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## [General Chapter Prospectus: <1567> Pyrrolizidine Alkaloids \(PAs\)](#)

**Type of Posting:** General Chapter Prospectus

**Posting Date:** 31-Jul-2020

**Expert Committee:** Botanical Dietary Supplements and Herbal Medicines (BDSHM)

**Input Deadline:** 30-Aug-2020

**Proposed New Title:** <1567> *Pyrrolizidine Alkaloids (PAs)*

**Suggested audience:** Suppliers of Botanical ingredients, Dietary supplement manufacturers of botanical products and testing laboratories.

**Estimated Proposal PF:** 47(1) [Jan. – Feb. 2021]

**Background and objective(s):** Pyrrolizidine Alkaloids (PAs) are esters of alkaloids consisting of a necine base moiety, esterified with a necic acid. Currently, more than 660 PAs and their respective N-oxides are known to be hepatotoxic, carcinogenic, and genotoxic. PAs have been identified in more than 6,000 plant species. The worldwide presence of these plants which may be inadvertently co-harvested with desirable plants could lead to contamination of food, food supplements, herbal medicines, and animal feed. USP is proposing the development of a general informational chapter to provide information about the potential for contamination, structures, and toxic characteristics of PAs .

**Preliminary outline:** The following sections will be included in the proposed General Chapter:

- Introduction
- Structures of PA families
- Review of Toxicological data: This section summarizes the risk associated with acute and chronic exposure to contaminant PAs.
- Limits of PAs:- This section provides information on the limits established by regulatory agencies.
- Recommended PAs for monitoring: This section provides the list of recommended PAs to be monitored.
- Suitable analytical technique: This section summarizes the available literature on the analytical techniques used in the quantification of

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contaminant PAs.

**Anticipated activities:** USP is requesting early input from stakeholders on this informational General Chapter <1567> *Pyrrrolizidine Alkaloids (PAs)* which is planned to be published for comment in *Pharmacopeial Forum* 47(1) [Jan.–Feb. 2021].

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