Summary of info provided in email updates to industry

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| 2021-05-14 | Only one announcement, but a big one: Phase II – full production (voluntary) will begin on June 14th. At that time, the new validation rules will go into effect, and the new CV website will be available. |
| 2021-05-10 | **Update to 2021-05-07 message:** In regards to the image file name outlined below, I have been informed that the white space in the file name causes an eCTD validation issue. As such, dashes are required. I have updated my message below to follow this guidance (highlighted). |
| 2021-05-07 | **Product Details**  This section has been moved to the end of the rendered XML PM so that the title page continues to be the first thing seen.  **Date format on title page**  In order to ensure consistent formatting of the Date of Initial Authorization and Date of Revision, sponsors are now requested to insert the date in the <paragraph> as YYYY-MM-DD. The style sheet will then render the date in the full text format as per Government of Canada standards. The English dates will render as month-day-year (e.g. January 15, 2021), and the French dates will render as jour-mois-année (e.g. 15 janvier 2015). This is also the expected date format for the date on the last page of the PMI. We are aware that this deviates from the 2020 Master Template, and are working to have it updated accordingly.  cid:image001.jpg@01D7457A.E32490B0cid:image002.jpg@01D7457A.E32490B0  **Revisions to validation rules**  In line with the changes to the dates on the title page, Rule 14.02 has been revised to reflect the new requirement. Rule 14.03 is no longer required and therefore has been deleted. These revisions have been incorporated into the validation rule cross-walk available on GitHub.  **Filing of an XML PM in eCTD format**  There has been a great deal of confusion regarding the XML PM when it is published in an eCTD sequence. While the XML file and it’s associated images must be named in a particular way in order to pass validation and render properly, the display in the eCTD sequence doesn’t match it’s associated guidance. The following is an example of what not to do:  cid:image003.jpg@01D7457A.E32490B0  Instead, sponsors should maintain the naming convention required for the files (xml and jpg), however, the leaf titles should be renamed to be inline with eCTD guidance.   |  |  |  | | --- | --- | --- | | File type | File name | Leaf Title | | .xml | GUID (<document> <ID> root attribute) | eID (seq#) – XML PM EN  eID (seq#) – XML PM FR | | .jpg | Must match the <reference> value attribute in the .xml file | eID (seq#) – PM-Image-1-EN  eID (seq#) – PM-Image-1-FR  eID (seq#) – PM-Image-1-EN-&-FR |   The leaf title for the XML does not need to include ‘annotated’ or ‘non-annotated’ as that is a not an XML concept.  The images must be referenced in the XML backbone, however are not needed to be reviewed outside of the rendering of the XML PM. This naming convention will indicate to reviewers that the image is part of the PM. Image files no longer need to follow the naming guidance as previously provided and can be up to the discretion of the sponsor, however the following should be noted:   * Since an image must be contained within the same folder as the .xml file in order to render correctly, they must be submitted as part of each eCTD sequence and cannot be re-used across sequences. * When an image does not contain any text (e.g. image for chemical structure in part 2), the image should be used for both the EN & FR versions of the XML PM.   cid:image004.jpg@01D7457A.E32490B0  cid:image005.jpg@01D7457A.E32490B0 |
| 2021-04-16 | We have completed an analysis on the feedback we received regarding the French translation of the section headings in the Master template. Though further work is required on the template itself, we took on the responsibility to ensure that the CVs required for the XML PMs would be addressed. We will be uploading the translations to the CV website in the next week, however please also find a copy attached for your convenience. For those that provided feedback, thank you! Please note that the final translation is not necessarily the same as what you/your group may have provided.  We have received several questions regarding putting common content in tables. We believe that the samples provided are misleading. Specifically Sample - 2020 PM Template (in either language), because it contains boxes with the instructions from the master template. We are working to revise and simplify the samples, hoping to post them to GitHub in the next week or so. In the meantime, the Sample - Lorum Ipsum (in either language) does reflect what the content should look like, though it is based the 2016 standard template (which is no longer accepted) it provides a good example of how the rendered PM should look.  Lastly, my usual reminder to make sure your CVs are up to date before submitting. The validation will be run against the terms on the CV website. |
| 2021-04-01 | We are planning on replacing the renderings of the sample XMLs next week. We will no longer be including the instructions from the PM Template (as shown in the Sample – 2020 PM Template, currently in single cell tables) in order to better demonstrate how the content is intended to be rendered. There will be only a single sample in each language, however, each sample will still contain several products. The current examples will be removed from GitHub.  I would like to remind everyone that XML PM file names MUST be a GUID, and image file names need to match the reference in the XML file. The name should not be changed to follow eCTD naming guidance (e.g. (0014) Non-annotated PM) as this causes validation errors. We have seen this several times and believe it happens during the eCTD publishing process. |
| 2021-03-19 | No real updates this week – we continue to make minor updates to the stylesheet related to accessibility, and will be updating the samples on GitHub this week.  As I have mentioned, we are working on revisions to the guidance. As we work through revisions, I will be including pieces of the draft for your information and comments.  -----------------  The style sheet controls the majority of the formatting based on the Master Template and CV (6.63). The following recommendations should be applied throughout the document.   * Underlining should only be used for hyperlinks. * Italics should only be used when specified in the template. * Bold should be used for section headings that are not part of the CV (6.63). * Use of bold should be limited for narrative text. * Ensure all symbols are compliant with XML and UTF-8 before use. * There are no spaces in codes. * All data elements associated with controlled vocabularies are case sensitive. There are no other case sensitivity rules aside from what is described in the SPL schema or XML specification. * Limit the use of line breaks to avoid unnecessary white space * Avoid combining styles. For example, applying both underline and bold.   It is recommended that sponsors review the rendered prior to submitting to ensure that their XML PM is in line with the Master Template. |
| 2021-03-12 | **The Therapeutic Class (OID 2.16.840.1.113883.2.20.6.6)**  In the email updated dated 2021-01-08, we announced the decision to revert to ATC code. The CV has been updated to include the 4th and 5th level codes, however, only the English descriptions for the 5th level are included at this time. We will be adding the 4th level and French translations in the coming weeks. It should be noted that the style sheet has been updated and only the code will be rendered at this time.  **Draft Validation Rules v2.0**  An updated version of the validation rules have been posted in GitHub (https://github.com/HealthCanada/HPFB/tree/master/product-monograph/guidance). The majority of the changes are only for clarity, and numbering of the rules. The document includes additional columns that indicate the old rule number and what has changed. These rules have not yet been implemented for the validation of XML PMs. We are currently testing and plan to implement in the next few months. I will provide more concrete timelines once they have been finalized.  **Style Sheet Changes**  We continue to make small changes to the style sheet. This weeks updates are related to accessibility requirements. |
| 2021-02-26 | Stylesheet changes related to accessibility requirements  Additional guidance regarding how to add the vertical line that is used to indicated revisions (RMLC) |
| 2021-02-12 | Stylesheet changes  Validation rules – notice they are being updated and will be available shortly  Guidance document – notice of revisions to streamline and provide additional clarity |
| 2021-01-08 | Changes related to CVs  **Therapeutic Class (OID: 6.6)**  We have decided to revert to the ATC code for therapeutic class at this time. We are working to update the CV list as quick as possible; unfortunately, it won’t be completed today.  **Combination Product Type (OID: 6.8)**  We are removing this product characteristic from the XML PM at this time.  **Date of Cancellation**  We are removing Date of Cancellation associated with the Packaging Status as packaging tends to be no longer available rather than cancelled.  **Regulatory Status (OID: 6.11)**  We are removing the Regulatory Status associated with both Packaging Status and Product Status from the XML PM at this time.  This OID has been repurposed and renamed with a different set of terms.  **Package Available (OID: 6.11)**  We have defined a new CV called PACKAGE AVAILABLE to the Packaging Status section. |
| 2020-12-11 | **Generics**  As long as the CRP has converted to the master PM template, generic product can move to the XML format. The assumption is that all PMs in the master template will have used the controlled vocabulary, regardless of format.  **Pharmaceutical Standard**  The term Professed / Reconnue has been added.  **Inactive Ingredients**  The active ingredients listed in the product metadata should match what is provided in 6 DOSAGE FORMS, STRENGTHS, COMPOSITION AND PACKAGING.  **Stylesheet**  Stylesheet changes are ongoing related to printing a rendered XML to PDF. |
| 2020-12-04 | Guidance provided around Empty titles in Section Headings and the use of Unassigned  **Empty Titles in Section Headings**  It is important to provide meaningful titles within section headings.  To support this, we have improved the logic to display a warning message if a <title> does not contain content.  cid:image001.jpg@01D7118C.D182C1A0  **UNASSIGNED**  We have been examining the XML documents we have received both visually and using our validation tool.  We have encountered several instances where the XML is authored to have document content section headings using the industry-defined display name ***UNASSIGNED*** incorrectly, which would not be detected during validation.  We wanted to use this as an opportunity to specify the correct usage of the ***UNASSIGNED*** section headings, as we are all still in the learning stages of this initiative.   * Sponsors should use the Health Canada section headings defined in controlled vocabularies to represent the section headings in their XML document; these are derived directly from the [Health Canada Product Monograph Template](https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/product-monograph/master-template.pdf). * Sponsors should use the ***UNASSIGNED*** section heading to represent concepts not covered (industry defined) in the Health Canada Product Monograph Template * Sponsors should not use the ***UNASSIGNED*** section heading to represent concepts found within content of the Health Canada Product Monograph Template.  For example: ***Absorption***, ***Distribution***, ***Metabolism*** should be authored as content within ***10.3 Ph*armacokinetics** instead of being defined using the ***UNASSIGNED*** section heading   cid:image003.jpg@01D7118C.D182C1A0 |
| 2020-11-27 | **Controlled Vocabulary**   * General reminder to ensure your XML authoring tool has performed a recent download to refresh CV terms. We are seeing a lot of validation errors when old terms or codes are used. * I have received a lot of questions regarding the French terms within CVs. As I have mentioned in the past, the user interface for our interim site is only available in English. The terms are downloadable in both languages in XML format. This is not always convenient for users, especially since November 1st with the expectation to use CVs in all PMs, regardless of the format (as per the [Implementation Notice](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/notice-product-monograph-implementation-plans.html)). In order to bridge this gap, we will be posting the attached spreadsheet that contains both the English and French list of terms. This list will be updated on a regular basis as we add more French terms (specifically to the ingredient identifier listing). Please feel free to share this with your colleagues until the posting is available. (Attached spreadsheet: 2020-11027 HC Controlled Vocabularies – Bilingual Listing.xlsx)   This spreadsheet is being provided as a supplement to the Controlled Vocabulary Listing to provide an alternative way to access the French terms. It is not intended to be imported into any systems being used to author product monographs. Once the new Listing (fully bilingual) is available, this document will no longer be maintained.   * We have made two changes to the CV to align better with Guidance and the Master Template:   + Document Type (6.10) – term changes   English -> MASTER TEMPLATE - 2020  French -> MODÈLE PRINCIPAL - 2020   * + Master Template Section Headings (6.63) - no changes to terms   English -> MASTER TEMPLATE - 2020  French -> MODÈLE PRINCIPAL - 2020  **Stylesheet updates**   * To align with the Master Template, we have added the following text directly under the Table of contents section heading:  *Sections or subsections that are not applicable at the time of authorization are not listed.* * We have removed the navigational arrow that is displayed in the bottom right corner of a rendered XML PM (cid:image001.jpg@01D6C4CF.DE311000) in the printable version of the XML. * As per SPL, in order for the XML to allow for multiple compositions within a product, the Dosage Form needs to be Kit at the highest level of the product. This allows for the product metadata to be repeated for each composition. As you are aware, Health Canada has very specific guidance around the term kit. The requirement for multiple compositions does not only apply to kits as per HC. Therefore, in order to avoid confusion, we are suppressing the term Kit from the rendering.   cid:image002.jpg@01D7118C.E15FE210 |
| 2020-11-20 | A few minor updates this week:   * OIDs and CVs related to the 2016 templates have been archived. The only exception is the standard template for the 3 XML PMs filed prior to the Nov 1 deadline. * Controlled Vocabularies - As per the Jan/May 2020 [Notice - Product Monograph Implementation Plans](https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/announcements/notice-product-monograph-implementation-plans.html), sponsors are now expected to use terminology from Health Canada approved controlled vocabularies when filing product monographs in the 2016 format. it is important to align terminology used throughout the document and across all products.  The expectation is that the CV term will be used, however, in some cases this may not be grammatically correct (e.g. Route of Admin and the word ‘use’). In these situations, please keep as close to the CV term as possible. * We continue to add French terms to Ingredient Identifier (2.16.840.1.113883.2.20.6.14). If there are specific terms you require that have not been translated, please let us know. |
| 2020-11-13 | No update, outline of schedule for project timelines (same one that was in association bilat deck) |
| 2020-10-16 | Clarification regarding use of Master template (2020)  Updates to CVs (case changes, French translations |
| 2020-10-13 | Initial email  Update  At this time, we have received XML PMs for 2 products, in both English and French, with several more expected in the next few months. We have been able to successfully validate these and are working with the sponsor to address any issues. These first two have helped us identify some gaps – some of which are addressed below. The French CVs were also identified as an issue, and we are working to address these issues as quickly as possible. While we are in the Phase I Soft Launch, it is likely that there will be updates to the CVs. In order to minimize any confusion, we will be limiting updates to the CVs on Fridays.  Master Template  As outlined in the Notice: Product Monograph Implementation Plans (May 12, 2020), beginning November 1, 2020, sponsors are expected to file Product Monographs under the 2016 Guidance and format for biologics, radiopharmaceuticals and prescription pharmaceutical products. With the goal of standardization, Health Canada has been working to combine the six 2016 templates into one. This new master template, along with updated guidance, is currently pending publication (behind due to COVID publication priorities). To avoid confusion, this master template will be known as the 2020 template moving forward. I have attached the final versions of the template and guidance for your convenience. No substantive changes have been made; the updates are in relation to the 2020 template. The section headings for the 2020 template are now associated with OID 2.16.840.1.113883.2.20.6.63  Instructions For Use  This section is no longer part of the XML PM. The goal of the project was to be inline with the official PM templates, which do not contain that section. This does not mean they can’t be included, only they will not be in a discrete section.  Regulatory Status (of packaging and product): Having only APPROVED and CANCELLED as acceptable terms was identified as a gap, so we are adding a third option to the CV – UNDER REVIEW. OID 2.16.840.1.113883.2.20.6.63 within the CV site has been updated.  How to deal with required information when it is unknown at the time of filing  • Dates of approval: When the date is unknown, sponsors can either omit the date or use a placeholder . When using a placeholder, sponsors should use 19000101.  • DIN: When the DIN is unknown, sponsors can either omit the or use a placeholder number. When using a placeholder, sponsors should use 90000000.  • Control Number: When the Control Number is unknown, sponsors can either omit the control number or use a placeholder. When a placeholder, sponsors should use 999999. |