Plasma Protein Therapeutics Association

January 11, 2011
Reference No.: FDAA11001

Division of Dockets Management (HFA-305) **VIA WEB**
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

SUBJECT: Draft Guidance for Industry and Food and Drug Administration Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information [Docket No. FDA-2010-D-0319]

Dear Sir or Madam:

The Plasma Protein Therapeutics Association (PPTA) is the international trade association and standards-setting organization for the world's major producers of plasma derived products and recombinant analogues, collectively referred to as plasma protein therapies. The therapies are used in the treatment of a number of rare diseases. The diseases are often genetic, chronic, life-threatening conditions that require patients to receive regular infusions or injections of plasma protein therapies for the duration of their lives. The therapies include clotting-factor therapies for individuals with hemophilia A and B and other bleeding disorders; immunoglobulins to treat a complex of diseases in individuals with immune deficiencies; therapies for individuals who have alpha-1 anti-trypsin deficiency, which typically manifests as adult onset emphysema and limits substantially life expectancy; and albumin, which is used in emergency-room settings to treat individuals with shock, trauma, burns, and other conditions. PPTA member companies are committed to assuring the safety and availability of these medically needed, life-sustaining therapies.

Introduction

PPTA welcomes the opportunity to discuss plasma protein therapies via written submissions. The Association would like to thank the Food and Drug Administration (FDA) for the opportunity to participate in the guidance process and is pleased to provide these written comments on the Draft Guidance for Industry and FDA Staff on Dear Health Care Provider Letters: Improving Communication of Important Safety Information [hereinafter, "Draft Guidance"].[1] PPTA appreciates FDA's efforts to improve the quality of Dear Health Care Provider (DHCP) letters to make them more effective communication tools for new information about marketed products.[2]

[1] Federal Register / Vol. 75, No. 218 / Friday, November 12, 2010 / Notices, pp. 69449-51
[2] Federal Register / Vol. 75, No. 218 / Friday, November 12, 2010 / Notices, p. 69449

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General Comments

PPTA agrees with FDA that "guidance concerning the format and content of the DHCP letter would be beneficial in improving the effectiveness of DHCP letters in communicating drug information."[3] Overall, the Draft Guidance is appropriate and provides welcome guidance for the preparation of DHCP letters. However, PPTA suggests that FDA may wish to provide guidance on the expected timelines for preparation and distribution of DHCP letters. In particular, FDA review cycles should be as short as reasonably possible so that the DHCP letter is not unduly delayed.

Specific Sections

IV. WHEN TO USE A DHCP LETTER/WHICH TYPES OF DHCP LETTER TO USE

PPTA particularly supports the emphasis on the use of DHCP letters only to convey important new safety information that "concerns a significant hazard to health."[4]

V. CONTENT AND FORMAT OF DHCP LETTERS

2. Addressees (Target Audience)

PPTA feels that the suggested addressees are overly broad and could result in dilution of the impact of DHCP letters. For any health care provider, the receipt of a DHCP letter should be a relatively unusual and significant event, and the guidance provided in the letter should be seen as very relevant to their practice. The language in the current document seems overly broad and would likely result in a large number of individuals receiving DHCP letters of marginal relevance. To refine the audience targeting, PPTA suggests the following wording:

> *A DHCP letter should be directed to all health care providers who are likely to prescribe, dispense, or administer the drug and others who would have a need to know the information being disseminated. Potential prescribers - the gatekeepers to access to the drug - are the most important audience for a DHCP letter. Depending on the particular circumstances of the safety issue, other health care providers who may not have prescribing authority, but for whom it could be important to know the information, could be part of the target audience. For example, in situations where an acute adverse reaction would be a possible outcome, emergency departments or primary care physicians who might not have occasion to prescribe the drug that is the subject of a DHCP letter, but could be providing care for patients with an acute drug-induced adverse reaction, should be included in the DHCP target audience. Similarly, a DHCP letter that announces the introduction of a new Medication Guide*

[3] Federal Register / Vol. 75, No. 218 / Friday, November 12, 2010 / Notices, p. 69450
[4] Draft Guidance, p. 2

should be directed to pharmacists who would be required to distribute the Medication Guide to patients.[5]

3. Subject Line

In the subject line, PPTA also would suggest the addition of the treatment indication of most relevance to the safety issue. In the second example given, the Association would suggest the following modification:

Subject: Limitations on Use of DRUG NAME for the management of Hypertension in Patients with Decreased Renal Function. Risk of Worsening Renal Function and Increased Mortality.[6]

VI. ASSESSMENT OF THE DHCP LETTER IMPACT

While the intent of Section VI is laudable, the actions suggested in the guidance could present significant practical challenges. PPTA suggests a flexible approach in implementation of this section. For example, when a DHCP is a component of a corrective and preventative action (CAPA), the expectation should be that manufacturers would open a CAPA over the safety issue and assess the effectiveness of the actions in accord with the processes for evaluation of CAPA efficacy. For issues where FDA is requiring a DCHP over a change in class labeling, no manufacturer specific action should be required.[7]

Conclusion

PPTA appreciates the opportunity to comment on the Draft Guidance and looks forward to continued work with FDA on efforts to improve the quality of DHCP letters to make them more effective communication tools for new information about marketed products. PPTA welcomes from FDA any questions regarding these comments or requests for additional information.

Respectfully Submitted,

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Plasma Protein Therapeutics Association

[5] Draft Guidance, p. 5
[6] Draft Guidance, p. 6
[7] Draft Guidance, p. 9