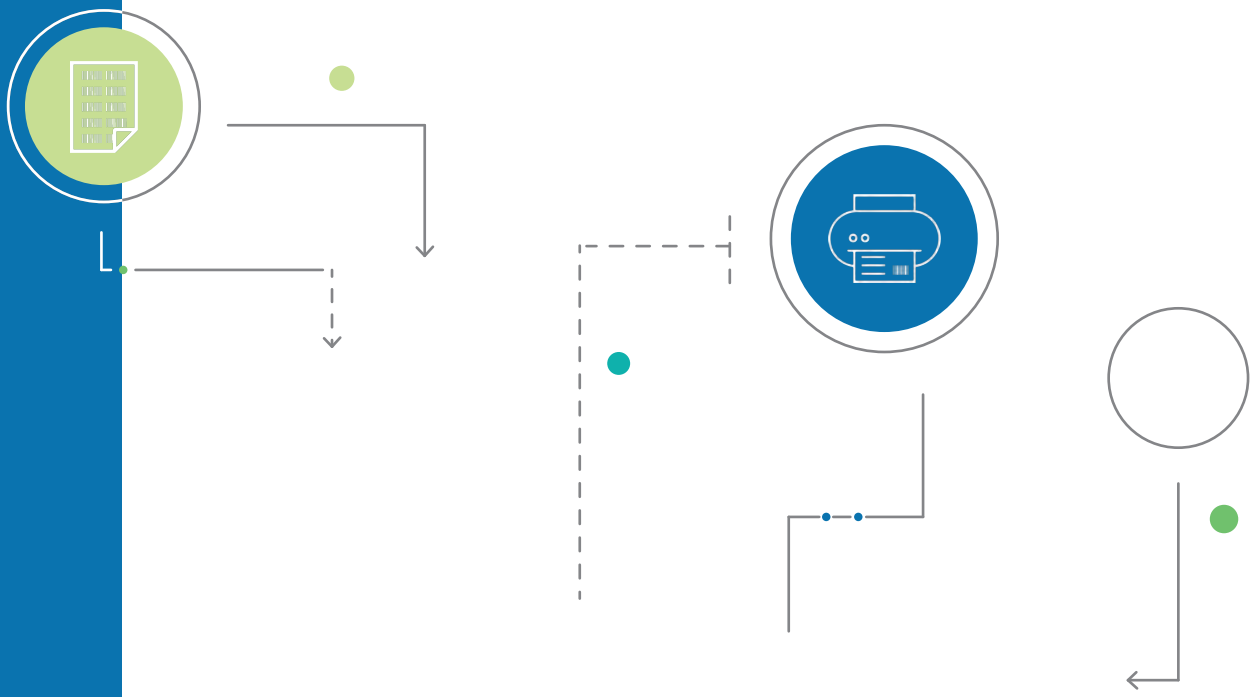

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U.S. Prescribing Information (USPI) & the Impact of Pediatric and Geriatric Guidance on Labeling

Ensure pharmaceutical labels are safe and effective for the pediatric and geriatric population through new guidance principles.

NUMBER ONE

Physician Labeling Rule (PLR)

The final rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 FR 3922, was published on January 24, 2006. This rule is commonly referred to as the Physician Labeling Rule (PLR) because it addresses prescription drug labeling that is used by prescribers and other healthcare professionals. It was not until February 2013 that the Labeling for Human Prescription Drug and Biological Products - Implementing the PLR Content and Format Requirements was finalized. The PLR is intended to organize prescription drug information to make it easier for health care professionals to understand.

The new pediatric and geriatric use information guidance on labeling in the U.S. Prescribing Information (USPI) impacts manufacturers by now requiring them to incorporate extensive information based on data available on:

· Specific risk or safety concerns

· Any limitations of use

· Differences in response (PK/PD data)

· Appropriate pediatric/geriatric use statements

· Geriatric exposure data

NUMBER TWO

Challenging Key Requirements of the Pediatric & Geriatric Use Labeling Guidance Documents

New Pediatric (patients aged 0 to 16 years, younger than 17 years) Use Information Requirements

In 1994, the FDA began the initiative to improve pediatric use information by issuing a final rule that revised the requirements of the pediatric use subsection. A few years later, pediatric legislations, Pediatric Research Equity Act (PREA) and Best Pharmaceuticals for Children Act (BPCA), were passed and made permanent in 2012. Data submitted under the BPCA and PREA must be described in labeling. Based on the final rule in 1994, the pediatric use labeling guidance recently became finalized (citations needed).

The guidance provides recommendations on the following subjects:

- Determining the appropriate placement and content of pediatric use information in labeling.
- Incorporating/rewriting pediatric information based on four scenarios:
  - The evidence supports safety and efficacy of the drug for pediatric use.
  - The evidence does not support safety and efficacy for pediatric use due to negative or inconclusive study results.
  - The evidence does not support safety and efficacy for pediatric use since the studies are not conducted or are ongoing.
  - The drug is contraindicated in pediatric patients.
- Content and condition for including juvenile animal toxicity data in the pediatric use subsection.

NUMBER TWO CONTINUED

Challenging Key Requirements of the Pediatric & Geriatric Use Labeling Guidance Documents

New Geriatric (patients aged 65 years or older) Use Information Requirements:

According to the 2013 census, 13% of the U.S. population was in the geriatric age group; it is estimated that by 2030, approximately 20% of the U.S. population (1 in every 5 Americans) will fall in the geriatric age group. Due to the increase in geriatric patients and limited clinical studies data available, it is difficult for health care professionals to make prescribing decisions. This issue has caused the FDA to emphasize the importance of obtaining geriatric patients' data across the entire age range.

These FDA initiatives and requirements in geriatric use labeling regulations lead to the introduction of the Geriatric Information in Human Prescription Drug and Biological Product Labeling Guidance for Industry, published in September 2020, that replaced the old guidance from October 2001.· Revising and updating the geriatric information in labeling based on the following scenarios:

The new guidance provides recommendation on the following subjects:

· Incorporating geriatric information from clinical studies in labeling.

· Determining the appropriate placement and content of geriatric use information in labeling.

· Geriatric exposure data.

Challenging Key Requirements of the Pediatric & Geriatric Use Labeling Guidance Documents

NUMBER TWO CONTINUED

· Revising and updating the geriatric information in labeling based on the following scenarios:

  · Insufficient information to detect differences in safety and/or effectiveness in geriatric patients compared to younger adults.

  · Based on sufficient data, no observed differences in safety and/or effectiveness in geriatric patients compared to younger adults.

  ·Based on sufficient data, observed differences in safety and/or effectiveness in geriatric patients compared to younger adults.

· Including specific risks, safety concerns, and specific monitoring required for the geriatric patients.

· Impact of geriatric use subsection on the following sections of labeling:

  ·Dosage & Administration

  ·Warnings and Precautions

  ·Adverse Reactions

  ·Clinical Pharmacology

  ·Clinical Studies

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NUMBER THREE

Achieve Compliance with Network Partners

To meet regulatory labeling requirements, FlexPro's team of elite subject matter experts provide support in converting old format labeling into the new PLR format that is compliant with the new pediatric and geriatric use guidance documents.

Regulatory support related to label submissions are:

- Support for strategy and preparation, including:
  - Initial submission
  - Amendments
  - Associated change control activities
  - Compliance initiatives
- Draft and review of clinical and post-market labeling, including:
  - U.S. Prescribing Information (USPI)
  - U.S. Medication Guide (MedGuide)
  - Patient Package Insert (PPI)
- Subject Matter Expert consulting on recent and upcoming global requirements to meet your needs.

Contact a Partner today to discover how FlexPro achieves regulatory compliance right the first time.