Health Canada   Santé Canada

DRAFT GUIDANCE DOCUMENT

Electronic Canadian Drug Facts Table (eCDFT) Technical Standards

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Health Products and Food Branch

Canada

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Our mission is to help the people of Canada maintain and improve their health.	The Health Products and Food Branch's mandate is to take an integrated approach to the management of the risks and benefits to health related products and food by:
Health Canada	• minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about

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36   *Également disponible en français sous le titre : [***FRENCH TITLE HERE***]*

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40 **Foreword**

41 Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with the
42 policies and governing statutes and regulations. They also serve to provide review and compliance guidance to staff,
43 thereby ensuring that mandates are implemented in a fair, consistent and effective manner.

44 Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach.
45 Alternate approaches to the principles and practices described in this document *may be* acceptable provided they are
46 supported by adequate scientific justification. Alternate approaches should be discussed in advance with the relevant
47 program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

48 As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or
49 material, or define conditions not specifically described in this guidance, in order to allow the Department to adequately
50 assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests
51 are justifiable and that decisions are clearly documented.

52 This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable
53 guidances.

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96   # 1. INTRODUCTION

97   ## 1.1 Objectives

98   The objective of the Electronic Canadian Drug Facts Table (eCDFT) Technical Standards
99   Guidance-document is to provide direction to sponsors, manufacturers and license holders (to be
100   referred to as 'sponsors' within this guide) on the technical web publication standards including ,
101   naming conventions for "user-friendly" URLs, implementation flexibilities, and the use of other
102   URL technologies.

103   This guidance document supports implementation of the *Plain Language Labelling (PLL)*
104   *Regulations* for non-prescription drugs by outlining approaches intended to provide consumers
105   with access to on-line information presented in a standardised, mobile-friendly format that can be
106   easily located, read and understood.

107   ## 1.2 Policy Statements

108   This document describes how Health Canada's Health Products and Food Branch (HPFB)
109   interprets the flexibility allowing for the use of a URL on Category IV products, mouthwash and
110   toothpaste as described in the *Good Label and Package Practices Guide for Non-prescription*
111   *Drugs and Natural Health Products (GLPPG)*[1].

112   ## 1.3 Scope and Application

113   Category IV products as well as mouthwash and toothpaste that limit information on the physical
114   label (as described in the GLPPG) are required to include either a patient insert or a URL linking
115   consumers to a complete Canadian Drug Facts Table (CDFT). The inclusion of a URL will be
116   optional for products that include a full CDFT on the physical label or within an insert. This
117   document outlines the parameters of how a standard Canadian Drug Facts Table will be provided
118   to the consumer via a URL in an eCDFT format. The scope of this document is limited to
119   technical standards associated with eCDFT.

120   This guidance must be used in conjunction with the GLPPG, the *Guidance Document: Drug*
121   *Facts Table for Non-prescription Drugs* and the relevant sections of other applicable Health
122   Canada regulations, guidance documents, and policies for non-prescription drugs. The GLPPG
123   outlines the formatting specifications to be applied by sponsors and the detailed implementation
124   dates for the Facts Table requirement.

125   The guidance document is intended to be used with the entire contents of the implementation
126   package that includes templates and style sheets for posting eCDFT on sponsor websites.

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[1] http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2016-label-package-practices-pratiques-etiquetage-emballage-non/index-eng.php

127 **1.4 Background**

128 The *PLL Regulations* aim to improve the safe use of drugs by making drug labels and packages
129 easier to read and understand For non-prescription drugs and contact lens disinfectants, the PLL
130 regulations will apply as of June 13, 2017 and impose new obligations on sponsors to include a
131 standard Facts Table on the outer label. Following extensive consultation with the non-
132 prescription drug industry, a series of progressive design, layout and content flexibilities are
133 available to sponsors to reduce the need to increase package sizes or introduce innovative labels
134 to comply with the new this facts table requirement. Linking consumers of Category IV products
135 as well as mouthwash and toothpaste to point of use information via a URL is one such
136 flexibility.

137 The principles to be respected in making the standard CDFT available to consumers via an
138 electronic format are as follows:
139 • Readable
140 • Factual/non-promotional
141 • Accessible
142 • Mobile friendly
143 • Built on an Open standards
144 • Multilingual
145 • Consistency

146 **2. TECHNICAL REQUIREMENTS FOR ELECTRONIC CANADIAN**
147 **DRUG FACT TABLE**

148 **2.1 URL (Uniform Resource Locator) conventions**
149 Uniform Resource Locators (URL), more commonly known as a web address, are a reference to
150 a web page and a mechanism for accessing it.

151 An eCDFT URL is a URL printed on the physical label of a non-prescription drug, directing
152 consumers to a location at which they can view a complete CDFT. A meaningful eCDFT URL
153 needs to be:
154 • User-friendly: using words rather than a series of numbers or random alphanumeric
155   characters.
156 • Not too long, and be easy for the consumer to enter in a browser.
157 • Bilingual.

158 **2.1.1 Selecting or Deciding on an Appropriate URL Convention**
159 Multiple URL conventions are provided for sponsors to address different market and logistical
160 realities. For example, although the choice of a brandname in the URL may be appropriate for
161 some products, it may not be a good fit for others due to length and complexity of a brand name

162   containing multiple chemical names. There are six different approaches available for selecting an
163   appropriate URL naming convention:

164   1. Canadian DINholderwebsite.ca(com)/brandname
165   2. Canadian DINholderwebsite.ca(com)/search and DINholderwebsite.ca(com)/recherche -
166   3. Canadian DINholderwebsite.ca(com)/info
167   4. brandname.ca(com)/cdft (for English) and brandname.ca(com)/tcim (for French)
168   5. brandname.ca(com)/search and brandname.ca(com)/recherche
169   6. brandname.ca(com)/ info

170   The scenarios presented in the table below should be considered in choosing an appropriate URL
171   convention :

Scenario	Suggested approach
Brand name length is greater than 10 characters	Use info or search URL
Brand name contains multiple ingredients	Use info or search URL
DINholderwebsite.ca(com)/search, or brandname.ca(com)/search already exists	Use info or cdft URL
there are multiple variants of a particular drug (such as for children, different drug strength, etc)	Use info URL

172

173   **2.1.2 Canadian DINholderwebsite.ca(com)/brandname, or brandname.ca(com)/cdft**
174   **guideline**
175   These are considered the default approaches. It uses the brand name or product name to take the
176   consumer directly to the eCDFT. It should be used if the brand name is relatively small (less than
177   10 characters) and easy to enter.

178   An example of this URL could be: https://www. http://DINholdercompany.com/ lozenge

179   **2.1.3 Canadian DINholderwebsite.ca(com)/search and**
180   **DINholderwebsite.ca(com)/recherche, or brandname.ca(com)/search and**
181   **brandname.ca(com)/recherche**
182   Most consumers are familiar with search feature and how to use it. As such this approach is a
183   good fit for longer or complicated brand names.

184   Examples of this URL could be: https://www.pharmacompany.com/search and
185   https://www.pharmabrand.ca/recherche

186   It is important to note that the search results should have URLs that are language appropriate.
187   They should either be bilingual or be in the language that the consumer intiaited the search. For
188   example, if the consumer searches in French, the page containing the eCDFT for the searched
189   drug should have URL that is either bilingual or in French.

190   **2.1.4 CanadianDINholderwebsite.ca(com)/info, or brandname.ca(com)/info guideline**
191   Ideal for brands with multiple line extensions. This approach using search functions provides
192   multiple mechanisms for accessing an eCDFT.

193   Example of this URL could be: http://www.DINholderwebsite.ca/info

194   It is important to note that the results should have URLs that are language appropriate. They
195   should either be bilingual or be in the language that the consumer intiaited the search . For
196   example, if the consumer searches in French, the page containing the eCDFT for the searched
197   drug should have an URL that is either bilingual or in French.

198   **2.1.5 URL Choices for Private Label Products**
199   For private labels, it is recommended to use the search approach i.e. Canadian
200   DINholderwebsite.ca(com)/search or CanadianDINholderwebsite.ca(com)/recherche

201   **2.1.6 URL placement**
202   The CDFT format specifications[2] do not prescribe a specific location for a user-friendly URL.

203   **2.2 Use of two-dimensional (2D) barcodes**
204   Category IV products as well as mouthwash and toothpaste that limit information on the physical
205   label (as described in the GLPPG) and do not include an insert, are required to include a URL
206   linking consumers to a complete CDFT. In addition to a URL, sponsors are permitted to include
207   a two dimensional bar code. A 2D barcode cannot be a replacement for a URL.

208   Automatic identification and data capture (AIDC) refers to the method of automatically
209   identifying objects, collecting data about them, and entering them directly into computer
210   systems, without human involvement. Barcodes represent one such example of this technology.

211   2D barcodes (for example QR codes) store information in a 2D pattern of black and white
212   squares. These 2D patterns are able to store more information per unit area than a 1-dimensional
213   barcode. With the aid of a scanning device, such as a scanning application on a mobile phone,
214   the matrix 2D barcode can be converted into a URL for a website. This offers consumers an
215   alternative means of accessing a website other than manually typing the URL into a browser.

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[2] http://www.hc-sc.gc.ca/dhp-mps/pubs/medeff/_guide/2016-label-package-practices-pratiques-etiquetage-emballage-non/index_longdesc12-eng.php

216 If a sponsor chooses to use a matrix 2D code, the following recommendations should be
217 considered:

- 218 The information contained within the automated identifier should not be considered a
  219 substitute for providing all required information directly on inner and outer labels.
- 220 Legibility and readability of key information on the label should not be impeded by the
  221 presence of the matrix 2D barcode.
- 222 Information embedded within the matrix 2D barcode should not include anything other
  223 than approved product information; be non-promotional in nature; and be focused on
  224 taking the consumer to the brand name specific page for the eCDFT.
- 225 Information contained in the eCDFT accessible via the matrix 2D barcode must be
  226 compliant with the regulatory requirements.
- 227 Sponsors should ensure that quality assurance processes are in place, including
  228 verification of the accuracy (e.g., the right barcode appearing on the right label) and
  229 readability of automated identifiers on health product labels.
- 230 Sponsors should ensure patients are aware that by accessing 2D barcodes with their
  231 mobile phones their personal information may be exposed or collected (e.g., location,
  232 purchases, spending habits). Sponsors are therefore advised to consider their obligations
  233 under *The Personal Information Protection and Electronic Documents Act (PIPEDA).*

234 **2.2.1 2D Barcode to brand name specific page or for accessing individual eCDFT**
235 Sponsors should consider including a callout near the 2D barcode to make consumers aware of
236 what the 2D barcode will do once scanned; For example, 'Scan here to go to [insert brand page
237 url]'.

238 **2.2.3 2D Barcode code placement**
239 The CDFT format specifications do not prescribe a specific location for a 2D code. However, the
240 following recommendations should be considered:

- 241 The location of the 2D barcode should take into account the overall readability of the
  242 labeling.
- 243 The inclusion of a 2D barcode should not compromise the readability of prescribed
  244 information and should be located in an area with minimal or no impact on readability.
- 245 Inclusion of more than one 2D barcode is not recommended.

246 **2.3 Technical approaches for accessing individual eCDFT via Search Functions**

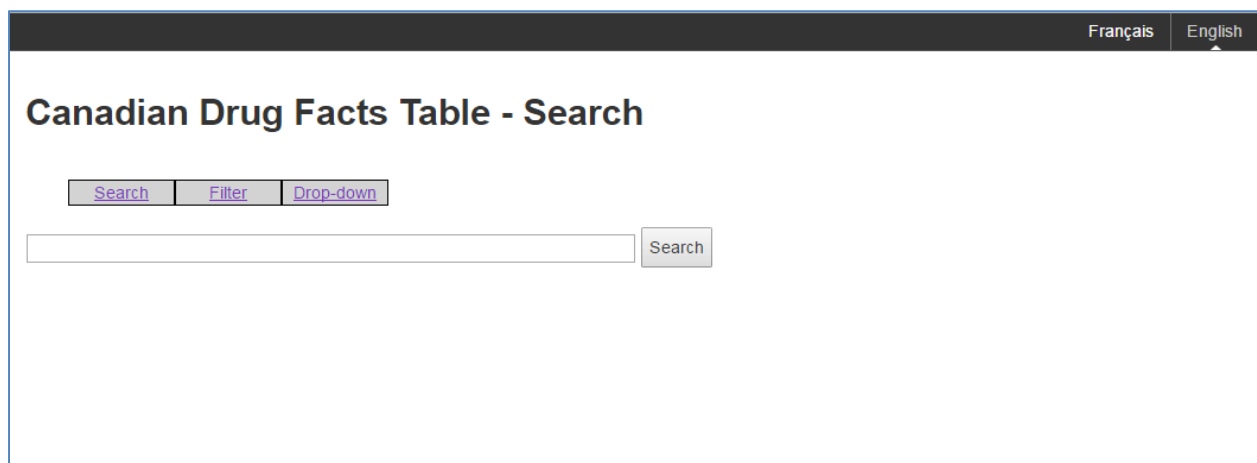247 **2.3.1 Search page**
248 When a URL does not link directly to an individual eCDFT, search functions must be used to
249 direct consumers in an intuitive and seamless manner to the relevant information. This process
250 should not require more than three "clicks" and contain one or more mechanisms for navigating
251 to a product-specific eCDFT, including text search, filter, and drop down menu.

252 The search page should use the following URL formats: DINholderwebsite.ca(com)/search and
253 DINholderwebsite.ca(com)/recherche, or brandname.ca(com)/search and
254 brandname.ca(com)/recherche. The other acceptable form is DINholderwebsite.ca(com)/info
255 (the consumer can select "Search" or "Recherche" from the menu).

256 The content of the search page must be language appropriate. They should either be bilingual or
257 be in the language that the consumer initiated the search or accessed the page. For example, if
258 the consumer visits http://www.Canadian DINholderwebsite.ca(com)/recherche, the content
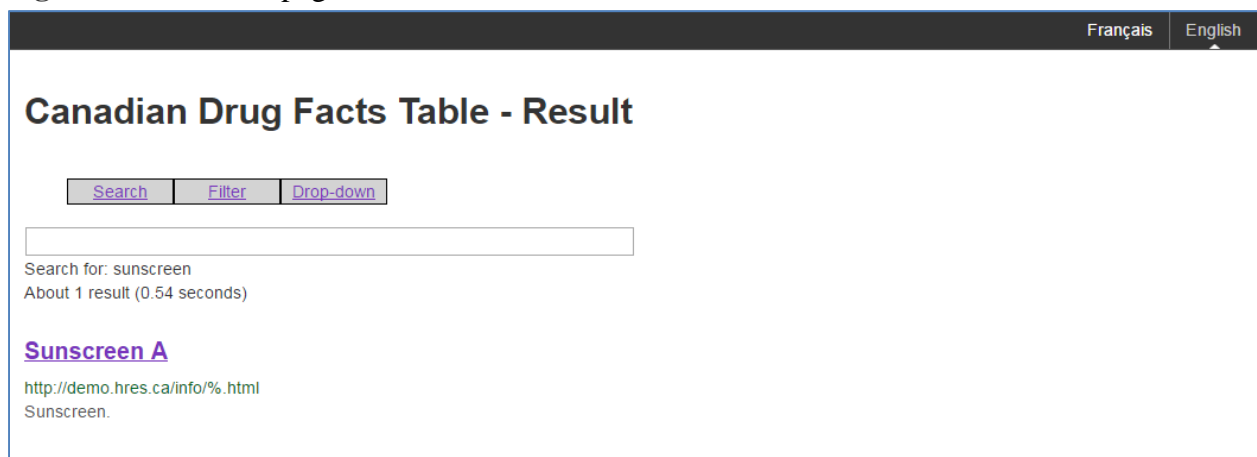259 should be in French.

260 The main search page will contain a simple search such as in Figure A.

261 **Figure A:** Search page

262
263
264 Consumers can search for a particular brand name and the search will display the closest
265 matching eCDFT.

266 **Figure B:** The result page associated with a search

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268
269

270   Any search should result in accessing an eCDFT. **The search mechanism should only search**
271   **for eCDFT, it should not search for other website content or company information.**

272   **2.3.2 Filter for brand name**
273   The filter page is accessed via: DINholderwebsite.ca(com)/info or brandname.ca(com)/info. The
274   consumer can select "Filter" or "Filtrer" from the menu.

275   The filter page will list all brand names.

276   **Figure C:** Filter mechanism

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280   The text box will allow the brand names to be filtered on the value the consumer has entered.

281   **Figure D:** Filtering for a particular brand name

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283
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285   **2.3.3 Drop down menu for brand name**
286   The filter page is accessed via: DINholderwebsite.ca(com)/info or brandname.ca(com)/info. The
287   consumer can select "Drop-down" or "Menu déroulant" from the menu.

288   The consumer can select the brand name from a drop down.

289   **Figure E:** Drop down mechanism.

290
291
292

293   **Figure F:** Selecting a particular brand name using the filter mechanism

294
295
296

297   By clicking on "Search" or "Recherche", the consumer will be taken to the eCDFT for the
298   selected brand name.

2.4 WET publication template

300   The Web Experience Toolkit (WET)[3] is a front-end framework that is used to provide accessible,
301   usable, multilingual and mobile-friendly websites.

302   Each sponsor will be provided access to the followingWET templates:
303   -   Search page
304   -   Results page
305   -   Filter page
306   -   Drop-down page
307   -   eCDFT content page

308   Per the GLPPG and the Guidance Document: Drug Facts Table for Non-prescription Drugs, the
309   eCDFT content must use plain language and must not be combined with additional non-approved
310   statements that are promotional in nature. If eCDFT are being used, the Health Canada approved
311   template files must be used.

2.4.1 Using search page template

313   The search page has an input button labelled "Search" or "Recherche". The HTML associated
314   with the button is:

315   `<input value="Search" aria-label="Search" name="btnK" onClick="document.location.href='result.html';" type="submit">`

316   The onClick should be redirected to the actual search mechanism which will search for the
317   appropriate eCDFT. The technology to use for the search mechanisms is outside the scope of this

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[3] The Toolkit can be found here https://wet-boew.github.io/v4.0-ci/docs/start-en.html

318   document. It is left to the sponsor to determine what programming language stack to use (e.g.,
319   .Net, LAMP, Java) and which technological tools (e.g., ElasticSEarch, Solr, HubbleDoNet) if
320   any, they prefer.

321   The results of the search should be presented in a results page such as Figure G.

322   **Figure G:** The result page associated with a search

323
324
325

326   The result page should have the following results presented dynamically:
327   • search query
328   • number of results (and optional query search time)
329   • brand name that is a link to the eCDFT of the brand name
330   • URL to the eCDFT of the brand name
331   • purpose of the drug

332   An example of the dynamic result would be:

333   ```
       <p>Search for: Brand name
334
About 1 result (0.54 seconds)
335   </p>
336
337   <h3>Brand Name</h3>
338   <div class="search_link">http://www.DINholderwebsite.ca/brandname.html</div>
339   <div class="search_result">Fever and pain relief medication.</div>
       ```

340 **2.4.3 Using filter for brand name template**

341 The filter page can be dynamically generated or can be manually updated as changes are

342 required.

343 The following code needs to be added for each eCDFT:

344 <div class="wrapper"><span class="medicine"><a href="brandname.html">Brand

345 name</span></a></div>

346

347 Where "brandname.html" is the filename of the eCDFT HTML file.

348

349 The added code needs to be inside of the gs_lc0 div, below the search input element.

350 An example of the content could be:

```
351    <div id="gs_lc0">

352        <input id="search" maxlength="2048" name="q" autocomplete="off" title="Search" value="" aria-label="Search"
353    aria-haspopup="false" role="combobox" aria-autocomplete="both" dir="ltr" spellcheck="false" type="text">

354        <div class="wrapper"><span class="medicine"><a href="brandname.html">Brand name</span></a></div>

355    </div>
```

356 **2.4.4 Using drop down for brand name template**

357 The drop down page can be dynamically generated or can be manually updated as changes are

358 required.

359 Each brand name should have an option element which specifies:

360 * filename of the eCDFT HTML file

361 * the brand name

362 An example of the content would be:

```
363    <select id="brand" class="entry-box"">
364        <option value"All">All</option>
365        <option value="brandname.html">Brandname</option>
366    </select>
```

367 Where "brandname.html" is the filename of the eCDFT HTML file and

368 "Brandname" is the brand name.

369 **2.4.1 Using eCDFT content template**

370 The content template is used to create an eCDFT for a particular brand name. The French and

371 English version of each brand must follow the requirements established for the standard CDFT.

372 The "Date modified" field should be updated each time there is a change.

373 The content pages can be dynamically generated or can be manually updated as changes are
374 required.

375 Clicking on the language button on the upper right hand side must toggle the language between
376 English and French

377 *2.4.1.1 Name of drug in page header*
378 The eCDFT must not be combined with additional non-approved statements . As such, it is
379 permissible to list the drug name in the header of the eCDFT only.

380 The format of the header should be "Canadian Drug Facts Table - BRAND NAME" where
381 "BRAND NAME" is the proprietary name (or product name, if there is no brand name).

382 **2.4.5 Use of pictures/images/branding**
383 Sponsors are permitted to include an image of the currently approved principal display
384 (branding) panel on the eCDFTpage below the Drug Facts title i.e. Drug Facts Table –BRAND
385 NAME), as long as the image is accurate, truthful and not misleading. No other promotional
386 content in the form of logos, wording or images are permitted. An example of using the brand
387 picture is in Figure H.

388 **Figure H:** Example of permissible brand picture

389

390 **2.5   Using a third party**
391 In some cases, Canadian DIN holders may choose to contract the services of a third party to host
392 their eCDFTs. It is important to note that contracting a third party to host the eCDFT does not
393 change the sponsors regulatory obligations. Sponsors are still accountable for ensuring their
394 eCDFT is compliant with the regulations regardless of its location or the host.

395 The PLL Regulations also apply to the eCDFT content hosted by the third party. In particular,
396 this also means third party's are subject to the rules on branding (e.g., the eCDFT is to be devoid

397   of any branding or promotional material other than what is prescribed); and redirection (e.g.,
398   consumers should be brought directly to the eCDFT).

399   ## 3. IMPORTANT CONSIDERATIONS WHEN PREPARING ELECTRONIC
400   ## CANADA DRUG FACTS TABLE

401   **3.1 Accessibility considerations**
402   Accessibility of content for all users is an important consideration when creating web content.
403   While much of the web template is already accessible, there are some content considerations
404   when making accessible pages, following the level AA standard of the World Wide Web
405   Consortium (W3C) Web Content Accessibility Guidelines (WCAG)[4]

406   **3.2 Non-text Content**
407   From the WCAG principle 1.1.1:"All non-text content that is presented to the user has a text
408   alternative that serves the equivalent purpose."

409   For the eCDFT, the product image, if included, must be descriptively labelled to help visually
410   impaired consumers. This achieved by appropriately labelling the image using the alt tag in the
411   template with an appropriate description. Examples of appropriate labelling include:

412   "Primary Label of < full drug name>"

413   "Image of <drug name /strength > in blue container"

414   "Image of <brand name> <drug name> <size>"

415   **3.3 Sensory Characteristics**
416   From the WCAG principle 1.3.3: "Instructions provided for understanding and operating content
417   do not rely solely on sensory characteristics of components such as shape, size, visual location,
418   orientation, or sound."

419   Any information conveyed on the web page should not rely solely on visual cues such as:
420   - "as shown below",
421   - "as per the next section "
422   - "as described in the red (text)"

423   Information should either appropriately describe the information or provide programmatic links
424   to the content. Since the location of the content can vary, identification based on location is best
425   avoided.

426   **3.4 Language of Parts**

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[4] https://www.w3.org/TR/WCAG20/

427　From the WCAG principle 3.1.2: "The human language of each passage or phrase in the content
428　can be programmatically determined except for proper names, technical terms, words of
429　indeterminate language, and words or phrases that have become part of the vernacular of the
430　immediately surrounding text."

431　The template, by default has a language tag set at the beginning of the web page (the language of
432　the page, WCAG principle 3.1.1). If there is no change in language no further action is required.
433　If however, another language is used anywhere in the template that differs from the base page
434　language, it would need to be identified by the appropriate language identifier. For example, the
435　French language selection on the English template is the following:

436　Français

437　Identifying the language allows screen readers to correctly pronounce the words in the intended
438　language.

439　4.　SUBMISSION PROCESS

440　During the filing of a submission, there should be a placeholder for the URL. For the content of
441　the URL, a "standard CDFT" must be submitted at the time of filing.

442　Activation of the URL is not required at the time of submission filing, but must be live at the
443　time of marketing the product so that consumers can access it at the time of purchase. The URL
444　can only be activated once the "standard CDFT" is approved by HC.

445　There is no requirement to make a submission for the review of the live-URL.