form separately via email to SIPD-DINREQUEST@HC-SC.GC.CA. Health Canada will internally route this transaction to the appropriate bureau.

20. If the eCTD sequence (regulatory transaction) was sent via CESG, should the same eCTD transaction also be sent on a CD with printed copy of the cover letter via courier?

(New question 2014-05-23)

No, If the regulatory transaction was sent via CESG, no additional copies of the same transaction should be sent on CD via courier.

21. What is the maximum allowed path length, including the file name, for regulatory transactions sent via CESG?

(New question 2014-06-24)

The maximum allowed path length in transactions sent via CESG is 180 characters.