

General Chapter <7> *Labeling* Updates PNP Stakeholders Forum

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General Chapter <7> Labeling



Status Since March 2020



*Commentary also posted

Updates to General Chapter <7> *Labeling*



- ▶ Updates to GC <7> that were published on July 31, 2020
 - Expiration date formats clarified: 4-digit year placed at the beginning of all formats
 - Provision for small containers
- ▶ Expiration date punctuation: dashes or forward slashes

Expiration Date Formats



▶ Acceptable formats

All-numeric

- YYYY-MM-DD (e.g., 2019-06-30, 2019/06/30)
- YYYY-MM (e.g., 2019-06, 2019/06)

Alphanumeric

- YYYY-MMM-DD (e.g., 2019-JUN-30, 2019/JUN/30)
- YYYY-MMM (e.g., 2019-JUN, 2019/JUN)

Small Containers



For containers that have insufficient space on the primary container to accommodate the full expiration date format described previously (e.g., topical ophthalmic ointment container crimps, blow-fill-seal ampules), use the all-numeric format YYYY-MM or the alphanumeric format YYYYMMM (without a hyphen or forward slash to accommodate space constraints). If there is a lack of space in close proximity to the expiration date, the term designated to represent “expiration date” (e.g., EXP) may be omitted if the specific alphanumeric format, YYYYMMM, is used. However, all other packaging, including but not limited to a carton, tray, or overwrap, must have the full expiration date format as described previously. ▲ (IRA 1-Sep-2023)

Small containers: YYYY-MM or YYYYMMM



- ▶ Nomenclature & Labeling Expert Committee created a [document](#) to explain the updates to the expiration date format
 - ▶ Patient safety concerns
 - Data provided by the Institute for Safe Medication Practices (ISMP) National Medication Error Reporting Program
 - ▶ Harmonization with ISO formats



Resources

- ▶ [Rationale Document](#)
- ▶ [GC <7> Commentary](#)
- ▶ [Nomenclature & Labeling Work Plan Page](#)
- ▶ [General Chapter <7> *Labeling* Web Page](#)
- ▶ NomenclatureSL@USP.org
- ▶ Sign up for [USP Healthcare Quality Standards Updates](#)

Questions



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Thank You



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