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American Pharmacists Association
House of Delegates – Seattle, Washington

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NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Jennifer Lamberts, Chair-elect, Basic Sciences Section, on behalf of APhA-APRS
(Name)

January 9, 2019
(Date)

APhA Academy of Pharmaceutical Research and Science (APhA-APRS)
(Organization)

Subject: Gluten Content and Labeling in Medications

Motion:

Move to MODIFY language of policy passed during the 2018 APhA House of Delegates,

1. APhA supports labeling of all prescription and over the counter ~~**medications that**~~ **drug products as well as dietary supplement products, to** indicate~~s~~ the presence of gluten.

Move to ADOPT the following policy statement,

2. APhA encourages the development of analytical methods that can accurately detect lower levels of gluten than the current standard (20 ppm), and for the establishment of evidence based gluten-free standards for the labeling of foods, excipients, dietary supplements, prescription and over the counter drug products.

Background:

Report from the 2018-19 APhA-APRS Gluten Working Group

- Chair: Walt Chambliss (Oxford, MS)
- Members: Robert A. Mangione (Queens, NY), William McLaughlin Germantown, TN), Steve Plogsted (Columbus, OH), Abu Serajuddin (Queens, NY), Carmela Silvestri (Flemington, NJ)
- Ex-officio: Ed Bednarczyk (APhA-APRS Executive Council Liaison to Work Group - Buffalo, NY) , Jennifer Lamberts (APhA-APRS Basic Science Section Chair-elect – Big Rapids, MI)

- Staff: Margaret Tomecki (Academy Staff Liaison)

Background

Eight policy statements related to gluten were introduced as New Business Items by the New Jersey Pharmacists Association at the 2018 APhA Annual Meeting. The following four statements were adopted by the APhA House of Delegates (HOD):

1. APhA supports labeling of all prescription and over the counter medications that indicates the presence of gluten.
2. APhA encourages manufacturers to formulate drug products without use of wheat, barley, rye or their derivatives whenever possible.
3. APhA supports additional research on the effects of gluten intolerance and celiac malabsorption, particularly as it related to medication absorption.
4. APhA supports pharmacist education regarding celiac disease and non-celiac gluten sensitivity.

The following four statements were referred to APhA-APRS for review by the APhA HOD:

1. APhA supports required gluten status verification for all plant derived excipients used in the manufacture of medications to assure that no cross-contamination has occurred, and in the absence of this verification, that batch testing of medication products be required to determine if they are free of detectable gluten.
2. APhA encourages the FDA to require post manufacturing testing of gluten content in oral drug products, and making quantitative information on gluten content easily accessible to health professionals.
3. APhA encourages USP to develop assays that can accurately detect trace levels of gluten in finished drug products and set appropriate standards.
4. APhA supports a mechanism for third party payers to acknowledge the need for, and accept responsibility for providing access to, medications with no detectable gluten when medically necessary.

The APhA-APRS Gluten Working Group was formed to review the four referred statements and make a recommendation to the APhA House of Delegates. The Working Group also reviewed the policy statements that were approved by the APhA HOD. The Working Group met by conference calls over a 3-month period to discuss the state of the science, how the industry and the FDA were addressing the issue, and patient care needs. Several documents were reviewed and discussed including review articles, the December 2017 FDA Draft Guidance on "Gluten in Drug Products and Associated Labeling Recommendations" (the "FDA Guidance") and responses from industry to the FDA Guidance. A previously conducted literature search on analytical methods for detecting gluten was updated.

Key Learnings

- The limit of detection of the existing analytical method (an ELISA method) is about 5 ppm with a 3- to 5-fold variation in the data. The limit of detection for the method is appropriate for testing food and dietary supplement products because the FDA requirement for "gluten-free" is 20 ppm or less. However, much lower levels of gluten (e.g. 1 ppm) in foods, dietary supplements and drug products could result in negative pharmacological and physiological effects.

- Because the "gluten free" standard for food is ≤ 20 ppm, many patients are unintentionally, and at times unknowingly, consuming dietary gluten in food, which is labeled "gluten free".

- The FDA Guidance states that gluten is not likely to be a significant issue in drug products because excipients known to contain gluten (wheat, barley and rye) are rarely, if ever, used; and any cross-

contamination from other grain based excipients (e.g. corn starch) would result in very small (non-detectible) quantities of gluten in a drug product.

- The International Pharmaceutical Excipient Council (IPEC) - Americas recommends labeling of excipients/drug products as "contains gluten" rather than "gluten-free". The FDA recommends labeling: "Contains no ingredient made from a gluten-containing grain (wheat, barely or rye)".

- The social science issues (e.g. patients not taking a drug product because it is not labeled "gluten-free") are as important as hard science issues.

- Labeling for the presence of gluten in drug products and dietary supplements should address both unit dose and daily dose quantities since acute and chronic exposure can cause different pharmacological problems. This issue should be kept in mind when a more sensitive analytical method is developed.

Work Group Recommendations

A. Policy statements adopted by the 2018 HOD

1. Statement #1. Consider revising to the following to be more inclusive:

   APhA supports labeling of all prescription and over the counter drug ***products*** as well as ***dietary supplement products***, to indicate the presence of gluten.

2. Statement #2 - no changes.
3. Statement #3 – no changes.
4. Statement #4 – no changes.

B. Policy statements deferred by the 2018 HOD

1. Statement #1 - not be adopted due to the lack of an appropriate analytical method.
2. Statement #2 - not be adopted due to the lack of an appropriate analytical method.
3. Statement #3 - consider a revised statement:

   APhA encourages the development of analytical methods that can accurately detect lower levels of gluten than the current standard (20 ppm), and for the establishment of evidence based gluten-free standards for the labeling of foods, excipients, dietary supplements, prescription and over the counter drug products.

4. Statement #4 – not be adopted due to the lack of an appropriate analytical method.

Current APhA Policy & Bylaws:

Gluten Content and Labeling in Medications

2018

1. APhA supports labeling of all prescription and over the counter medications that indicates the presence of gluten.
2. APhA encourages manufacturers to formulate drug products without use of wheat, barley, rye or their derivatives whenever possible.

3. APhA supports additional research on the effects of gluten intolerance and celiac malabsorption, particularly as it relates to medication absorption.
4. APhA supports pharmacist education regarding celiac disease and non-celiac gluten sensitivity.

(JAPhA 58(4):356 July/August 2018)

New Business Items are due to the Speaker of the House by **February 20, 2019** (30 days prior to the start of the first House session). Consideration of urgent items can be presented with a suspension of the House Rules at the session where New Business will be acted upon. Please submit New Business Items to the Speaker of the House via email at hod@aphanet.org.