

Rx DTx Compendia Submission & Tracking

Similar to pharmaceuticals and medical devices, digital therapeutic products need to be included in pricing compendia in order to be integrated into the full healthcare system from provider to payor to pharmacy workflows.

Submission timelines vary but generally take between several days to several weeks if approved.

This checklist serves as a guide to compendia requirements but each compendia is subject to their individual policies.

Required Documents

- GS1 Company Registration:
 - Client must be registered with GS1
 - Company will be visible on GS1 Website (<https://gepir.gs1.org/>)
 - Acquire a Company Prefix
 - If the company has an FDA Labeler Code, ensure it is incorporated into the GS1 Company Prefix when requesting Company Prefix (<https://www.gs1.org/standards/id-keys/company-prefix>)
- UDI product creation: Once the GS1 company prefix has been established, you must:
 - Create your UDI/GTIN product identifier(s)
 - Update artwork files with UDI/GTIN details (if applicable)
- GUDID product upload:
 - Product must be listed with the GUDID (NLM database)
 - Submit to GUDID: <https://www.fda.gov/medical-devices/global-unique-device-identification-database-gudid/submit-data-gudid>
 - Access GUDID: <https://accessgudid.nlm.nih.gov/>
 - This task will be completed by the Labeler
- FDA Letter of Designation:
 - Software Only
 - Device Only
 - Includes Both
 - List components (if applicable)

Product Labeling:

- Brand Name
- Label Name (Product Name & Attributes)
- Barcode details and image(s)
 - GTIN12
 - GTIN14
 - UDI

 Product Information:

- Operating system: iOS, android, or both
- Instruction for use (IFU)
- Clinical indication information (if applicable)
 - Age range
 - Duration of therapy
- Flyers/posters
- Users manual
- Image of product
- Identify the intended use (for classification purposes)
- Identify all Product Codes/SKUs
- Identify if Prescription Use Only (Rx or OTC)
- Pricing Information Required (Price Type to be submitted)
- Launch Date

 Authorized Distributors:

- Is Pharmacy involved (adjudication/processing)?
- Limited Distribution Pharmacy? (y/n)

 Submission Form (sample):

- Company Name
- Contact Name
- Contact Telephone Number
- Contact E-mail
- Product Code ID
 - GTIN/UDI/UPC Number
 - NHRIC (if applicable)
- Product Name
- Package Size
- Dosage Form
 - Application
 - VR Headset
 - Kit
 - Other
- Rx or OTC
- Wholesale Acquisition Cost
- Direct Price
- Suggested Average Wholesale Price
- Effective Date
- Product Physical Description if not provided in package insert or label (if applicable)

Version Tracking: *Compendia must be notified when an update is significant enough to require a change in UDI. It is at the discretion of each compendia, their editorial policy and ability as to whether products can be linked.*