

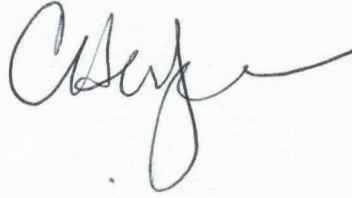
CSHP

PROPOSED RESOLUTION

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Date: September 29, 2017

Subject: Excipients in Medications

Description of Current Situation:

1. CSHP Professional Policy 2015-04 directs CSHP to adopt ASHP policies and other guidance documents as CSHP Professional policy
2. To adopt as CSHP policy all ASHP Policy Positions, Guidelines, Bulletins and all official Statements in the current edition of the Best Practices for Health-System Pharmacy of the ASHP, except when such policies differ substantially from CSHP policy.
3. To endorse the use of ASHP Position Statements, Guidelines and Technical Assistance Bulletins by its members in their practice settings.
4. CSHP will review all ASHP Policy Positions by 2020 for possible adoption as CSHP Professional Policy.
5. CSHP does not have a policy with respect to excipients in medications.
6. ASHP Professional Policy was adopted in 2015:

1528 EXCIPIENTS IN DRUG PRODUCTS

Source: Council on Pharmacy Practice

To advocate that manufacturers remove unnecessary, potentially allergenic excipients from all drug products; further,

To advocate that manufacturers declare the name and derivative source of all excipients in drug products on the official label; further,

To advocate that vendors of medication-related databases incorporate information about excipients; further,

To foster education on the allergenicity of excipients and documentation in the patient medical record of allergic reactions to excipients.

ASHP Rationale:

Excipients are intended to be inactive ingredients that assist in delivering a pharmaceutically elegant medication. In some patients, however, excipients cause allergic responses or aggravate medical conditions. Examples include patients with celiac disease reacting to gluten in a drug product or pediatric patients with a red-dye allergy reacting to a suspension containing red dye. Inclusion of excipients in drug product labeling, including their derivative source (the botanical, animal, or other source from which the excipient is originally derived), would allow substitution of nonallergenic alternative, but in many cases patients may not be aware of the allergy or it may not be documented in the patient medical record. Manufacturers are therefore encouraged to avoid putting allergenic excipients (e.g., red or yellow dye, gluten) in drug products when possible.

Education of manufacturers, pharmacists and other healthcare professionals, and patients regarding the allergenicity of excipients will be required. Medication-related databases will need to be configured to include information about drug product excipients, and electronic health record systems will need to permit documentation of allergies and medical conditions related to excipients.

Target:

1. CSHP provides resources to its members, their patients, and the public per the 2017-2021 Strategic Priorities and Goals.
2. CSHP develops professional policy in congruence with other professional organizations, but adopts policy as an independent professional society
3. CSHP provides professional policy that addresses excipients in medications.

Proposal:

Adopt the following as CSHP Professional Policy:

Excipients in Medication Products

1. To support the ~~advocate that~~ manufacturers removal of e unnecessary, potentially allergenic excipients from all medications; further,
2. To encourage ~~advocate that~~ manufacturers to declare the name and derivative source of all excipients in medications on the official labels; further,
3. To strongly encourage ~~advocate that~~ vendors of medication-related databases incorporate information about excipients; further,
4. To foster education on the allergenicity of excipients and documentation in the patient medical record of allergic reactions to excipients.

Resources Required for Proposed Action(s):

Financial: Minimal CEO time: Minimal Staff time: Minimal

CSHP Board Action: The Board of Directors reviewed this proposal on October 3, 2017 and recommends approval of this resolution.