Summary Report

Podophyllum

Prepared for:

Food and Drug Administration
Clinical use of bulk drug substances nominated for inclusion on the 503B Bulks List
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REVIEW OF NOMINATIONS

Podophyllum (UNII code: 2S713A4VP3, L36H50F353) was nominated for inclusion on the 503B Bulks List by the Specialty Sterile Pharmaceutical Society and the Outsourcing Facilities Association (OFA) for use as a keratolytic to treat condylomata acuminate and human papillomavirus (HPV). Podophyllum will be compounded as a topical cream and solution. Podophyllum was nominated for use in combination with additional active pharmaceutical ingredients (API), refer to Table 7 for the nominated combination formulations.

Reasons provided for nomination to the 503B Bulks List include:

- Prescribers and hospital formularies have different preferences or requirements for
- concentrations, volumes, or final product containers for administration.
- It is relatively unsafe to expose the direct compounding area to hundreds of vials or ampules and hundreds of aseptic manipulations during the compounding of a typical batch size for an outsourcing facility; compounding from bulk is more safe and efficient.
- Commercially available finished products have an inherent variance in potency creating an uncertain final concentration for the new product.
- Use of state-of-the-art equipment, like the SKAN isolator technology, requires the use of bulk starting materials.
- Patients respond differently to drug products and the compounded product may be the only product to effectively treat the indication for which it is intended to treat.
- There is no comparable FDA-approved product commercially available.
- Patients may need a dosage form or strength that is not commercially available.
- Possible patient sensitivities to dyes, fillers, preservatives, and other excipients in the commercially available product.
- Manufacturer backorders.

METHODOLOGY

Background information

The national medicine registers of 13 countries and regions were searched to establish the availability of podophyllum products in the United States (US) and around the world. The World Health Organization, the European Medicines Agency (EMA), and globalEDGE were used to identify regulatory agencies in non-US countries. The medicine registers of non-US regulatory agencies were selected for inclusion if they met the following criteria: freely accessible; able to search and retrieve results in English language; and desired information, specifically, product trade name, active ingredient, strength, form, route of administration (ROA) and approval status, provided in a useable format. Based on these criteria, the medicine registers of 13 countries/regions were searched: US, Canada, European Union (EU), United Kingdom (UK), Ireland, Belgium, Latvia, Australia, New Zealand, Saudi Arabia, Abu Dhabi, Hong Kong, and Namibia. Both the EMA and the national registers of select EU countries (Ireland, UK, Belgium, and Latvia) were searched because some medicines were authorized for use in the EU and not available in a member country and vice versa.

Each medicine register was searched for podophyllum; name variations of podophyllum were entered if the initial search retrieved no results. The following information from the search results of each register was recorded in a spreadsheet: product trade name; active ingredient; strength; form; ROA; status and/or

schedule; approval date. Information was recorded only for products with strengths, forms and/or ROA similar to those requested in the nominations.

In addition to the aforementioned medicine registers, the DrugBank database (version 5.1.4) and the Natural Medicines database were searched for availability of over-the-counter (OTC) products containing podophyllum. The availability of OTC products (yes/no) in the US and the ROA of these products were recorded in a spreadsheet. Individual product information was not recorded.

Systematic literature review

Search strategy

Two databases (PubMed and Embase) were searched including any date through March 29, 2019. The search included a combination of (Podophyllum[TIAB] OR Condyline[TIAB] OR Condylox[TIAB] OR Epipodophyllotoxin[TIAB] OR Podofilox[TIAB] OR Podophyllotoxin[TIAB] OR Wartec[TIAB]) AND (treat*[TIAB] OR therap*[TIAB] OR clinic*[TIAB] OR topical[TIAB] OR hpv[TIAB] OR "human papillomavirus"[TIAB]) AND (humans[MeSH Terms] AND English[lang] NOT Autism). Peer-reviewed articles as well as grey literature were included in the search. Search results from each database were exported to Covidence®, merged, and sorted for removal of duplicate citations.

Study selection

Articles were not excluded on the basis of study design. Articles were considered relevant based on the identification of a clinical use of podophyllum or the implementation of podophyllum in clinical practice. Articles were excluded if not in English, a clinical use was not identified, incorrect salt form, or if the study was not conducted in humans. Screening of all titles, abstracts, and full-text were conducted independently by two reviewers. All screening disagreements were reconciled by a third reviewer.

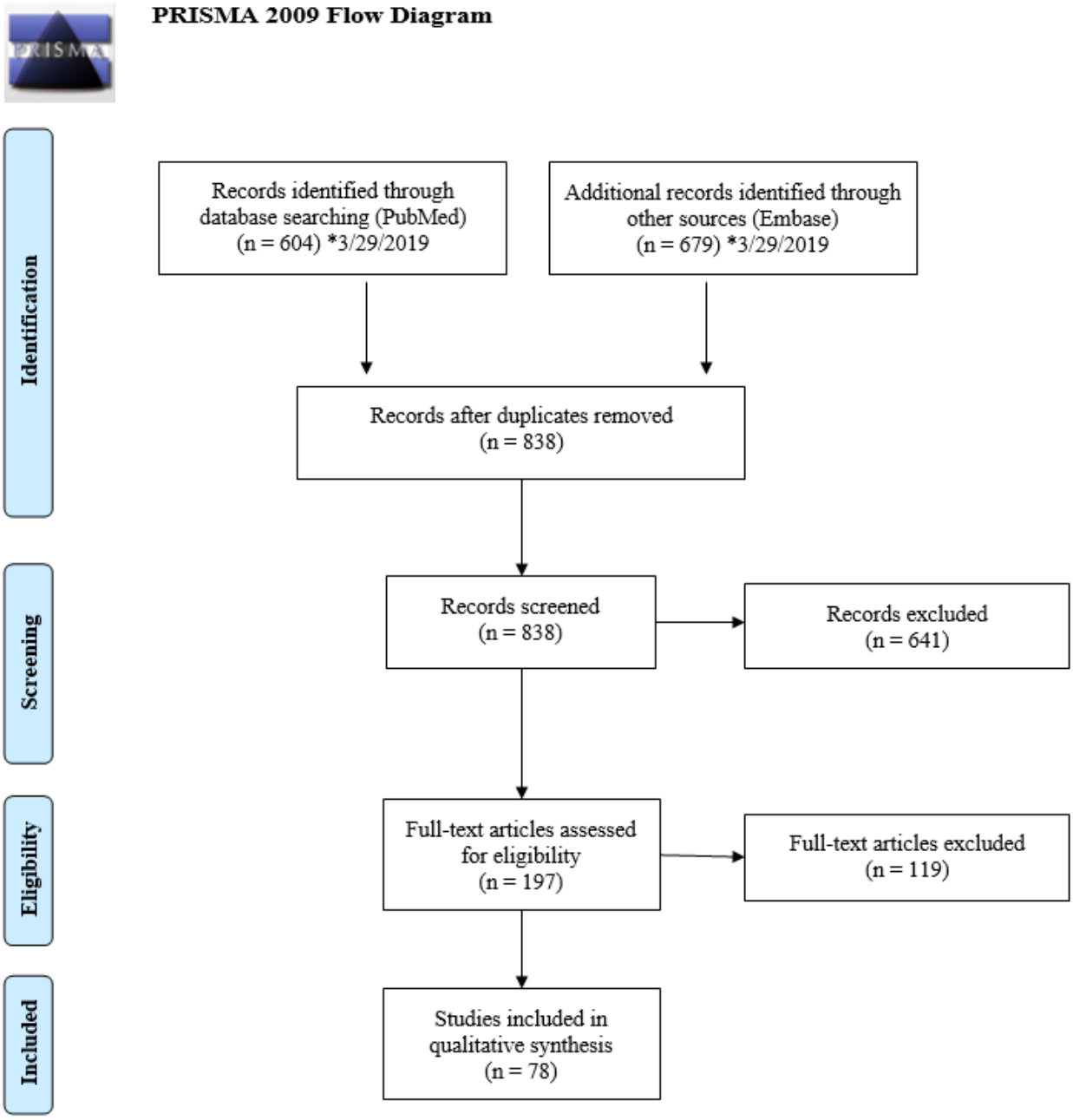
Data extraction

A standard data extraction form was used to collect study authors; article title; year published; journal title; country; indication for podophyllum use; dose; strength; dosage form; ROA; frequency and duration of therapy; any combination therapy utilized; if applicable, formulation of compounded products; study design; and any discussion surrounding the use of podophyllum compared to alternative therapies.

Results

Please refer to Figure 1.

Figure 1. Summary of literature screening and selection (PRISMA 2009 Flow Diagram)



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Outreach to medical specialists and specialty organizations

Using the indications from the nomination and the results of the literature review, three (3) medical specialties that would potentially use podophyllum were identified: dermatology, obstetrics and gynecology, and oncology. Semi-structured interviews were conducted with subject matter experts within this/these specialties. Interviews lasted from 30-75 minutes and were conducted either via telephone or in-person. Criteria for selecting subject matter experts included recommendations provided by specialty professional associations, convenient geographic location, authorship within the specialty, or referral by an interviewee. Up to nine (9) interviews were conducted per substance. Two (2) medical experts were contacted for interviews, of which one (1) accepted. One (1) medical expert specializing in oncology failed to respond to the interview request. The interviews was recorded and transcribed via ©Rev.com. QSR International's Nvivo 12 software was utilized for qualitative data analysis. The University of Maryland, Baltimore IRB and the Food & Drug Administration RIHSC reviewed the study and found it to be exempt. Subject matter experts provided their oral informed consent to participate in interviews.

Survey

General professional medical associations and specialty associations for dermatology, obstetrics and gynecology, and oncology, identified from the nomination, literature review, and interview, were contacted to facilitate distribution of an online survey. A Google™ search was conducted to identify relevant professional associations within each specialty. Associations were included if their members are predominantly practitioners, national associations, and organizations focused on practice within the US. Organizations without practicing physicians and state or regional organizations were excluded. The association's website was searched in order to identify the email of the executive director, regulatory director, media director, association president, board members, or other key leaders within the organization to discuss survey participation. If no contact information was available, the "contact us" tab on the association website was used.

The online survey was created using Qualtrics® software (Provo, UT). The survey link was distributed to six (6) associations. If an association had more than one (1) substance with indications relevant to that specialty, substances were combined into one (1) survey with no more than 14 substances per survey. Table 1 highlights the associations that agreed to distribute the survey link and Table 2 includes the associations that declined to participate. Additionally, single substance surveys were created and posted on the project website which was shared with survey participants.

Participation was anonymous and voluntary. The estimated time for completion was 30 minutes with a target of 50 responses per survey. The Office of Management and Budget (OMB) approved this project.

Table 1. Participating associations

Specialty	Association
Dermatology	American Academy of Dermatology (AAD)
	American Society for Dermatologic Surgery (ASDS)

Table 2. Associations that declined participation

Specialty	Association	Reasons for Declining
Medicine	American Medical Association (AMA)	Failed to respond
	American Osteopathic Association (AOA)	Failed to respond
Obstetrics and Gynecology	American College of Obstetricians and Gynecologists (ACOG)	Declined, survey not approved for distribution
Oncology	American Society of Clinical Oncology (ASCO)	Declined

CURRENT AND HISTORIC USE

Summary of background information

- Podophyllum is available as an FDA-approved product, but not in the nominated combination.
- Podophyllum is available as an OTC product in the US.
- There is a current United States Pharmacopeia (USP) monograph for podophyllum.
- Podophyllum is available in Australia, Canada, Ireland, Namibia, New Zealand, and UK as single agent. In Abu Dhabi and Saudi Arabia, it is available, but not in the in nominated dosage form. In Hong Kong, it is available as an OTC product.

Table 3. Currently approved products – US[a]

Active Ingredient	Concentration	Dosage Form	ROA	Status	Approval Date[b]
Podofilox	0.5%	Gel, solution	Topical	Prescription	12/13/1990

Abbreviation: ROA, route of administration.
[a]Source: US FDA *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book).
[b]If multiple approval dates and/or multiple strengths, then earliest date provided.

Table 4. Currently approved products–select non-US countries and regions[a]

Active Ingredient	Concentration	Dosage Form	ROA	Approved For Use		
				Country	Status	Approval Date[b]
Podophyllotoxin	0.5%	Solution	–	Namibia	–	8/20/2008
			Topical	Australia	Schedule 4 - Prescription	2/7/1992
				Canada	Prescription	12/31/1992
				Ireland	Prescription-only	9/25/1996
				New Zealand	Prescription	10/20/1988
				UK	Prescription-only	6/21/1999

Abbreviations: "–", not mentioned; ROA, route of administration.

[a]Medicine registers of national regulatory agencies were searched if they met the following criteria: freely accessible; able to search and retrieve results in English language; and desired information (product trade name, active ingredient, strength, form, route of administration and approval status) provided in a useable format. Information was recorded only for products with strengths, forms and/or routes of administration similar to those requested in the nominations. See Methodology for full explanation.

[b]If multiple approval dates and/or multiple strengths, then earliest date provided.

Summary of literature review

- Total number of studies included: 78 studies (19 descriptive, 56 experimental, and 3 observational).
- Most of the studies were from Sweden (19 studies).
- The most common indication for the use of podophyllum in the US and non-US studies was genital warts.
- Compounded products were identified from the non-US studies, one of which was utilized in the nominated formulation.

Table 5. Types of studies

Types of Studies	Number of Studies
Descriptive[1–19]	19
Experimental[20–75]	56
Observational[76–78]	3

Table 6. Number of studies by country

Country	Number of Studies
Austria[72]	1
Belgium[4]	1
Brazil[11,27,78]	3
China[42]	1
Denmark[47,77]	2
France[61,65]	2
Germany[75]	1
Greece[52,63]	2
Ireland[8]	1
Italy[29,76]	2
The Netherlands[19]	1
Poland[3,43]	2

Romania[51]	1
Slovakia[18]	1
Spain[64]	1
Sweden[7,33,35,53–60,66–71,74]	18
Turkey[10,34]	2
UK[1,2,5,9,12,21,22,25,28,36,39,41,44–46,48,73]	17
US[6,13–17,20,23,24,30–32,37,38,49,50,62]	17
Multiple Countries • Finland, France, Sweden[26]	1
	Total US: 17 Total Non-US Countries: 61

Table 7. Number of studies by combinations

	Combination Formula	Number of Studies
Nominated	Podophyllum 5% / Cantharidin 1% / Salicylic acid 30% - Topical solution[10,64]	2
Others found in literature	Not applicable	0

Table 8. Dosage by indication – US

Indication	Dose	Concentration	Dosage Form	ROA	Duration of Treatment
Genital warts[6,13–17,20,23,24,31,32,37,38,49,50,62]	–	0.15-0.5%	Cream	Topical	1-12 weeks
	0.5mL/day	0.05-0.5%	Gel		4-8 weeks
	0.5mL/day	0.5%	Solution		4-12 weeks
Verruca plana[30]	–	–	Gel	Topical	4 weeks

Abbreviations: "–", not mentioned; ROA, route of administration.

Table 9. Dosage by indication – non-US countries

Indication	Dose	Concentration	Dosage Form	ROA	Duration of Treatment
Genital Warts[1–3,7,8,18,21,25–29,33,35,36,39,40,43–48,51–57,59,60,63,65–71,73,74,76,77]	–	0.15-0.5%	Cream	Topical	3 days-8 weeks
	–	0.5%	Lotion		5 weeks
	–	0.25-8%	Solution		Once-8 weeks
	–	0.5%	–		1-4 weeks
Neovulvar lesion condylomata[19]	–	0.15%	Cream	Topical	–

Vulvar Condyloma[11]	–	–	Cream	Topical	–
Plantar Warts[10,64]	–	5%	Solution	Topical	Once
	–	5%	–		2-10 weeks
Palmoplantar Warts[75]	–	0.5%	Solution	Topical	4-6 weeks
Molluscum Contagiosum[4,9,22,34,58,61]	–	0.3-0.5%	Cream	Topical	1-4 weeks
	5.4mcL	0.5%	Solution		6-30 days
	–	0.5-2%	–	–	Up to 3 weeks
Psoriasis Vulgaris[41,72]	–	0.1-0.5%	Ointment	Topical	4-12 weeks
	0.5mg	0.5%	Solution	Topical	At least 4 weeks
Grade 3 Vulvar and Anal Borders Neoplasia[78]	–	–	–	Topical	–
Vaginal Intraepethelial Neoplasa (VAIN)[42]	–	–	–	–	–
Acquired Epidermodysplasia Verruciformis (AEV)[12]	–	–	–	–	–

Abbreviations: "–", not mentioned; ROA, route of administration.

Table 10. Compounded products – US

No compounded products from reported studies

Table 11. Compounded products – non-US countries

Indication	Compounding Method	Dosage Form	Final Strength
Genital Warts[53,55–57,66-68,70]	• The cream preparations of podophyllotoxin consisted of an oil phase blended into a purified water phase, with 75% water and 25% oil phase comprising propylene glycol, cetyl alcohol, isopropyl myristate, liquid paraffin and fractionated coconut oil. Methyl-p-hydroxy-benzoate and sorbic acid (Merck) were used as preservatives[53,57] • Incorporated in a hydrophilic cream[55,56]	Cream	0.15-0.5%
	• The 0.5% podophyllotoxin solution contained 5mg podophyllotoxin blended with 640 mg 70% ethanol, 0.5 mg methylrosaniline as color indicator, purified water and phosphoric acid, pH 5[53] • 0.3% podophyllum solution contained 3mg podophyllotoxin blended with 640mg 70% ethanol, 0.5mg methylrosaniline as color indicator, purified water, and phosphoric acid pH5[57] • In preparation of 8% solution, absolute ethanol was used to avoid precipitation.[66] 0.5-1% podophyllotoxin was dissolved in 70% ethanol, with methylrosaniline 0.05% as color indicator[67,68] • Contained methylrosaniline 0.05g, spir.dil 70g, crystalline podophyllotoxin 5mg/ml or 2.5mg/ml, acetic acid 1M, aqua steril ad. 100ml[70]	Solution	0.25-8%
Molluscum Contagiosum[58]	• Castor oil and 0.5% podophyllotoxin	Cream	0.3-0.5%
Plantar Warts[64]	• Cantharidin, 1%; salicylic acid, 30%; podophyllotoxin, 5%; and 2 mL of flexible collodion	Solution	5%

Summary of focus groups/interviews of medical experts and specialty organizations

One (1) interviews were conducted. One (1) medical expert specializing in oncology was contacted for interview however the interviewee failed to respond to the interview request.

Table 12. Overview of interviewee

Interviewee	Level of Training	Specialty	Current Practice Setting	Experience with Podophyllum	Interview Summary Response
DER_06	MD	Dermatology/ Immunology	Independent Consultant	Not specified	• Prefers the pure form (podophyllum, podophyllotoxin, podofilox) over the extract form (podophyllum resin, podophyllin), but reluctant to use in combination product.

Abbreviation: MD, Doctor of Medicine.

Use of podophyllum

- Earlier in practice, the interviewee used podophyllum resin, but now there is podophyllum (purified version) available which is a better approach.
- Prefers the pure form (podophyllum, podophyllotoxin, podofilox) over the extract form (podophyllum resin, podophyllin) due to low quality control and high variability in active pharmaceutical ingredient in the extract, which could be a risk to patient safety.

Use of combination product

- Hesitant in advocating the use of nominated combination (salicylic acid can change pH and affect the structure). Would use one ingredient at a time to see the therapeutic response.
- "If you're going to say that you're going to make one available. My preference in the office is to have the one in which you have better control over the API."

Office use

- "I think there's still a law potentially for being able to treat somebody in the office. I'm not going to say we shouldn't have that be an option, that's the place where the bulk compounding comes into place."

Summary of survey results

Table 13. Characteristics of survey respondents [5 people responded to survey]

Board Certification	MD	No response
Dermatology	2	0
No response	0	3

Abbreviation: MD, Doctor of Medicine.

Table 14. Types of products used, prescribed, or recommended

Types of Products	Respondents, n (N=1[a])
Compounded	0
FDA-approved	0
Over-the-counter	0
Dietary	0
Unsure	0
No response	1

[a]Out of five (5) respondents, one (1) reported using, prescribing, or recommending podophyllum products.

Table 15. Compounded use of podophyllum in practice

No survey respondents provided this information

Table 16. Indications for which podophyllum is considered a standard therapy

Indication	Standard therapy		
	Compounded, n (N=0)	Non-Compounded, n (N=0)	No Response, n (N=1)
No Response	0	0	1

Table 17. Reasons for using compounded product instead of the FDA-approved products

No survey respondents provided this information

Table 18. Change in frequency of compounded podophyllum usage over the past 5 years

No survey respondents provided this information

Table 19. Do you stock non-patient specific compounded podophyllum in your practice?

No survey respondents provided this information

Table 20. Questions related to stocking non-patient specific compounded podophyllum

No survey respondents provided this information

CONCLUSION

Podophyllum (UNII code: L36H50F353) was nominated for inclusion on the 503B Bulks List by the Specialty Sterile Pharmaceutical Society and the Outsourcing Facilities Association (OFA) for use as a keratolytic to treat condylomata acuminate and human papillomavirus (HPV). Podophyllum will be compounded as a topical cream and solution. Podophyllum is available in Australia, Canada, Ireland, Namibia, New Zealand, and the UK.

From the literature review conducted, the most common indication for the use of podophyllum in the US and non-US studies was genital warts. Compounded products were identified from non-US studies, one of which was utilized in nominated formulation.

From the interviews, the interviewee preferred the pure form (podophyllum) over the extract form (podophyllum resin). The interviewee was hesitant about the nominated combination.

From the survey responses, one (1) out of five (5) respondents used podophyllum, but did not report using the compounded product.

APPENDICES

Appendix 1. References

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Appendix 2. Survey instrument

Start of Block: Welcome Page

The University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI), in collaboration with the Food and Drug Administration (FDA), is conducting research regarding the use of certain bulk drug substances nominated for use in compounding by outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act. In particular, we are interested in the current and historic use of these substances in clinical practice. This survey is for **podophyllum**. As a medical expert, we appreciate your input regarding the use of this substance in your clinical practice. This information will assist FDA in its development of a list of bulk drug substances that outsourcing facilities can use in compounding under section 503B of the Act. All responses are anonymous.

OMB Control No. 0910-0871
Expiration date: June 30, 2022

The time required to complete this information collection is estimated to average 30 minutes, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. If you have additional questions or concerns about this research study, please email: compounding@rx.umaryland.edu. If you have questions about your rights as a research subject, please contact HRPO at 410-760-5037 or hrpo@umaryland.edu.

End of Block: Welcome Page

Start of Block: Podophyllum

Q1. What type(s) of product(s) do you use, prescribe, or recommend for **podophyllum**? Please check all that apply.

- ☐ Compounded drug product
- ☐ FDA-approved drug product
- ☐ Over the counter drug product
- ☐ Dietary supplement (e.g. vitamin or herbal supplement products sold in retail setting)
- ☐ Unsure

Skip To: Q13 If What type(s) of product(s) do you use, prescribe, or recommend for podophyllum? Please check all th... != Compounded drug product

Skip To: Q2 If What type(s) of product(s) do you use, prescribe, or recommend for podophyllum? Please check all th... = Compounded drug product

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Display This Question:

If What type(s) of product(s) do you use, prescribe, or recommend for podophyllum? Please check all th... = Compounded drug product

Q2. Please list any conditions or diseases for which you use compounded **podophyllum** in your practice. Please include the strength(s), dosing frequency(ies), dosage form(s), route(s) of administration, duration of therapy, and patient population (ex. age, gender, comorbidities, allergies, etc).

	Strength(s) (please include units)	Dosing frequency(ies)	Dosage form(s)	Route(s) of administration	Duration of therapy	Patient population
Condition 1 (please describe)						
Condition 2 (please describe)						
Condition 3 (please describe)						
Condition 4 (please describe)						
Condition 5 (please describe)						

Q3. Do you use compounded **podophyllum** as a single agent active ingredient, or as one active ingredient in a combination product? Please check all that apply.

- ☐ Single
- ☐ Combination

Skip To: Q5 If Do you use compounded podophyllum as a single agent active ingredient, or as one active ingredient... != Combination

Display This Question:

If Loop current: Do you use compounded podophyllum as a single agent active ingredient, or as one active ingredient... = Combination

Q4. In which combination(s) do you use compounded **podophyllum**? Please check all that apply.

- ☐ Podophyllum 5% / Cantharidin 1% / Salicylic acid 30%
- ☐ Other (please describe) _____

Q5. For which, if any, diseases or conditions do you consider compounded **podophyllum** standard therapy?

_____

Q6. Does your specialty describe the use of compounded **podophyllum** in medical practice guidelines or other resources?

_____

Q7. Over the past 5 years, has the frequency in which you have used compounded **podophyllum** changed?

- o Yes - I use it **MORE** often now (briefly describe why) _____
- o Yes - I use it **LESS** often now (briefly describe why) _____
- o No - use has remained consistent

Q8. Why do you use compounded **[substance]** instead of any FDA-approved drug product?

_____

Q9. Do you stock non-patient-specific compounded **podophyllum** in your practice location?

- o Yes
- o No

Skip To: End of Block If Do you stock non-patient-specific compounded podophyllum in your practice location? = No

Display This Question:

If Do you stock non-patient-specific compounded podophyllum in your practice location? = Yes

Q10. In what practice location(s) do you stock non-patient-specific compounded **podophyllum**? Please check all that apply.

- ▢ Physician office
- ▢ Outpatient clinic
- ▢ Emergency room
- ▢ Operating room
- ▢ Inpatient ward
- ▢ Other (please describe) _____

Q11. How do you obtain your stock of non-patient-specific compounded **podophyllum**? Please check all that apply.

- ▢ Purchase from a compounding pharmacy
- ▢ Purchase from an outsourcing facility
- ▢ Compound the product yourself
- ▢ Other (please describe) _____

Q12. Why do you keep a stock of non-patient-specific compounded **podophyllum**? Please check all that apply.

- ▢ Convenience
- ▢ Emergencies
- ▢ Other (please describe) _____

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded podophyllum? Please check all that apply. = Convenience

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded podophyllum? Please check all that apply. = Emergencies

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded podophyllum? Please check all that apply. = Other (please describe)

Q13. For which, if any, diseases or conditions do you consider **podophyllum** standard therapy?

_____

Q14. Does your specialty describe the use of **podophyllum** in medical practice guidelines or other resources?

_____

End of Block: Podophyllum

Start of Block: Background Information

Q15. What is your terminal clinical degree? Please check all that apply.

- ☐ Doctor of Medicine (MD)
- ☐ Doctor of Osteopathic Medicine (DO)
- ☐ Doctor of Medicine in Dentistry (DMD/DDS)
- ☐ Naturopathic Doctor (ND)
- ☐ Nurse Practitioner (NP)
- ☐ Physician Assistant (PA)
- ☐ Other (please describe) _____

Q16. Which of the following Board certification(s) do you hold? Please check all that apply.

- ☐ No Board certification
- ☐ Allergy and Immunology
- ☐ Anesthesiology
- ☐ Cardiovascular Disease
- ☐ Critical Care Medicine
- ☐ Dermatology
- ☐ Emergency Medicine
- ☐ Endocrinology, Diabetes and Metabolism
- ☐ Family Medicine
- ☐ Gastroenterology
- ☐ Hematology
- ☐ Infectious Disease
- ☐ Internal Medicine
- ☐ Medical Toxicology
- ☐ Naturopathic Doctor
- ☐ Naturopathic Physician
- ☐ Nephrology
- ☐ Neurology
- ☐ Obstetrics and Gynecology
- ☐ Oncology
- ☐ Ophthalmology
- ☐ Otolaryngology
- ☐ Pain Medicine
- ☐ Pediatrics
- ☐ Psychiatry
- ☐ Rheumatology
- ☐ Sleep Medicine

- ☐ Surgery (please describe) _____
- ☐ Urology
- ☐ Other (please describe) _____

End of Block: Background Information