

# Patient Labeling Industry Perspective

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Global Regulatory Affairs (GRA) Labeling  
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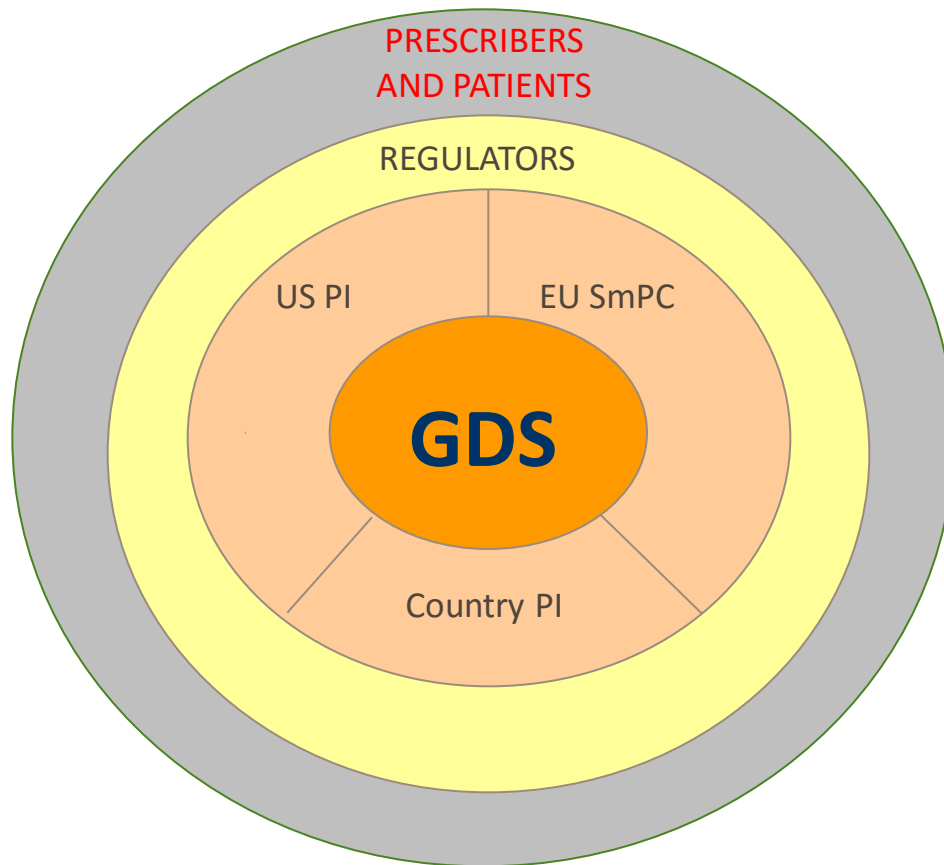
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***The views expressed in this presentation are my personal views and do not necessarily represent the views of GlaxoSmithKline***

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- Overview of Prescriber and Patient Labeling Development at GSK
    - Global Datasheet (GDS) and Local Labels
    - Labeling Development: Timing for prescribing and patient labeling
  
  - Industry Perspective on Challenges in Patient Labeling
    - Format and Content
    - Electronic availability
    - Instructions for Use/Devices
    - Simplicity
    - Timing of review
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# From the Global (Core) Datasheet to the Patient

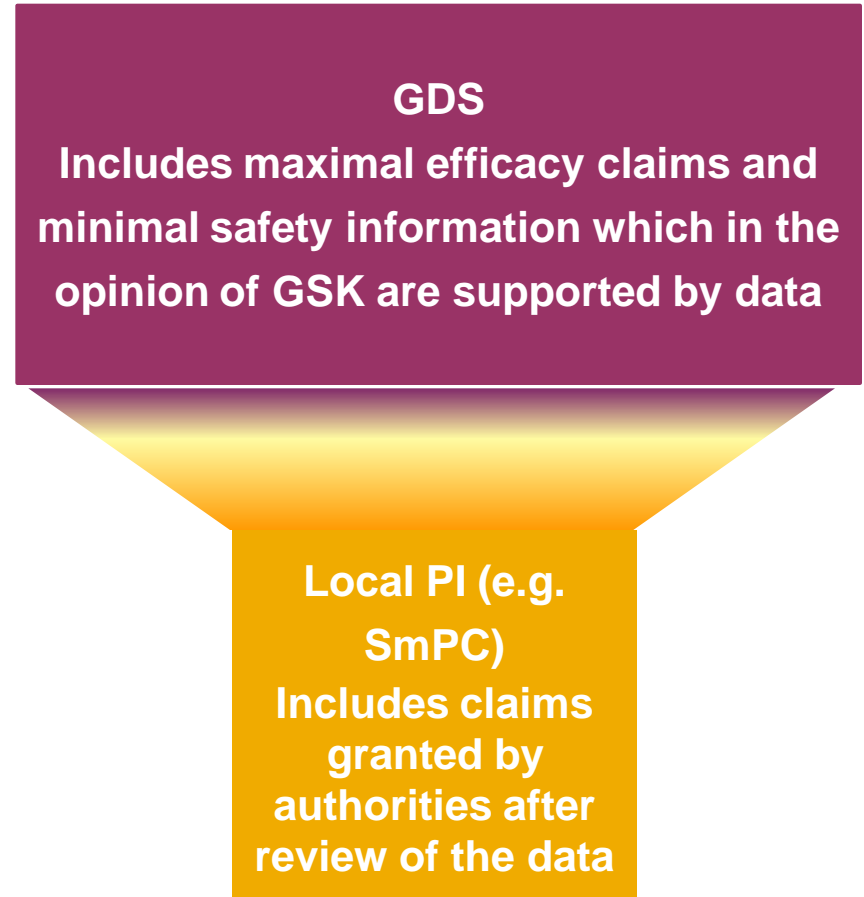
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# What is the Global (Core) Datasheet?



- The GDS is the company position
  - Internal document stating the **company's medical and scientific position** regarding the **safe and effective use** of a product, active ingredient or device
- It defines:
  - The **maximum efficacy claims** that can be made
  - The **minimum essential safety information** that must be included in the prescribing information worldwide
- Consists of 3 parts:
  - global prescriber information
  - **global patient information, instructions for use**
  - global packaging components



# Who creates the GDS?



- **Global Regulatory Affairs Labeling** creates and maintains GDS and local labels such as USPI in collaboration with functional experts
- Creation, update, closure of GDS is approved by **Global Labeling Committee (GLC)**.
  - must occur prior to any regulatory submission
- Key differences between a local label and GDS are approved by Global Labeling Committee as a **Country Local Difference**.

## Functional Experts



# Key Principles for Label Development

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- Drafting label requires understanding of the following
    - Target product profile
    - Competitor labeling (what are differentiators?)
    - Global strategy
    - Data available, supporting documentation
  - Start early!
    - Target label as early as Phase 1 (key concepts) but most often ~EOP2.
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# Patient Labeling

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- Patient labeling typically developed once full prescribing information draft is well advanced.
    - Patient Information Leaflet or Medication Guide
    - ~3-6 months prior to submission
  - Exception: Instructions for Use development starts much earlier as Human Factors Analysis may need to be done; included in the submission (CMC section).
  - Reviewed and signed off by team in conjunction with full prescribing information.
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# Challenges or Issues for Patient Labeling

## Industry Perspectives

# Patient Labeling Challenges

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## No prescribed U.S. format

- Template varies from company to company
  - GSK uses Q/A text format similar to MG for both MGs and PILs with exception of ‘What is the most important information...?’
  - Recent GSK approvals (MGs, PILs) of the ‘boxed format’
  - Use of a standardized format will require testing to identify the best template
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- GSK involvement in Patient Medication Information initiative with FDA/Brookings
    - ‘bubble’ example: Ventolin

# From this... ..to this



Don't let anyone else use your inhaler. Ask your pharmacist any questions you have about refilling your prescription.

1. Remove one vial of albuterol solution from the foil pouch. Leave the rest of the vials in the pouch until you are ready to use them.

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### Ventolin HFA (albuterol sulfate) Inhalation Aerosol (VEN - toe - lin)

**Uses**

- Ventolin HFA is a medicine used to:
  - Treat breathing problems or wheezing (bronchospasm) in people with lung diseases like asthma
  - Prevent asthma attacks caused by exercising

**Common Side Effects**

- Palpitations (fast or irregular heart beat)
- Chest pains
- Rapid heart beats
- Tremors
- Nervousness

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**Tell Your Doctor Before Using Ventolin HFA if you:**

- have had an allergic reaction to Ventolin HFA or to any ingredients in Ventolin HFA (e.g., albuterol)
- have heart disease, fast or irregular heart beats (arrhythmias) or high blood pressure
- have seizures (convulsions, epilepsy) or thyroid problems
- are pregnant or will be breast feeding
- are taking a monoamine oxidase inhibitor (MAOI) medicine, or any other antidepressant medication
- are taking any other asthma medications or any other medications

**How to Take**

- Take Ventolin HFA exactly as directed by your doctor.
- Do not take extra puffs of Ventolin HFA or take it more often than you were told without talking to your doctor.
- See the Instruction sheet on how to use and how to clean your Ventolin HFA Inhaler. The inhaler must be used correctly and kept clean to be sure that you are getting the right dose.

**When to Call Your Doctor Right Away**

- Call your doctor if:
  - it does not work as well in relieving your symptoms
  - you use 4 or more puffs for 2 or more days in a row
  - you use 1 whole canister in 8 weeks' time.
- If your breathing problems get worse right after taking Ventolin HFA, stop using it and get medical help right away.
- If you have an allergic reaction to Ventolin HFA (have a rash, severe problems breathing, swelling of the face or tongue), stop using Ventolin HFA and get immediate medical help.

**Need More Information?**

- This does not include all the possible risks. Ask your doctor, nurse or pharmacist for more information.
- Go to [www.ventolin.com](http://www.ventolin.com) or call 1-888-825-5249.

June 2012

## Content: Relationship between Highlights, Section 17, and patient labeling

- What is expectation of content in relationship to the PIL or MG?
  - Should all Warnings and Precautions be included in PIL or limited to significant W/P?
  - Should all information in Section 17 be covered in patient labeling?
  - Should only most common adverse reactions be presented similar to Highlights?
  - How much information is acceptable in Indications (ie., if mechanism of action is novel)?

# Patient Labeling Challenges



## Electronic Availability



**Costco PHARMACY** 814 895 1002 WARFARIN SODIUM 5MG TABLET TAR  
 PRICE \$6.99  
 RX 22845 N  
 83142011

**WARFARIN - ORAL**  
 COMMON BRAND NAME(S): Coumadin  
 Call your doctor for medical advice about this medicine. You may report side effects to FDA at 1-800-FDA-1088.

**CVS/pharmacy** 800-848-8111 WARFARIN SODIUM 5 MG TABLET  
 PRICE \$11.99  
 83142011

**GI PROMISED 05-31**  
 CVS/pharmacy 800-848-8111  
 COUNSEL  
 WARFARIN SODIUM 5 MG TABLET  
 TAKE 1 TABLET EVERY DAY  
 PRICE \$11.99  
 83142011

Please note that an important notice related to privacy of your personal healthcare information has been printed on the reverse of this receipt. Please review the provided information carefully.

CVS/pharmacy requests that you acknowledge receipt of this notice by signing the user's acknowledgment log or you may sign the coupon below and mail to the CVS Privacy Office at the address set forth on the Notice.

If you have any questions or concerns please first try to contact the CVS Privacy Office in writing or by calling 1-800-287-2414.

**CVS/pharmacy**  
 Acknowledgment  
 I have received CVS/pharmacy's Notice of Privacy Practices.  
 Signature: \_\_\_\_\_  
 Date: \_\_\_\_\_

Please check and return this Acknowledgment to your local CVS Pharmacy or to the address specified on the Notice.

**CVS/pharmacy**

- No central electronic repository
  - Would help industry benchmark
  - Allow for better readability
  - Provide alternative to paper (especially for pt labeling appended to PI in packaging)
  - XML availability for downstream use by other users
- What are plans going forward in relation to **PMI initiative** and Consumer Medication Information (**CMI**)?
- Proposed rule for electronic distribution of prescribing information currently excludes patient labeling

## Modifying Instructions for Use following approval. What is required?

- When is usability or user testing required?
- Does simplification or improvement of graphics require usability testing?
- What should be included in supporting package (e.g., summary of medication errors, product complaints)?

# Patient Labeling Challenges

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## Maintaining Simplicity: Creating clear patient labeling is harder than it looks

- Staying patient friendly without losing important context or precision
  - Staying within reasonable space limits
    - e.g., A good 2-page leaflet can be better than a crowded 1-page leaflet
  - Balance in IFU's between handling issues from Failure Mode Analysis adequately and keeping text and graphics simple and uncrowded
  - Companies may have challenges balancing brevity with legal concerns about content
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# Patient Labeling Challenges

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## Timing of Review of Patient Labeling

- Review of patient labeling comes at the very end of the review cycle
- Often 1-3 days prior to expected approval
- Comments may come from different parts of the Division
  - especially in case of IFU + patient labeling





**Q&A**