Core Patient Labeling and Core Labeling for Non-Prescription Drugs, Devices and Nutraceuticals

Barbara J Fanelli
Gerrit-Jan Nijveldt

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Core Labeling

- Discussed so far - “core labeling” for medicinal products for healthcare professionals.

- What about core labeling for the following:
  - Patient Information
  - Medical Devices
  - Non Prescription Products “OTC”
  - Nutraceuticals

Is Core labeling possible? And does it add value?

Core Labeling

Patient Information
Medical Devices
Non Prescription Products “OTC”
Nutraceuticals
Core Patient Labeling

Patient labeling for prescription products is information for the patients/consumers concerning the safe and effective use of the product.

– It should:
  • be based on the country’s physician labeling.
  • contain the information needed to properly use the product
  • provide information regarding any safety or compliance concerns when using the product.
  • Be written at a 5th or 6th grade (11 to 12 years of age) reading level to help with comprehension of the information.

• Examples of Major Countries/Regions with “mandatory” patient labeling:
  – Canada: part 3 of the Product Monograph (only mandatory for new drugs)
  – EU: Package Leaflet (CP: Annex IIIb)
  – US: Medication Guide
  • US – Not for all products (PPI used but not mandatory)
Core Patient Labeling - Yes

- Can be similar to CCDS process
- Company Core Patient Information document, or
- Can be part of the product’s CCDS

In both cases should contain the mandatory patient text regarding indications, dosage and any safety information.

Experience: Limited, but growing
Core Patient Labeling - No

- As patient labeling is based on the country’s physician labeling
  - Would there be a need to prepare core patient labeling that may provide the information differently than the country’s physician labeling?

Core Labeling

- Patient Information
- Medical Devices
- Non Prescription Products “OTC”
- Nutraceuticals
Device - What is it??

**EU definition:**
any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human …
...and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

**US definition:**
• A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
• recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
• .../...
• and which does not achieve any of its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.


Devices – Labeling?

**Issue:**
• Compared to medicinal products there are fewer labeling guidances for medical devices.

• The instructions are often far less detailed than medicinal products
Subpart A--General Labeling Provisions
Sec. 801.5 Medical devices; adequate directions for use. Adequate directions for use means directions under which the layman can use a device safely and for the purposes for which it is intended.
Section 801.4 defines intended use. Directions for use may be inadequate because, among other reasons, of omission, in whole or in part, or incorrect specification of:
(a) Statements of all conditions, purposes, or uses for which such device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the device is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.
(b) Quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions.
(c) Frequency of administration or application.
(d) Duration of administration or application.
(e) Time of administration or application, in relation to time of meals, time of onset of symptoms, or other time factors.
(f) Route or method of administration or application.
(g) Preparation for use, i.e., adjustment of temperature, or other manipulation or process.

EU Devices Directive

COUNCIL DIRECTIVE 93/42/EEC
of 14 June 1993
concerning medical devices

THE COUNCIL OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Economic Community, and in particular Article 100a thereof,
In cooperation with the European Parliament (OJ No C 150, 31.5.1993 and OJ No C 176, 23.8.1993),
Having regard to the opinion of the Economic and Social Committee (OJ No C 79, 30.3.1992, p. 13).

EU Devices Directive - 2

Labeling mentioned in section 13:

- As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.
- Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.
  Note: e.g. insulin pens are class IIb

Device Labeling

- Is Core Labeling needed and where (and when) do you start?
Core Device Labeling - Yes

- The CCDS structure can be followed. Depending on the type of device, this can be done for healthcare providers and/or for patients. In general it will be text for patients.

- In the latter case the core label will look different because it should be written in simpler language (reading level: 5 to 6th grade)

Core Device Labeling

- Reading comprehension testing should be included in the development plans; e.g.,
  - Human factor testing in the US
  - Readability testing in the EU
Core labeling Devices

Possible solution

Core Labeling – Solution

Device Core Label

Mandatory Concept

Mandatory format

Note to translators

Pictures

Mandatory message or wording

The way the leaflet is formatted is very important to the readability

Some text needs to be “localized”

If included these need to be country neutral and clear

Note to translators

Some text needs to be “localized”

If included these need to be country neutral and clear
Example make 2 slides

Pictures with words that need to be translated

Important information for use of McPen:

- Always attach a new needle before each use. Needles are manufactured for a single use in a single package. If more than one needle is required, add a new one to each syringe. For further information, contact your physician or pharmacist.
- Always perform the exercise: roll up before injection (see page 11).
- Always check the level of your drug before use.
- If you use different types of drug with McPen, you should use a different color pen for each drug. McPen is available in different colors.
- Take PBS in the mouth. Do not use it with an needle.
- If you are rinsing an injection to another person or if you inject a person with another drug that is not yours, please let your physician or pharmacist know. To avoid medical malpractice and potential liability issues.
- If you are not aware of the medication or if you are not sure of the dosage, please do not use McPen unless instructed.
- Always let your physician or pharmacist know if you are using McPen, especially if you are pregnant or breastfeeding.

Note for translator in red

Core Labeling

Patient Information
Medical Devices
Non Prescription Products “OTC”
Nutraceuticals
First what are non-prescription pharmaceutical products or “OTC products”?
- Medicines that may be sold directly to a consumer without a prescription from a healthcare professional

Regulations for labeling?
- vary among countries

TITLE 21--FOOD AND DRUGS CHAPTER I--FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES SUBCHAPTER C--DRUGS: GENERAL PART 201 -- LABELING
- Subpart C--Labeling Requirements for Over-the-Counter Drugs
- Sec. 201.66 Format and content requirements for over-the-counter (OTC) drug product labeling.
  - (a)Scope. This section sets forth the content and format requirements for the labeling of all OTC drug products. Where an OTC drug product is the subject of an applicable monograph or regulation that contains content and format requirements that conflict with this section, the content and format requirements in this section must be followed unless otherwise specifically provided in the applicable monograph or regulation.
• Is core labeling needed and/or possible?

– Issue: Format and content change across and among all countries
Core OTC Labeling – Solution

**OTC Core Labeling**

- **Mandatory Information with Optional Wording**
  - Wording will be based on local requirements
- **Optional Format**
  - The way the leaflet is formatted is very important to the readability; however must conform to local regulations
- **Note to translators**
  - Some text needs to be “localized”
- **Pictures**
  - If included these need to be country neutral and clear

Core Labeling

Patient Information
Medical Devices
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Nutraceuticals

What are nutraceuticals?
• A food or food product that provides health and medical benefits, including the prevention and treatment of disease.

Regulatory?
• Not subject to the same testing and regulations as pharmaceutical drugs

Nutraceuticals Core Labeling

• Core labeling could provide:
  – Minimum requirements for general information to be provided in the labeling
    • Standard naming convention
    • Standard presentation of strengths and quantities
    • Restriction of promotional claims
  – Standard requirements for listing of uses
  – Requirements for data to support any product claims
**Nutraceuticals Core Labeling**

**Issues:**

- Products differ throughout the world
- Guidelines differ throughout the world
- What is the basis for the claims?
- Labeling is short and promotional and not consistent among different manufacturers

**Summary**

- New categories for central core labeling would:
  - increase harmonization of product information worldwide
  - encourage harmonization of labeling regulations/guidances worldwide
  - mandate the need for supporting data for any claims
  - based on local requirements could initially be difficult to maintain consistency across regions
Summary

- But should it be tried?
  - Core Patient Labeling
  - Core Device Labeling
  - Core OTC Labeling
  - Core Nutraceutical Labeling