



Writing a Dear Healthcare Professional Letter

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A Dear Healthcare Professional (HCP) Letter is a risk communication tool that is often included as an element of a Risk Evaluation and Mitigation Strategy (REMS) Communication Plan. The Dear HCP Letter highlights important safety information related to prescribing and dispensing the product and actions the HCP can take to help ensure appropriate use. It complements other REMS educational tools, as well as the approved Full Prescribing Information.

The Dear HCP Letter should include an overview of medication risks; roles of different stakeholders; key steps in patient selection, monitoring, and management; patient counseling; and references to other REMS tools and resources.

The Dear HCP Letter is intended for HCP stakeholders identified as the targeted HCP audience in the Communication Plan section of the Proposed REMS and REMS Supporting Document. This may include, but not be limited to, specialist and/or generalist physicians, nurse practitioners, physician assistants, medical educators, and pharmacists.

The length of the Dear HCP Letter can vary, but it is typically between one (1) and three (3) pages long, excluding attachments. It should be a succinct, relevant document that does not place undue burden on the HCP.

Source Documents

The following documents are useful resources for developing the Dear HCP Letter:

- Prior examples of Dear HCP Letters (approved Letters are preferred, if available).
- Full Prescribing Information (approved FPI is preferred but, if not available, may use latest draft)
- Summary of Clinical Safety (SCS)/Integrated Summary of Safety (ISS)
- Summary of Clinical Efficacy (SCE)/Integrated Summary of Efficacy (ISE)
- REMS Documents (Proposed REMS and REMS Supporting Document), particularly the sections on REMS Goals and Objectives
- Other REMS tools, such as a Prescriber Brochure

Use in Regulatory Documentation

Content of the Dear HCP Letter should be consistent with the corresponding descriptions in the Proposed REMS (Section II.B. Communication Plan) and REMS Supporting Document (Sections on Communication Plan and Information Needed for Assessments). The Dear HCP Letter is included as one of the Appendices to the Proposed REMS.

Structure of a Dear HCP Letter

Introductory paragraph

- Identify the brand name, generic name, and approved indication
- State the purpose of the Letter (e.g., to highlight important safety information for prescribing and dispensing the product and actions the HCP can take to ensure appropriate use)

About the Product

- Identify the active ingredient and mechanism of action
- Briefly summarize evidence of clinical efficacy, recognizing the focus of the Letter is on safety risks
- Briefly describe the identified and/or potential safety risk(s) to be mitigated by the REMS, signs and symptoms, etc., and how the risk was characterized
- Briefly describe the occurrence of the identified and/or potential risk(s) associated with approved uses of the product (if pertinent)

About the Risk Evaluation and Mitigation Strategy (REMS)

- Briefly describe, in general terms, how the REMS will assist the stakeholder with ensuring that the benefits of therapy outweigh the risks; i.e., how the REMS will mitigate the identified and/or potential risk(s)
- Outline the desired activities and behaviors for each stakeholder (e.g., what prescribers, pharmacists, and patients need to do)
- Describe any counseling instructions that need to be provided to the patient

Additional Sources of Safety Information

- Reference and attach other important safety information about managing the identified and/or potential risk(s)
 - Full Prescribing Information
 - Other REMS tools (e.g., Medication Guide, Prescriber Brochure)

Reporting Adverse Events

- Include contact information for reporting adverse events to the sponsor and the FDA (e.g., phone and fax numbers, mailing addresses, websites, etc.)
- Include contact information for additional questions about the product