EUROGUIDERM GUIDELINE ON THE SYSTEMIC TREATMENT OF PSORIASIS VULGARIS— METHODS & EVIDENCE REPORT

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The EuroGuiDerm Team declares to not have any personal-financial conflict of interests regarding the subject at hand.

ABSTRACT

This evidence- and consensus-based guideline on the treatment of psoriasis vulgaris was developed following the EuroGuiDerm Guideline and Consensus Statement Development Manual (https://www.guidelines.edf.one/guideline-methods).

A pan-European guideline development group was nominated, conflicts of interest were declared and management strategies pursued in line with the methods manual. The group discussed and selected the relevant health care questions, taking the result of the prior scoping process into account. The search for evidence and critical appraisal of the literature was done together with the working group of the Cochrane Review: 'Systemic pharmacological treatments for chronic plaque psoriasis: a network meta-analysis'. We developed an evidence-to-decision framework following GRADE methods. The chapters on special/comorbid situations were developed by their respective authors based either on a systematic or narrative review.

The experts drafted all texts and recommendations. Online voting took place before the consensus conference. During the consensus conference, texts and recommendations were voted on using a structured, nominal group technique: presentation of draft recommendations was followed by open discussion, voting and/or generating alternative phrasing and final voting.

Extensive external review of the guideline including supporting national societies was performed. Strategies for implementation, including national adaptation and roll out were developed. Procedures for updating were determined.

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Version 3, 2025

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Notes on use/Disclaimer

This is the methods & evidence report of the EuroGuiDerm guideline for the systemic treatment of psoriasis vulgaris in adults.

The EuroGuiDerm guideline on the systemic treatment of psoriasis vulgaris was developed in accordance with the EuroGuiDerm Methods Manual v1.3, which can be found on the website of the European Dermatology Forum (EDF), subsection EuroGuiDerm/EDF Guidelines https://www.guidelines.edf.one/guideline-methods

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These evidence- and consensus-based guidelines contain recommendations that were developed to assist clinicians in the care of patients in specific clinical conditions. The recommendations are based on the available evidence and their development followed a pre-specified, standardized process. Nevertheless, guidelines do not replace the clinicians' knowledge and skills, since guidelines never encompass therapy specifications for all medical decision-making situations. Guidelines should not be deemed inclusive of all proper methods of care nor exclusive of other methods of care reasonably directed to obtaining the same results. Deviation from the recommendations may be justified or inevitable in specific situations. The ultimate judgment regarding patient care must be individualized and must be made by the physician and patient in the light of all presenting circumstances.

Safety aspects that were considered within these guidelines do not represent a comprehensive assessment of all available safety information for the included interventions. They are limited to those aspects chosen for evaluation and the information available in the included clinical trials. Readers must carefully check the information in these guidelines and determine whether the recommendations (e.g. regarding dose, dosing regimens, contraindications, or drug interactions) are complete, correct, up-to-date and appropriate.

European guidelines are intended to be adapted to national or regional circumstances (regulatory approval and availability of treatments, health care provider and insurance systems). Particularly, the approval situation/availability/reimbursement of the different treatment options has to be adapted to the national situation. Thus, the national medical societies associated adopting European Guidelines will be responsible for the adoption and implementation of the guidelines on a national level.







Funding

The development of this EuroGuiDerm guideline was funded through the EuroGuiDerm Centre for Guideline Development. The European Dermatology Forum is responsible for fundraising and holds all raised funds in one account. The EuroGuiDerm Team is not involved in fundraising or in the decision making on which guideline (GL) or consensus statement (CS) development is funded. The decisions on which GL/CS is funded are made by the EuroGuiDerm Board of Directors independently. The EDF or any other body supporting the EuroGuiDerm is never involved in the guideline development and had no say on the content or focus of the guideline.







Update 2023-2025

See chapter 'Original Version June 2020' for methodolocigal details that have not changed over time.

In May 2022, an update of the Cochrane review has been published ¹.

The EuroGuiDerm Team updated the three systematic reviews supporting the chapters on psoriatic arthritis, heart disease and diabetes. Author groups were provided with a summary of the results (details on the methods and results can be found in the individual chapters, see website).

In March 2023, deucravacitinib has been licensed for the treatment of psoriasis vulgaris, consequently all authors reviewed their chapters. The following sections changed and were voted on:

- New chapter on deucravacitinib,
- Psoriatic arthritis
- Diabetes mellitus
- Viral hepatitis
- Depression
- Tuberculosis screening
- Wish for child/ Pregnancy
- The algorithm as well as the decision grid.

The above-mentioned changes were presented to the GDG in an online survey. All experts were asked to vote (agree / disagree/comment). Alternative suggestions could be entered as a reply option. Voting was not anonymous but experts could not see how others had voted. Only the EuroGuiDerm Team had access to the results. All authors could participate but the votes of those with personal financial conflicts of interest did not count.

Nine of 28 experts (32%) declared personal-financial conflicts of interest (see below), meaning that they did not vote or their vote was not counted. One external expert declared personal-financial conflicts of interest but was not entitled to vote. Alexander Nast is the guideline coordinator and did not vote. He does not have any personal-financial conflicts of interests.

TABLE 1 DECLARATIONS OF PERSONAL-FINANCIAL CONFLICTS OF INTERESTS AS PROVIDED BY EXPERT 2022-2025

Title	First name	Last name	Personal- financial conflicts of interest	
Prof.	Zsuzsanna	Bata-Csörgő	none	
Prof.	Ivan	Bogdanov	2022: None	





Title	First name	Last name	Personal- financial conflicts of interest		
			2025: Advisory Board/Speaker Bureau for: UCB, Johnson&Johnson, BMS, Pfizer, Novartis, and Abbvie		
Dr.	Hugo	Boonen	I have been asked for presentations concerning different products to treat psoriasis. But I don't get money for prescription of certain medication. I am also member of the Belgian Psoriasis working group who gives advice to all kinds of treatment options.		
Prof.	Elke MGJ	de Jong	none		
Dr	Sarah	Drummond	none		
Dr.	Ignacio	Garcia-Doval	2022: Reports payment from Novartis and UCB for presentations unrelated to psoriasis (on meta-analysis and critical reading); personal payment 2025: none		
Prof.	Paolo	Gisondi	I have received compensation (payments) for acting as a speaker for Abbvie, Novartis, UCB 2025: I have received honoraria for acting as a speaker for Abbvie, Almirall, and UCB. I have received honoraria for participating in an advisory board for Janssen-Cilag and Bristol-Myers Squibb		
Dr.	Diljit	Kaur-Knudsen	none		
Prof.	Pietro	Lampertico	Advisory Board/Speaker Bureau for: - ROCHE PHARMA/DIAGNOSTICS, GILEAD SCIENCES, GSK, ABBVIE, JANSSEN, MYR, EIGER, ANTIOS, ALIGOS, VIR, GRIFOLS, ALTONA, ROBOSCREEN (external expert, not entitled to vote)		
Dr.	Satveer	Mahil	none		
Dr.	Tarja	Mälkönen	Consultancy fees (Abbvie, Janssen, Lilly, Novartis)		
Prof.	Vincent	Mallet	None (external expert, not entitled to vote)		
Prof.	Julia- Tatjana	Maul	none		
	Sicily	Mburu	none		
Dr.	Liam	Mercieca	none		
Prof.	Ulrich	Mrowietz	Honoraria as advisor and/or speaker: AbbVie, Aditxt, Almirall, Amgen, Aristea, Boehringer-Ingelheim, Bristol-Myers Squibb, Eli Lilly, Immunic, Janssen-Cilag, LEO Pharma, Merck, Sharp & Dohme, Novartis, UCB Pharma, UNION therapeutics.		
Prof.	Alexander	Nast (AN)	none		
Prof.	Eva	Remenyik	none		
Prof.	Dimitris	Rigopolous	2022: None 2025: I have received honoraria from Abbvie, UCB, Genesis, LEO for advisory boards and as a speaker		
Dr.	Kirsten Marthine	Rønholt Stausholm	Has left the group		
Prof.	Paul- Gunther	Sator	none		
Prof.	Marcus	Schmitt- Egenolf	none		
Dr.	Mariusz	Sikora	none		
Prof.	Catherine	Smith	2022: None 2025: I am paid by the Leo Foundation to review their Project Grants. Otherwise – none		
Prof.	Phyllis I.	Spuls	none		
Dr.	Olav	Sundnes	none		
Dr.	Klaus	Strömer	none		
	David	Trigos	Has left the group		







Title	First name	Last name	Personal- financial conflicts of interest	
	Gayle	van der Kraaij	none	
Prof.	Nikhil	Yawalkar	Personal fees from Abbvie, Allmiral, Amgen, Celgene, Boehringer Ingelheim, Bristol Myers Squibb, Essex/MSD, Janssen, Leo, Lilly, Novartis, Pfizer, UCB	
	Martin	Dittmann	none	
Dr.	Maria	Kinberger	none	
Dr	Antonia	Pennitz	none	
	Isabell	Vader	none	
	Christoph	Zeyen	none	

The EuroGuiDerm Living Psoriasis Guideline was updated and we disseminated this through various channels including social media and newsletters.

We would like to thank the following experts for their input on a specific chapter:

TABLE 2: EXTERNAL EXPERTS

Viral hepatitis	The update of this chapter was developed together with Professor Pietro Lampertico, Milan, Itlay and Professor Vincent Mallet, Paris, France.
	Both were nominated by the European Association for the Study of the Liver (EASL)

TABLE 3: OVERVIEW OF CHAPTER AUTHOR/GROUPS

Chapters	Author (group)
Actretin	Paolo Gisondi
CSA	Paolo Gisondi
FUMAR	Ulrich Mrowietz
MTX	Ulrich Mrowietz
Apremilast	Paolo Gisondi
Adalimumab	Paul-Gunther Sator
Certolizumab	Elke de Jong
Deucravatinib	M Sikora
Etanercept	Paul-Gunther Sator
Infliximab	Satveer Mahil
Guselkumab	Diljit Kaur Knudsen
Risankizumab	Diljit Kaur Knudsen
Tildrakizumab	Julia-Tatjana Maul
Ustekinumabik	Satveer Mahil
Brodalumab	Gayle van der Kraaij
Ixekizumab	EMGJ de Jong
Secukinumab	Paolo Gisondi
Bimekizumab	P Gisondi, A Nast
Biosimilars	E Remenyik, H Boonen
New drugs	E Remenyik, H Boonen
Specific clinical and comorbid situations	
PsA	A Nast, M Sikora, T Mälkönen;
IBD	Z Bata-Csörgö, T. Mälkönen, L Mercieca
Cancer	O Sundnes, EMGJ de Jong, J-T Maul, I Garcia Doval
Depression	C Smith, N Yawalkar
Neurology	C Smith, N Yawalkar
Diabetes Mellitus	P Gisondi, M Sikora, J-T Maul, I Bogdanov





Chapters	Author (group)
Heart Disease	P Gisondi, M Sikora,
Kidney	U Mrowietz, K Strömer
Viral Hepatitis	P Spuls, EMGJ de Jong, A Nast
TB screening	A Nast, P Spuls, M Schmitt-Egenolf, O Sundnes
TB treatment	M Schmitt-Egenolf, O Sundnes
Wish for child/pregnancy	C Smith, S Mahil, S Drummond
Vaccinations	U Mrowietz, N Yawalkar
Immunogenicity	separate publication

TABLE 4: OVERVIEW OF SPECIFIC TOPICS & TYPE OF EVIDENCE REVIEW THE RECOMMENDATIONS ARE BASED ON

Topic	Type of evidence review		
Evidence review methods for	part 1: general recommendation for adult patients with plaque type psoriasis:		
	Sbidian E, Chaimani A, Garcia-Doval I, Doney L, Dressler C, Hua C, Hughes C, Naldi L, Afach S, Le Cleach L.		
Psoriasis vulgaris	Systemic pharmacological treatments for chronic plaque psoriasis: a network meta- analysis. Cochrane Database of Systematic Reviews 2022, Issue 5. Art. No.: CD011535. DOI: 10.1002/14651858.CD011535.pub5. https://doi.org/10.1002/14651858.CD011535.pub5		
Evidence review methods for comorbid conditions and/or s	part 2: specific recommendations for adult patients with plaque type psoriasis and pecific issues:		
Psoriasis Arthritis	Systematic review. The Method & Evidence Reports are included in the individual chapter, see website.		
Inflammatory Bowel Disease	Not updated in the 2023/2024 version		
Cancer	Search for systematic reviews in one database (Medline), a methodologist (GA) with medical background from the EuroGuiDerm Team conducted a topic specific but non-systematic screening		
Depression	Search for systematic reviews in one database (Medline), a methodologist (GA) with medical background from the EuroGuiDerm Team conducted a topic specific but non-systematic screening		
Diabetes mellitus	Systematic review. The Method & Evidence Reports are included in the individual chapter, see website.		
Heart Disease	Search for systematic reviews in one database (Medline), a methodologist (GA)with medical background from the EuroGuiDerm Team conducted a topic specific but non-systematic screening		
Kidney Disease	Narrative review		
Neurological diseases	Narrative review		
Viral hepatitis	Systematic review. The Method & Evidence Reports are included in the individual chapter, see website.		
Tuberculosis Screening	Search for systematic reviews in one database (Medline), a methodologist (GA) with medical background from the EuroGuiDerm Team conducted a topic specific but non-systematic screening		
Tuberculosis Treatment	Search for systematic reviews in one database (Medline), a methodologist (GA) with medical background from the EuroGuiDerm Team conducted a topic specific but non-systematic screening		
Pregnancy	Search for systematic reviews in one database (Medline), a methodologist (GA) with medical background from the EuroGuiDerm Team conducted a topic specific but non-systematic screening		
Vaccinations	Narrative review by co-authors		





Topic	Type of evidence review
Immunogenicity	Not updated in the 2023/2024 version

Update 2021

In April 2021, an update of the Cochrane review has been published ². Shortly thereafter an online survey was conduting asking the guideline development group if any updates to the guideline are needed. The group agreed that all chapters were still up to date.

At the same time, the EuroGuiDerm Team updated the three systematic reviews supporting the chapters on psoriatic arthritis, heart disease and diabetes. Author groups were provided with a summary of the results (details on the methods and results can be found online).

In August 2021, bimekizumab has been licensed for the treatment of psoriasis vulgaris, consequently all authors reviewed their chapters. The following sections changed and were voted on:

- Brodalumab: section on IBD updated,
- New chaper on bimekizumab,
- PsA: guselkumab was added,
- IBD: bimekizumab was added, recommendation updated,
- Neurology: new data on ixekizumab was added,
- Heart diease: bimekuzumab added in line with other IL 17 inhibitors
- Wish for child: bimekizumab added
- Vaccinations: bimekizumab added
- Bimekizumab was added to the algorithm as well as the decision grid.

The above mentioned changes were presented to the GDG in an online survey. All experts were asked to vote (agree / disagree/comment). Alternative suggestions could be entered as a reply option. Voting was not anonymous but experts could not see how others had voted. Only the EuroGuiDerm Team had access to the results. All authors could participate but the votes of those with personal financial conflicts of interest did not count.

For the first update in 2021, the group comprised of 25 dermatologist and two patient representatives from 17 European countries. Five experts declared personal-financial conflicsts of interest, see below. Alexander Nast, the guideline coordinator, does not have any personal-financial conflicts of interests.

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TABLE 5: DECLARATIONS OF PERSONAL-FINANCIAL CONFLICTS OF INTERESTS AS PROVIDED BY EXPERT 2021

Title	First name	Last name	Personal- financial conflicts of interest	
Prof.	Zsuzsanna	Bata-Csörgő	none	
Prof.	Ivan	Bogdanov	none	
Dr.	Hugo	Boonen	I'm member of the BPWG (Belgian Psoriasis Working Group) - Most companies ask our advice concerning reimbursement.	
Prof.	Elke MGJ	de Jong	none	
Dr.	Ignacio	Garcia-Doval	Reports payment from Novartis and UCB for presentations unrelated to psoriasis (on meta-analysis and critical reading); personal payment	
Prof.	Paolo	Gisondi	none	
Dr.	Diljit	Kaur- Knudsen	none	
Dr.	Satveer	Mahil	none	
Dr.	Tarja	Mälkönen	Tarja Mälkönen has received honoraria from Abbvie, Eli Lilly, Janssen –Cilag, Novartis, and Pfizer for consulting and/or speaking.	
Dr.	Julia- Tatjana	Maul	none	
	Sicily	Mburu	none	
Dr.	Liam	Mercieca	none	
Prof.	Ulrich	Mrowietz	not declared	
Prof.	Alexander	Nast (AN)	none	
Prof.	Kristian	Reich	Has left the group	
Prof.	Eva	Remenyik	advisory member of Janssen	
Prof.	Dimitris	Rigopolous	none	
Dr.	Kirsten Marthine	Rønholt Stausholm	none	
Dr.	Paul- Gunther	Sator	none	
Prof.	Marcus	Schmitt- Egenolf	none	
Dr.	Mariusz	Sikora	none	
Prof.	Catherine	Smith	none	
Prof.	Phyllis I.	Spuls	none	
Dr.	Olav	Sundnes	none	
	David	Trigos	none	
	Gayle	van der Kraaij	none	
Prof.	Nikhil	Yawalkar	N Yawalkar reports personal fees from Abvive, personal fees from Almirall, personal fees from Amgen, grants and personal fees from Celgene, personal fees from Lilly, personal fees from Galderma, personal fees from Janssen, personal fees from Leo, personal fees from Novartis, personal fees from MSD, personal fees from Pfizer, personal fees from UCB, outside the submitted work;	
Dr.	Klaus	Strömer	none	

The EuroGuiDerm Living Psoriasis Guideline was updated and we disseminated this through various channels including social media and newsletters.

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Original Version June 2020

Involving stakeholders and forming the guideline subcommittee

A direct invitation to nominate an expert to participate in the GL development was send to all EuroGuiDerm funding societies (n=9, in March/April 2019, email see Scoping Document Appendix 1). Additionally, an open call went out to all EDF members.

All persons nominated received an invitation to submit their conflict of interest (COI) declaration online and to self-declare their 1) personal-financial interests (P-F) 2) non-personal financial interests (NP-F), and 3) their personal non-financial interests (P-NF). The EuroGuiDerm Board of Directors made the final decision on which candidates may participate considering these declarations during their meeting on May 21st 2019. Experts were informed thereafter.

Initially, 34 experts from 15 countries were nominated to co-develop the *EuroGuiDerm Psoriasis Guideline* and 11 declared personal financial (P-F) COI (32%). There were ten exclusion due to: P-F COI (3), overrepresentation from a country (3), cancellation (2), missing COI declaration (1). The final group consists of 25 members from 14 countries, seven of which declared to have P-F COI, which is a total of 28% of the group members (see Table 6). All experts are dermatologists. The two International Federation of Psoriasis Associations (IFPA) nominated patient representatives were not counted here.

TABLE 6: MEMBERS OF THE EUROGUIDERM PSORIASIS GUIDELINE DEVELOPMENT GROUP 2020

Title	First name	Last name	Institution	Society/ representing	Role
Prof.	Zsuzsanna	Bata-Csörgő	University of Szeged	The Hungarian Dermatological Society	Co-author
Dr.	Hugo	Boonen	Belgium	U.E.d.M.S. dermatology section	reviewer
Prof.	Elke	de Jong	Radboud University	International Psoriasis Council (IPC)	Co-author
Dr.	Ignacio	Garcia-Doval	Unidad de Investigación. Fundación Piel Sana AEDV	Spain	Co-author
Prof.	Paolo	Gisondi	University of Verona	Italy	Co-author
Dr.	Diljit	Kaur- Knudsen	University hospital Copenhagen	Danish Dermatological Society	Co-author
Dr.	Satveer	Mahil	Guy's and St Thomas' NHS Foundation Trust, London, UK	The United Kingdom	Co-author
Dr	Tarja	Mälkönen	Helsinki University Central Hospital	Finnish Dermatological Society	Co-author
Dr.	Julia- Tatjana	Maul	Department of Dermatology, University Hospital of Zürich	Switzerland	Co-author
	Sicily	Mburu	International Federation of Psoriasis Associations (IFPA); patient representative	IFPA Global Organisation	Patient rep



Title	First name	Last name	Institution	Society/ representing	Role
Prof.	Ulrich	Mrowietz	Universitätsklinikum Schleswig- Holstein	Germany	Co-author
Prof.	Alexander	Nast (AN)	Charité - Universitätsmedizin Berlin	EuroGuiDerm Centre Team, Germany	Coordinator, co- authored chapters
Prof.	Kristian	Reich	Institute for Health Services Research in Dermatology and Nursing, University Medical Center Hamburg-Eppendorf	Germany	Co-author
Prof.	Eva	Remenyik	University of Debrecen	The Hungarian Dermatological Society	Co-author
Dr.	Kirsten Marthine	Rønholt Stausholm	Aarhus University Hospital	Danish Dermatological Society	Co-author until 2022
Dr.	Paul- Gunther	Sator	Municipal Hospital Hietzing, Vienna	Austria: AG für Biologika und Immuntherapie bei chronisch entzündlichen Hauterkrankungen der ÖGDV	Co-author
Prof.	Marcus	Schmitt- Egenolf	Umeå university	Sweden	Co-author
Dr.	Mariusz	Sikora	Department of Dermatology, Medical University of Warsaw	Poland	Co-author
Prof.	Catherine	Smith	St John's Institute of Dermatology	the United Kingdom	Co-author
Prof.	Phyllis I.	Spuls	Academic Medical Centre Amsterdam	The Netherlands	Co-author
Dr.	Olav	Sundnes	Oslo University Hospital	Norwegian Society of Dermatology and Venereology	Co-author
	David	Trigos	IFPA, patient representative	IFPA and Europso (vice president)	Patient rep. until 2022
	Gayle	van der Kraaij	Academic Medical Centre Amsterdam	The Netherlands	Co-author
Prof.	Nikhil	Yawalkar	Inselspital Uni Bern	Switzerland	Co-author
Dr.	Klaus	Strömer	Mönchengladbach	U.E.d.M.S. dermatology section	Co-author
EuroG	uiDerm Team				
	Gabriela	Avila Valle (GA)	Charité - Universitätsmedizin Berlin	EuroGuiDerm Centre Team	Methodologist
	Martin	Dittmann (MD)	Charité - Universitätsmedizin Berlin	EuroGuiDerm Centre Team	Team Support; Information Specialist
Dr.	Corinna	Dressler (CD)	Charité - Universitätsmedizin Berlin	EuroGuiDerm Centre Team	Methodologist: GL development & Cochrane Review
	Rhea	Jakubzyk (RJ)	Charité - Universitätsmedizin Berlin	Doctoral student: systematic review of hepatitis, diabetes and kindey disease in psoriasis patients	
Cochra	ne Review liais	on			
Dr	Emilie	Sbidian (ES)	Equipe d'accueil Epidemiology in Dermatology and Evaluation of	Cochrane Review "Systemic pharmacological treatments for chronic plaque psoriasis:	methodologist (NMA text), dermatologist

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Title	First name	Last name	Institution	Society/ representing	Role
			therapeutics (EpiDermE), Université Paris Est Créteil (UPEC)	a network meta-analysis" coordinating author	
Dr	Laurence	Le Cleach			

We would like to thank the following experts for their input on specific chapters:

Psoriatic Arthritis	Rheumatologist Dr n. med Ewa Więsik-Szewczyk, Department of Internal Medicine, Pneumonology,
	Allergology, and Clinical Immunology, Central Clinical Hospital of the Ministry of National Defense, Military
	Institute of Medicine, Warsaw, Poland.

Declaration and management of conflicts of interest

Experts were asked to self-declare their interests as describes above via the online tool: *Declaration of Interests for EuroGuiDerm Guidelines*.

As suggested in the EuroGuiDerm Manual, all experts can participate in the discussion. However, declaring personal-financial COI has consequences: no vote/count on recommendations. Seven experts declared to have personal-financial COIs, the details are listed below.

TABLE 7: DECLARATIONS OF PERSONAL-FINANCIAL CONFLICTS OF INTERESTS AS PROVIDED BY EXPERT 2020

Title	First name	Last name	As declared by the person:
Dr	Hugo	Boonen	In the past I got a fee for presentations from different companies active in the field of dermatology
Dr.	Ignacio	Garcia- Doval	I have received over the last 10 years travel grants for congresses from Merck/Schering-Plough Pharmaceuticals, Pfizer and Janssen. I have been paid by Novartis for a talk about "The value of registries in pharmacovigilance" I have been paid by Leo Pharma for talks to residents on "Introduction to clinical research" within a course organized by the Spanish Academy of Dermatology.
Prof.	Tarja	Mälkönen	I have received educational grants and honoraria for speaking and consulting from Abbvie, Celgene, Eli Lilly, Janssen Cilag, and Novartis.
Prof.	Ulrich	Mrowietz	Ulrich Mrowietz has been an advisor and/or received speakers honoraria and/or received grants and/or participated in clinical trials of the following companies: AbbVie, Almirall, Aristea, Boehringer-Ingelheim, Celgene, Dr. Reddy's, Eli Lilly, Foamix, Formycon, Forward Pharma, Janssen, Leo Pharma, Medac, Novartis, Sanofi-Aventis, UCB, Xenoport
Prof.	Kristian	Reich	Professor Reich has served as advisor and/or paid speaker for and/or participated in clinical trials sponsored by Abbvie, Affibody, Almirall, Amgen, Avillion, Biogen, Boehringer Ingelheim, Bristol-Myers Squibb, Celgene, Centocor, Covagen, Dermira, Forward Pharma, Fresenius Medical Care, Galapagos, GlaxoSmithKline, Janssen-Cilag, Kyowa Kirin, Leo, Lilly, Medac, Merck Sharp & Dohme, Novartis, Miltenyi Biotec, Ocean Pharma, Pfizer, Regeneron, Samsung Bioepis, Sanofi, Sun Pharma, Takeda, UCB, Valeant, Xenoport.
Dr.	Mariusz	Sikora	Payment for lectures (Janssen, Novartis) Payment for development of educational presentations (Novartis) Sub-Investigator in clinical trials (Janssen)
Prof.	Nikhil	Yawalkar	Yawalkar N has received honoraria for consulting and advisory board attendance from Abbvie, Almirall, Amgen, Celgene, Eli Lilly, Galderma, Janssen, Leo, Novartis, MSD and Pfizer.





Scope and purpose of the guideline

The EuroGuiDerm staff (CD) prepared a scoping document in line with the requirements of the EuroGuiDerm Methods Manual. The draft was sent to EDF members and the EuroGuiDerm Board of Directors in March/April 2019 for commenting, see Scoping Document Appendix 1. This version was also circulated to the guideline subcommittee for further comments and consideration before the kick-off conference.

The aim of the guideline is to develop management and treatment recommendations for the care of adults with plaque type psoriasis. Based on the scoping results and the opinion of the subcommittee, the objectives of the *EuroGuiDerm psoriasis guideline* are to:

- Include new treatments and the evidence that has become available
- Update the recommendations regarding biologic systemic treatment options (Part 1)
- Develop a treatment algorithms including biologic and nonbiologic systemic treatment options
- Provide clear recommendations on how to best monitor and manage patients considering the available treatment options
- Develop several, short guidance documents with visual tools for ease of implementation
- Provide guidance on the treatment of special populations and difficult clinical situations (mostly expert consensus; Part 2)

Population and health questions covered by the guideline

The target population are adult patients with psoriasis vulgaris, moderate to severe severity, and adult patients with psoriasis arthritis, who have also been diagnosed with moderate to severe psoriasis vulgaris. This guideline applies to Europe and both, hospital and practice based (private and public) dermatologists are the target users.

Leading health questions - all referring to adult individuals (all genders) with moderate or severe plaque type psoriasis – are:

- Which treatment option should be chosen with regard to patients' needs, taking efficacy, safety/tolerability of the different treatment options and comorbidities into consideration?
- How should the selected treatment option best be managed and monitored?
- How should frequent comorbid situations (e.g. concomitant arthritis) best be managed?





The relevant interventions discussed during the kick-off conference are listed in Table 8. This list was generated based on the update of the Cochrane review on systemic treatments for psoriasis vulgaris ³, which we collaborated with. The subcommittee decided to exclude those that are crossed out in Table 8 because they were not licensed for psoriasis vulgaris at that time. Relevant comparison are head-to-head studies of the below mentioned drugs or versus placebo. The outcomes chosen are: 90% improvement in the Psoriasis Area Severity Index (PASI 90) and severe adverse events (SAEs), and PASI 75 and adverse events (AEs).¹.

We worked in collaboration with the team updating the Cochrane review.

TABLE 8: SYSTEMIC INTERVENTIONS FOR PSORIASIS VULGARIS

Systemic conventional treatments	Small molecules	TNFi	Anti- IL12/23	Anti-IL17	Anti-IL23
FAEs	Apremilast	Infliximab	Ustekinumab	Secukinumab	Tildrakizumab
Acitretin	Tofacitinib	Etanercept		Brodalumab	Guselkumab
Ciclosporin	BMS-986165	Adalimumab		Ixekizumab	Rizankizumab
Methotrexate		Certolizumab		Bimekizumab	Mirikizumab

⁻ treatments crossed out are included in the Cochrane Review but not in the guideline

Additionally, the below listed comorbidities and special situations are addressed by the guideline.

TABLE 9: OVERVIEW OF TOPICS & KEY QUESTION IN RELATION TO COMORBIDITIES AND SPECIAL PATIENT POPULATIONS/ISSUES

TOPIC	QUESTION(S)
Psoriatic arthritis	- How should psoriasis patients with concomitant psoriatic arthritis be managed?
Inflammatory bowel disease	– How should psoriasis patients with inflammatory bowel disease be managed?
Cancer	 How should psoriasis patients with a history of malignancies be managed?
Depression	 How should psoriasis patients with a history of depression and/or suicidal ideation be managed?
Diabetes mellitus	How should psoriasis patients with diabetes mellitus be managed?
Heart disease	 How should psoriasis patients with ischaemic heart disease and/or congestive heart failure be managed?
Kidney disease	 How should psoriasis patients with kidney failure / renal impairment be managed?

 $^{^{}m 1}$ The Cochrane Review 2020 reported PASI75 and AE outcome data as secondary analysis, see sections:

PASI75 Analysis 3.1 – 3.10 (pages 469 – 505) and AE Analysis 6.1.- 6.10 (pages 528 – 536)

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TOPIC	QUESTION(S)
Neurology	 Which treatments are appropriate for psoriasis patients with neurological diseases?
Hepatitis	 When and how should psoriasis patients be screened for viral hepatitis and how should patients who test positive be managed?
Tuberculosis screening	How to screen for tuberculosis before and during biologic treatment
Tuberculosis and treatment	 How to manage psoriasis in patients with positive tuberculosis test results
Pregnancy	 How should psoriasis patients with a wish for pregnancy in the near future or who are pregnant be managed?
Vaccinations	 How should vaccinations in psoriasis patients on systemic treatment be managed?
Immunogenicity	– What is the role of anti-drug antibodies in biologic treatments?
COVID 19	- Guidance for systemic therapy of psoriasis during Covid 19 pandemic

Selecting and specifying guideline questions

This guideline is an update of the European Psoriasis Guideline 2015 & 2017 ^{4,5}. The subcommittee considered the range of topics addressed in the previous version(s) as well as new ones, and then choose the key questions to focus on accordingly during the kick-off meeting (see Table 9).

Search methods and results, evidence selection & critical appraisal of evidence

We were aware that the Cochrane Review "Systemic pharmacological treatments for chronic plaque psoriasis: a network meta-analysis" published in 2017 is a living review and an update was underway. Since Cochrane reviews represent the gold standard with regard to methodological rigor, a member of the EuroGuiDerm Team (CD) joined the Cochrane Team to support efficient work and save resources and to foster the production of one rigorously conducted, high quality systematic review and networkmeta analysis. The methods used in the conduct of this review are transparently reported in the full review document: https://doi.org/10.1002/14651858.CD011535.pub3.

Additionally, we developed an **evidence to decision framework** outlining: PICO, setting, perspective, purpose of the guideline & research evidence on problems (based on the scoping process), *benefits* & *harms of the interventions* (evidence from above mentioned review), and also different disease definitions & treatment goals to foster national considerations/implementation options. We included a flow chart and a decision grid, which display the most important recommendations. The subcommittee reviewed this framework, comments were integrated

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Furthermore, a number of special topics were supported by systematic searched or systematic literature reviews. A detailed description of the methods and procedures applied to review and evaluate the literature for each chapter on special patient populations/specific treatment circumstances are provided in the appendix. An overview is show in Table 10, all details are reported in the Appendices.

TABLE 10: OVERVIEW OF SPECIFIC TOPICS & TYPE OF EVIDENCE REVIEW THE RECOMMENDATIONS ARE BASED ON

Topic	Type of evidence review		
Evidence review methods for p	part 1: general recommendation for adult patients with plaque type psoriasis:		
Psoriasis vulgaris	Sbidian E, Chaimani A, Afach S, Doney L, Dressler C, Hua C, Mazaud C, Phan C, Hughes C, Riddle D, Naldi L, Garcia-Doval I, Le Cleach L. Systemic pharmacological treatments for chronic plaque psoriasis: a network meta-analysis. Cochrane Database of Systematic Reviews 2020, Issue 1. Art. No.: CD011535. DOI: 10.1002/14651858.CD011535.pub3.		
	The methods are reported in the full review document : https://doi.org/10.1002/14651858.CD011535.pub3 (also available upon request euroguiderm@debm.de)		
	A protocol 'Systemic pharmacological treatments for chronic plaque psoriasis' (Sbidian 2015) was published for the first review. This review is an update of 'Systemic pharmacological treatments for chronic plaque psoriasis: a network meta-analysis' (Sbidian 2017).		
Evidence review methods for properties comorbid conditions and/or specific comorbid conditions and/or specific comorbid conditions and conditions and conditions and conditions are conditions.	part 2: specific recommendations for adult patients with plaque type psoriasis and pecific issues:		
Psoriasis Arthritis	Systematic review. The Method & Evidence Reports are included in the individual chapter, see website.		
Inflammatory Bowel Disease	Narrative review by co-authors		
Cancer	Systematic search, a methodologist (GA) with medical background from the EuroGuiDerm Team conducted a topic specific but non-systematic screening		
Depression	Systematic search, a methodologist (GA) with medical background from the EuroGuiDerm Team conducted a topic specific but non-systematic screening		
Diabetes mellitus	Systematic review. The Method & Evidence Reports are included in the individual chapter, see website.		
Heart Disease	Systematic search, a methodologist (GA)with medical background from the EuroGuiDerm Team conducted a topic specific but non-systematic screening		
Kidney Disease	Narrative review		
Neurological diseases	Narrative review		
Viral hepatitis	Systematic review. The Method & Evidence Reports are included in the individual chapter, see website.		
Tuberculosis Screening	Systematic search, a methodologist (GA) with medical background from the EuroGuiDerm Team conducted a topic specific but non-systematic screening		

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Topic	Type of evidence review
Tuberculosis Treatment	Systematic search, a methodologist (GA) with medical background from the EuroGuiDerm Team conducted a topic specific but non-systematic screening
Pregnancy	Systematic search, a methodologist (GA) with medical background from the EuroGuiDerm Team conducted a topic specific but non-systematic screening
Vaccinations	Narrative review by co-authors
COVID19	Narrative review by co-authors
Immunogenicity	Narrative review by co-authors

Several chapters /author groups were supported by a methodologist who conducted systematic search. The non-systematic selection of published materials was not restricted by publication tyoe. Guideline were included, also from other specialisties. We used the AGREE II instrument domain 8 to evaluate the 13 identified evidence-based guidelines ⁶. The evaluations are included in the appendix 12 . There were 13 guidelines referred to with regards to the "specific circumstances" chapters. Only two were not evidence based.

Developing background texts

Background texts were drafted by individuals or groups of experts. Those who had reported P-F COIs did not work on a background text alone but got assigned a co-coordinator where possible. The drafts were then thoroughly reviewed by the entire group. All background texts were subject to explicit voting.

TABLE 11: OVERVIEW OF CHAPTER AUTHOR/GROUPS

Chapters	(new) responsible person/group	
Actretin	P Gisondi	
CSA	P Gisondi	
FUMAR	U Mrowietz* & A Nast	
MTX	U Mrowietz* & A Nast	
Infliximab	S Mahil	
Ustekinumab	S Mahil	
Adalimumab	P-G Sator	
Etanercept	P-G Sator	
Apremilast	P Gisondi	
Secukinumab	P Gisondi	
Tildrakizumab	J-T Maul	
Brodalumab	G van der Kraaij	
Guselkumab	K Reich* & A Nast	
Ixekizumab	E de Jong	
Risankizumab D Kaur Knudsen		







Chapters	(new) responsible person/group	
Certolizumab	E de Jong	
Biosimilars	E Remenyik & A Nast	
New drugs	E Remenyik & A Nast	
Psoriatic Arthritis	A Nast, M Sikora, T Mälkönen*	
IBD	Z Bata-Csörgö, T. Mälkönen*, K Reich*	
Cancer	O Sundnes, E de Jong, J-T Maul, I Garcia Doval*	
Depression	C Smith, Kirsten Ronholt	
Diabetes Mellitus	P Gisondi, K Reich*, M Sikora*, J-T Maul	
Heart Disease	P Gisondi, K Reich*, M Sikora*	
Hepatitis	P Spuls, E de Jong, A Nast	
Kidney U Mrowietz*		
Neurology	C Smith, K Ronholt	
TB screening	A Nast, P Spuls, M Schmitt-Egenolf, O Sundnes	
TB treatment	K Reich*, M Schmitt-Egenolf, O Sundnes	
Pregnancy	C Smith, S Mahil, E de Jong, J-T Maul	
Vaccinations	U Mrowietz, N Yawalkar	
COVID-19	P Gisondi, M Sikora, U Mrowietz*	
Immunogenicity	K Reich* (no recommendations; separate publication developed)	

^{*} P-F COIs

Developing recommendations and the consensus process

Recommendations were drafted by the chapter co-authors. As detailed in Table 10, the general recommendations for the treatment of psoriasis vulgaris as well as the recommendations for hepatitis, diabetes mellitus and psoriasis arthritis are evidence and consensus-based recommendations. For each of these a systematic review had been conducted.

Co-authors submitted draft background texts and the drafted recommendations, at times multiple suggestion with different strength and/or wording, all of which were subject to (pre-)voting.

Three consensus conferences were scheduled. Prior to each one, an online survey tool (limesurvey) was used so that each member of the guideline development subcommittee was able to have time to read each draft including the suggested recommendations and vote.². Voters were able to agree or disagree with a) the text and b) the recommendation(s). In case of disagreement, it was mandatory to give a reason why and cite supporting literature. Subcommittee members were hence able to vote without

² The drafts on depression, malignancy, guselkumab and certolizumab were circulated prior to the final consensus conference but no pre-voting took place due to a lack of time.







others being present or seeing what others had chosen. This made it possible for members who may be less comfortable to engage in group discussions to participate.

The consensus conferences were online conference for which participants dialled in by telephone. We used a screen sharing tool to show the drafts that were discussed. The conferences took place on 27 November 2019, 3 December 2019, 4 February 2020.

Each chapter/topic was discussed separately. The EuroGuiDerm Team prepared the drafts showing the pre-voting results and any comments submitted during online voting. No names were displayed to foster an open discussion.

Alexander Nast facilitated all three consensus conferences. He presented results from the pre-voting alongside the background text and after discussion, the recommendation(s). After each section he opened up the floor for discussion. Benefits, harms, processes and procedures were extensively discussed. The nominal group techniques was chosen to facilitate the consensus process ⁷. As suggested by the EuroGuiDerm Methods Manual, the (pre-)votes of those with personal financial COIs were not counted.

In accordance with the EuroGuiDerm Manual, we used phrasing suggested by the GRADE Working Group to standardize the wording of all recommendations ⁸. This is reported as show in Table 12. The strength of the consensus is also reported. Recommendations and texts were discussed and voted upon until a majority of more than 50% agreed.

TABLE 12: WORDING OF RECOMMENDATIONS 9-12

Strength	Wording	Symbols	Implications
Strong recommendation for the use of an intervention	'We recommend '	个个	We believe that all or almost all informed people would make that choice. Clinicians will have to spend less time on the process of decision-making, and may devote that time to overcome barriers to implementation and adherence. In most clinical situations, the recommendation may be adopted as a policy.
Weak recommendation for the use of an intervention	'We suggest'	↑	We believe that most informed people would make that choice, but a substantial number would not. Clinicians and health care providers will need to devote more time on the process of shared decision-making. Policy makers will have

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Strength	Wording	Symbols	Implications
			to involve many stakeholders and policy making requires substantial debate.
No recommendation with respect to an intervention	'We cannot make a recommendation with respect to . '	0	At the moment, a recommendation in favour or against an intervention cannot be made due to certain reasons (e.g. no reliable evidence data available, conflicting outcomes, etc.)
Weak recommendation against the use of an intervention	'We suggest against'	\	We believe that most informed people would make a choice against that intervention, but a substantial number would not.
Strong recommendation against the use of an intervention	'We recommend against'	↓ ↓	We believe that all or almost all informed people would make a choice against that intervention. This recommendation can be adopted as a policy in most clinical situations.

TABLE 13: STRENGTH OF CONSENSUS

Strong consensus	Agreement of >95% participants	
Consensus	Agreement of >75-95% participants	
Agreement of the majority	Agreement of >50-75% participants	

The final presentation of the recommendations looks as shown below. When the consensus strength identical for more than one recommendations, this was only displayed once in the left column of the recommendation block, where applicable. Evidence and consensus based recommendations are presented as such with a clear link to the evidence base used.

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FIGURE 1: EXAMPLE OF HOW RECOMMENDATIONS ARE PRESENTED

We **recommend** to do tuberculosis screening according to local regulations.



¹ due to personal-financial conflict of interest x abstentions

Additionally, the management recommendations and lab controls were also voted on. The consensus strength is displayed in the upper right corner of the management recommendation field (light blue) but encompassed also the voting on lab control.s

Internal and external review

The internal and external review took place. The guideline document and the methods & evidence report (Version 1.0 February 2020) as well as the review commenting form were send to: all 23 experts and both patient representatives (IFPA), all EDF members and the EDF Board, all supporting societies (n= 11), the EuroGuiDerm Board of Directors and the Methods Boards members, the EADV Board, and pharmaceutical companies. Additionally, we invited societies representing other specialities: Rheumatology (EULAR), UEMS Rheumatology, UEMS Gastroentorology/Hepatology, UEMS Infection diseases, European Society of Endocrinology, UEMS Cardiology, UEMS Psychiatry, UEMS Neurology, UEMS Malignancy, ERBP (European Renal Best Practice), EBCOG Working group (pregnancy).

The review phase was 6 weeks long (19 February 2020 – 1 March 2020). Two reminder were sent.

The members of the guideline development group reviewed the guideline and the guideline development report and submitted feedback. Additionally, we received feedback from the below listed external statekholders, whom we would like to thank for their input!

TABLE 14: EXTERNAL STAKEHOLDER WHO SUBMITTED FEEDBACK DURING THE REVIEW PHASE

EuroGuiDerm Methods Board
L Naldi
O Chosidow
OTHER STAKEHOLDERS
C Paul (EDF)
C Sunderkötter (EDF)
W Sondermann (EDF)
OTHER SPECIALITIES
HEART DISEASE- Chris Pulmers
IBD - Isabelle Cremers
KINDEY - Evi Nagler
INFECTIOUS DISEASE ID Stabl

INFECTIOUS DISEASE - JP Stahl

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RHEUMATOLOGY - Peter Härle
FUNDING SOCIETIES
Greece
Norway
Finland
Danemark
Belgium
Hungary
UK
Germany
INDUSTRY
Leo Pharma
UCB Biopahrma
Ely Lilly
Enbrell
Almirall
Janssen
Novartis

All comments were combined in an excel table. Editorial comments were resolved by the EuroGuiDerm Team. All other comments were sent to the author/author groups on 24 April 2020 to be resolved within 10 days.

All changes to the guideline and this report were made using the "track changes" function in word (track change versions 1.1 May 2020). Any changes in response to each and all comments received were clearly recorded in the excel table. All reviewers received feedback to their comments alongside the GL and the report where all changes resulting from the commenting phase are clearly visible.

The guideline development group received the GL and report (track change versions 1.1 May 2020) alongside the anonymised excel table containing all comments and responses for final review and approval. The EuroGuiDerm Board of Directors also received these documents. The experts from other specialities that had commented also received the version 1.1. May 2020.

The "track change versions 1.1 May 2020" were also submitted to the JEADV for peer-review (19 May 2020). Please note that the chapter on covid-19 was developed later and hence only reviewed by the group and through the JEADV peer-review process. Immunogenicity is being developed and published as a separate research project.

The national societies received the track change version 1.1 May 2020 alongside the overview of all comments and responses submitted by all societies.

An anonymised version of all comments, feedback and action taken are available from euroguiderm@debm.de.





Dissemination and Implementation

A decision grid I + II and a flow chart were developed to foster implementation. We included both in the external reviews. Feedback was collected and the comments we received were overall positive: "helpful", "clear", "useful" etcetera.

Furthermore, we developed a dissemination and implementation plan, see Table 15.

Barriers and facilitators to implementation/application

By implementation one refers to patient care following the recommendations presented in the guideline 13. As described in the EuroGuiDerm Methods Manual (see **EDF** https://www.guidelines.edf.one/guideline-methods) guideline implementation is effected by a variety of factors, which are specific to location and setting. The main barrier to implementation may be the national/local definitions of disease and treatment goals as well as drug costs and drug availabilities. Main facilitators to implementation may be the decision grid and the flow chart we developed. Also, we included 11 national societies and experts from 14 countries to foster national/local adoption/adaption. The national societies were informed about the status of the guideline development and invited to form nation review committees early on to encourage adaption/adoption - this process is also clearly laid out in the EuroGuiDerm Manual (Chapter 10).

Quality standards and monitoring indicators

Over the two years following the publication of the EuroGuiDerm Psoriasis guideline on the EDF website we will assess:

- Number of accesses and/or downloads from the EDF website
- Number of countries which adopted (translated the guideline as is, without change of content)
 by European countries, regions and non-European countries
- Number of countries which adapted the guideline (used parts of the guideline, or some recommendations) by European countries, regions and non-European countries

Evaluation Methods

Monitoring and evaluation is to be done on national levels.

- Change in practice performance
- Change in health outcomes
- Change in end-user knowledge and understanding

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As an example for national monitoring and evaluation strategies, see BAD ¹⁴ or for an example of a cross sectional survey about psoriasis patient care ¹⁵. We plan to submit the guideline and all accompanying documents to the ECRI trust for external evaluation.

Lastly, the reporting was guided by the EuroGuiDerm Manual, the RIGHT statement and the AGREE II point. In appendix 13, we included the AGREE II checklist. This may help others when assessing the EuroGuiDerm Psoriasis guideline.

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TABLE 15: DISSEMINATION PLAN

Audience	Responsible Subcommittee member(s)	Communication and implementation tools to be used	Time at which they are to be developed, piloted or to take place	Is EuroGuiDerm support needed, and if yes what kind of support?
Dermatologist & researchers, societies, pharmaceutical companies	EuroGuiDerm Team	 Full guideline & methods report, decision grid I +II & flow chart: EDF website Guidelines International Network (GIN) 	After final approval of EuroGuiderm BoD	EuroGuiDerm Team to manage submission
Dermatologist & researchers, societies, pharmaceutical companies	EuroGuiDerm Team	TWITTER & NEWSLETTER (EDF/ all national societies, pharma contacts, IFPA) Flow chart Decision grid I+II	After final approval of EuroGuiderm BoD	EuroGuiDerm Team to manage social media output
Dermatologist in Europe	Alexander Nast	EDF quideline mobile phone APP Inform users via newsletter, social media once updated	start during review process	n/a
Patients	David Trigos & Sicily Mburu (IFPA)	JOINT Q & A for patients on the most mentioned topics by patients in the IFPA survey OR mini toolkit for patients	in parallel to external review	Corinna Dessler to support
Patient Organizations	2-3 co-authors	IPFA Webinar	After final approval of EuroGuiderm BoD	EuroGuiDerm Team to coordinate
Dermatologist & researchers	Alexander Nast	Journal publication JEADV	After external review	EuroGuiDerm Team to coordinate, formatting and submission
All	EuroGuiDerm Team	guideline & guideline report submitted to the ECRI Trust for external evaluation	After final approval of EuroGuiderm BoD	EuroGuiDerm Team to managem submission and coordination



Research priorities

- Which are the predictors for treatment success or the occurrence of adverse events?
- What is the role of therapeutic drug monitoring?
- When should a treatment be stopped in case of clearance?
- Which treatments can be combined safely and lead to improved efficacy?
- What is the most suitable treatment option in given comorbid situations?

Cost and economic considerations

Cost and economic considerations were discussed but due to differences in the different health care systems this was not a focus. Cost considerations are subject to local adaptation.

Patient-perspective and needs

We contacted the International Federation of Psoriasis Associations (IFPA) and invited them to nominate two patient representatives ideally considering representation regarding gender and disease severity/comorbidities or similar. Both nominees participated in the pre-voting and all consensus meetings, they had one vote each.

The EuroGuiDerm Psoriasis GL project was presented at the IFPA annual board meeting with multiple suggestions and input on how IFPA could contribute following an overview of the final draft guideline.

- a) Joint Q&A:
 - a. To provide patients/lay persons with an understanding on how to use the guideline or how they could understand the new EuroGuiDerm guideline
 - The choice of topics will be guided by the IFPA members survey: Biosimilars, Psoriasis and Pregnancy, Awareness and Attention to Comorbidities - CVD, Depression, Nutrition and Vaccinations

OR

b) A mini toolkit to assist Psoriasis Patient Treatment and care pipeline: what is the guidelines for?, whom can they contact?, what are the next steps after receiving care? What is the after-care management? After examination?

IFPA developed a patient guide including a Q&A section and a mini toolkit. The Q&A section has been integrated into the main guideline text and published.

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Strength and Limitations

The guideline development group members – representing 14 countries - contributed a variety of issues to the discussions around, for example, availabilities of drugs, local clinical practice and national guidelines. A total of 9 national societies had nominated experts.

Furthermore, to forgo the potential influence of personal-financial conflicts of interests, few experts with P-F COIs were able to participate in the guideline development.

The strength of the body of evidence used, the Cochrane systematic review, lies within the application of rigorous and systematic methods. An expert and a methodologist from the guideline development group were involved in the conduct of the review. Additionally, we developed an evidence to decision framework, see appendices. In a structured way we presented: PICO, setting, perspective, purpose of the guideline & research evidence on problems (based on the scoping process), benefits & harms of the interventions (evidence), and also different disease definitions & treatment goals to foster national considerations/implementation options. This was done for systemic treatment of plaque type psoriasis overall (appendix 1) as well as for psoriatic arthritis (appendix 2).

Furthermore, the EuroGuiDerm Team supported the co-authors working on chapters with specific topics with systematic literature searches and focused screening, see Table 10. While not all chapters were supported with evidence generated through a systematic review, through this support an independent element was added.

Cost and economic considerations were discussed but are not subject to this guideline due to the different local and national requirements. These barriers to implementation need to be considered within the national or local context.

Update and Methods

The general recommendations developed in this guideline are based on the Cochrane Review published in January 2020. As this review is a living systematic review updated yearly, new evidence and new results may become available in this rapidly evolving field. The guideline subcommittee will consider 1) each review update and 2) important clinical key questions and decide whether an update of the guideline, or parts of the guideline, for example, the flow chart, is necessary, see Figure 2. Every 12-18 months, the GDG is asked to review the current guideline in light of newly available evidence and complete a structured online survey about the necessarily of updating each section/recommendation.

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This process and updates will be available on the EDF website and communicated through appropriate channels.

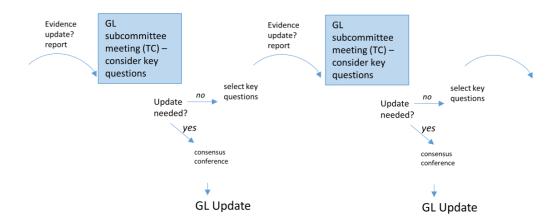


FIGURE 2: PROCESS OF UPDATING THE GUIDELINE



APPENDIX AGREE II EVALUATION 2019

AGREE II Evaluation of guidelines used by the GDG

In the special population group, we included as evidence 13 guidelines. We appraised the methodological quality of each guideline using the Domain 3 of the AGREE II tool. Of these, 11 were evidence-based guidelines and two of the guidelines included no evidence-based recommendations but expert recommendations, as shown below.

					AGREE II-Domain 3: Rig	gour of development				
Guidelines	7. Systematic methods were used to search for evidence.	8. The criteria for selecting the evidence are clearly described.	9. The strengths and limitations of the body of evidence are clearly described.	10. The methods for formulating the recommendations are clearly described.	11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	12. There is an explicit link between the recommendations and the supporting evidence.	13. The guideline has been externally reviewed by experts prior to its publication.	14. A procedure for updating the guideline is provided.	Quality score (0%- 100%)	Chapters
Amatore et al. 2019 French guidelines on the use of systemic treatments for moderate-to-severe psoriasis in adults	Medline search between January 2014- October 2017, search given in appendix but not full search described with boolean operators search strategy might not be extensive filters not	Focused on large and or prospective cohorts and or controlled randomize dimited to English paper, comparisons selected PICO not clearly stated.	AGREE score of each guideline not reported. The articles were all selected through GRADE methodology. No report of studies limitations in Appendix just level of evidence reported in each chapter for studies.	If a consensus was not achieved for a recommendation, a vote was performed, and participants were asked to agree or disagree with the recommendation. No outcome of voting procedures reported for the recommendations.	For each chapter and medication health benefits, side effects and risk are reported	Each recommendation in main article are stated in text and table, but somehow the recommendations are not clearly identified which makes it hard to identify recommendations with key evidence	This document was then reviewed by public and private practice practitioners involved in psoriasis treatment. No description on which methods were undertake for external review and what outcomes were gathered after external review. No description on how information gathered was used.	An update of the present guidelines will be necessary by 2020. No methodology of update reported		3.6. Cancer: how should psoriasis patients with a history of malignancies be managed? 3.13. Inflammatory bowel disease: how should psoriasis with inflammatory bowel disease be managed



					AGREE II-Domain 3: Rig	our of development				
Guidelines	7. Systematic methods were used to search for evidence.	8. The criteria for selecting the evidence are clearly described.	9. The strengths and limitations of the body of evidence are clearly described.	10. The methods for formulating the recommendations are clearly described.	11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	12. There is an explicit link between the recommendations and the supporting evidence.	13. The guideline has been externally reviewed by experts prior to its publication.	14. A procedure for updating the guideline is provided.	Quality score (0%- 100%)	Chapters
	explained if used									
Rating	5	4	4	4	7	5	5	6	67%	
Carretero et al. 2013 Guidelines for the use of acitretin in psoriasis. Psoriasis Group of the Spanish Academy of Dermatology and Venereology	No search strategy reported in main article	No selection of study criteria reported	No strength and limitation of evidence included is described	We felt it would be of interest to develop guidelines by consensus among the members of the Psoriasis Group of the Spanish Academy of Dermatology and Venereology.	Benefits, side effects, situations of risk, drug interactions and contraindications were extensively described	Recommendations are not clear but statements made are supported by evidence of studies given for each section	No description if guideline was externally reviewed	No statement of update is given or timescale		3.5. Kidney disease: How should psoriasis patients with kidney failure/renal impairment be managed?
Rating	1	1	1	2	7	4	1	1	21%	
Chadban 2012 KHA-CARI guideline: KHA- CARI adaptation of the KDIGO Clinical Practice Guideline for the Care of Kidney Transplant Recipients	Databases searched given and date of search, search strategy described in Table 32 in Appendix but Appendix material	Found no additional informatio n on which studies were selected and what PICOS were used	Unclear how the risks of bias of included studies was evaluated, but GRADE methodology was used and is not clear which outcomes were evaluated and how they were rated.	KDIGO also provide —ungraded statements (or consensus driven statements) that reflect clinically relevant advice that is not supported by the evidence base for the question. Unclear how consensus voting is performed, how disagreements are	Outcomes for each topic where not clearly presented but in evidence text adverse events and contraindications are taken into account but is not easy to find benefits and harms for each topic.	Recommendations are given for each topic and relate to evidence text but recommendation but difficult to link studies in which recommendation in which is based.	No information if guideline was externally reviewed or not	No statement on update or time interval		3.5. Kidney disease: How should psoriasis patients with kidney failure/renal impairment be managed?



					AGREE II-Domain 3: Rig	our of development				
Guidelines	7. Systematic methods were used to search for evidence.	8. The criteria for selecting the evidence are clearly described.	9. The strengths and limitations of the body of evidence are clearly described.	10. The methods for formulating the recommendations are clearly described.	11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	12. There is an explicit link between the recommendations and the supporting evidence.	13. The guideline has been externally reviewed by experts prior to its publication.	14. A procedure for updating the guideline is provided.	Quality score (0%- 100%)	Chapters
	could not be found			resolved and outcome of voting not reported						
Rating	4	1	5	4	5	4	1	1	35%	
Elmets et al. 2019 Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with awareness and attention to comorbidities	We obtained evidence by searching the PubMed and Medline databases for reports published during January 1, 1980-December 31, 2017. Search limited to English. Search terms are given but no complete full search strategy with boolean operators could be found	After removal of duplicate data, 516 articles were retained for final review on the basis of relevancy and the highest level of available evidence for the outlined clinical questions. Not a clear PICO and outcomes selection	The available evidence was evaluated using a unified system called the Strength of Recommendati on Taxonomy. Not the best method available.	Clinical recommendations were developed on the best available evidence tabled in the guideline. For situations in which documented evidence based data was not available, we have utilized expert opinion to generate our clinical recommendations. Unclear how voting was performed and the outcomes of voting.	Benefits and harms for each patient population is taken into consideration also citing evidence for contraindications with certain drugs. But difficult to identify in the evidence text	Every recommendation has level of evidence and studies cited at the side. Also presented in main text	Guidelines was reviewed by the national psoriasis foundation and provided feedback and also reviewed by the ADD board. No results of reviews described and how information was used.	This guideline will be considered current for a period of 5 years from the date of publication unless reaffirmed, updated, or retired before that time.		3.2. How should psoriasis patients with a history of depression and/or suicidal ideation be managed? 3.3. Diabetes: How should psoriasis patients with diabetes mellitus be managed? 3.13. Inflammatory bowel disease: How should psoriasis patients with inflammatory bowel disease be managed?



					AGREE II-Domain 3: Rig	our of development				
Guidelines	7. Systematic methods were used to search for evidence.	8. The criteria for selecting the evidence are clearly described.	9. The strengths and limitations of the body of evidence are clearly described.	10. The methods for formulating the recommendations are clearly described.	11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	12. There is an explicit link between the recommendations and the supporting evidence.	13. The guideline has been externally reviewed by experts prior to its publication.	14. A procedure for updating the guideline is provided.	Quality score (0%- 100%)	Chapters
Rating	5	4	4	4	5	7	4	6	65%	
Holroyd et al. 2019 The British Society for Rheumatology biologic DMARD safety guidelines in inflammatory arthritis	A comprehensi ve literature search was undertaken by two reviewers, using MEDLINE, Cochrane, PubMed and EMBASE databases with specific search terms (Table 3). Search strategy given but not for each database	Only articles in the English language containing informatio n on the safety of biologic therapies were included. No additional informatio n of outcomes included and study design for inclusion	The GRADE method was used to assess the quality of evidence and the strength of recommendatio n. Unclear about the limitations of included studies, which outcomes were evaluated and no summary of finding tables provided.	Based on the strength of recommendation and level of evidence, each recommendation was subject to a vote by all members of the GWG; a scale of 1 (no agreement) to 10 (complete agreement) was used. Each recommendation reports strength of agreement	Benefits, harms, and contraindications were taken into account this is reported in text and in recommendations but can be difficult to identify in evidence text.	Each recommendation has the evidence text supporting it and studies cited but it would have been easier to identify if in the recommendation studies were also cited (evidence summaries or tables)	No mention of external review or patient representatives review.	In line with BSR's guideline protocol, this guideline will be updated in 3 4 years, but if there is a significant change in the evidence base then an earlier update may be undertaken. No report of methodology of update		3.6. Cancer: how should psoriasis patients with a history of malignancies be managed 3.10. Tuberculosis: How to manage psoriasis in patients with positive tuberculosis test results?
Rating	6	4	5	7	6	6	1	6	69%	
Lewinsohn et al. 2019 Official American Thoracic Society/Infectious	Databases searched and search strategy not reported	The subcommi ttees sought diagnostic accuracy	GRADE methodology was used but summary of finding tables are not shown	Open discussion was used to arrive at a consensus for each of the recommendations.	The decision to recommend for or against an intervention was based upon consideration of the balance of desirable	Evidence found for each recommendations is clearly described in the evidence text also rationale and limitations.	No information if guideline was externally reviewed	No information on guideline update		3.9. Tuberculosis: How to screen for tuberculosis before and



					AGREE II-Domain 3: Rig	gour of development				
Guidelines	7. Systematic methods were used to search for evidence.	8. The criteria for selecting the evidence are clearly described.	9. The strengths and limitations of the body of evidence are clearly described.	10. The methods for formulating the recommendations are clearly described.	11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	12. There is an explicit link between the recommendations and the supporting evidence.	13. The guideline has been externally reviewed by experts prior to its publication.	14. A procedure for updating the guideline is provided.	Quality score (0%- 100%)	Chapters
Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children		studies. No descriptio n of language given but table for included studies are provided for each question.	but method of rating accuracy studies described	An open voting procedure was reserved for situations when the subcommittee could not reach consensus through discussion. The method used do not reports the extent in which consensus was reached	consequences and undesirable consequences. Pros and cons for each diagnostic methods and limitations are given also contraindications.					during biologic treatment? 3.10. Tuberculosis: How to manage psoriasis in patients with positive tuberculosis test results?
Rating	1	4	5	4	7	6	1	1	44%	
Menter et al. 2009 Guidelines of care for the management of psoriasis and psoriatic arthritis: section 4. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents	An evidence- based model was used and evidence was obtained using a search of the MEDLINE database spanning the years 1960 through 2008. Only English- language publications	Only English- language publicatio ns were reviewed. No additional informatio n given on study selection	The available evidence was evaluated using a unified system called the Strength of Recommendati on Taxonomy.	In those situations where documented evidence based data are not available, we have used expert opinion to generate our clinical recommendations.	Each drug included in the guideline has the included benefits, harms and contraindications and it is taken into account in the recommendations	Each recommendation has the evidence text supporting it and studies cited but sometimes it is difficult to identify which studies were used for the specific recommendation	No information of external review or patient representatives review.	No information on update		3.5. Kidney disease: How should psoriasis patients with kidney failure/renal impairment be managed?

EUROPEAN CENTRE FOR GUIDELINES



					AGREE II-Domain 3: Rig	gour of development				
Guidelines	7. Systematic methods were used to search for evidence.	8. The criteria for selecting the evidence are clearly described.	9. The strengths and limitations of the body of evidence are clearly described.	10. The methods for formulating the recommendations are clearly described.	11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	12. There is an explicit link between the recommendations and the supporting evidence.	13. The guideline has been externally reviewed by experts prior to its publication.	14. A procedure for updating the guideline is provided.	Quality score (0%- 100%)	Chapters
	were reviewed.									
Rating	3	2	4	4	7	6	1	1	42%	
Ormerod et al. 2010 British Association of Dermatologists guidelines on the efficacy and use of acitretin in dermatology	EMBASE, MEDLINE, CINAHL, PubMed, The Cochrane Library, RCP Guidelines Database, DARE; this gave 1325 hits	We included in the search papers written in English, French, Spanish, Italian and German, and those describing adverse drug reactions, clinical monitoring and consensus statement s from respected authorities based on clinical experience and	Unclear how recommendatio ns were formulated only a box at the end with level of evidence is provided. Recommendati ons do not provide information on level of evidence and strength of recommendatio ns.	Unclear how recommendations were formulated only a box at the end is provided on strength of recommendation. Recommendations do not provide information on level of evidence and strength of recommendations.	Benefits, side effects, situations of risk, drug interactions and contraindications were extensively described	Recommendations and evidence are presented but not clearly linked because recommendations boxes are after the evidence text at the end.	The draft guideline was made available for consultation and review by the BAD membership. The final document was peerreviewed by the Clinical Standards Unit of the BAD (made up of the Therapy & Guidelines and Audit & Clinical Standards Subcommittees) prior to publication.	No information provided		3.5. Kidney disease: How should psoriasis patients with kidney failure/renal impairment be managed?



					AGREE II-Domain 3: Rig	gour of development				
Guidelines	7. Systematic methods were used to search for evidence.	8. The criteria for selecting the evidence are clearly described.	9. The strengths and limitations of the body of evidence are clearly described.	10. The methods for formulating the recommendations are clearly described.	11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	12. There is an explicit link between the recommendations and the supporting evidence.	13. The guideline has been externally reviewed by experts prior to its publication.	14. A procedure for updating the guideline is provided.	Quality score (0%- 100%)	Chapters
		consensus committee s.								
Rating	7	4	2	2	7	5	3	1	48%	
Singh et al. 2019 Special Article: 2018 American College of Rheumatology/Na tional Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis	We searched OVID Medline, PubMed, Embase, and the Cochrane Library from the beginning of each database through November 15, 2016 and updated searches were conducted on May 2, 2017, and again on March 8, 2018. All search strategies	Outcomes: panels chose the critical outcomes for all compariso ns at the initial scoping; these included the: ACR20 , the Health Assessmen t Questionn aire disability index, the PASI 75% response criteria, and serious	Risk of bias of each primary study was assessed using the Cochrane risk of bias tool. We exported RevMan files into GRADEpro software to formulate a GRADE summary of findings (SoF) table for each PICO question.	The Voting Panel voted on the direction and strength of the recommendation related to each PICO question. Recommendations required a 70% level of agreement, as used previously in other similar processes and in the previous ACR guidelines. Could not identify outcomes of voting procedures	The supplementary material gives a description of the evidence found with benefits and harms for each intervention if available and also main article takes into account contraindications.	Each recommendation is linked to main evidence and also reference given and when based on clinical experience no reference are cited but in text it is not clear if this is by consensus opinion or not	In additional to journal peer reviews, the manuscript was reviewed by the following committees and subcommittees of the ACR and NPF: ACR Guideline Subcommittee; ACR Quality of Care Committee; ACR Board of Directors; and NPF Medical Board. These ACR and NPF oversight groups did not mandate that certain recommendations be made within the guideline, but rather, served as peer reviewers. Also patient organizations were included.	We anticipate future updates to the guideline when new evidence is available.		3.3 Diabetes: How should psoriasis patients with diabetes mellitus be managed?



					AGREE II-Domain 3: Rig	our of development				
Guidelines	7. Systematic methods were used to search for evidence.	8. The criteria for selecting the evidence are clearly described.	9. The strengths and limitations of the body of evidence are clearly described.	10. The methods for formulating the recommendations are clearly described.	11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	12. There is an explicit link between the recommendations and the supporting evidence.	13. The guideline has been externally reviewed by experts prior to its publication.	14. A procedure for updating the guideline is provided.	Quality score (0%- 100%)	Chapters
	are for each database are given in Appendix 3	infections. Target population is given as PsA but also indirect population used. Type of studies also described and english language selected but PICOS for all question are not given.								
Rating	7	7	7	5	7	6	7	3	85%	
Schaberg et al. 2020 Tuberculosis Guideline for Adults Guideline for Diagnosis and	No search strategy reported in main article	No selection of study criteria reported	No strength and limitation of evidence included is described	Consensus based and discussions were undertaken for each chapter	Benefits, side effects, situations of risk, drug interactions and contraindications were extensively described	Recommendations are not clearly given but statements made are supported by evidence of studies given for each section	It was send to external reviewer who gave feedback and also to participating organization to review the guidelines for 8 weeks and give feedback	The guidelines will be considered current for the next 5 years, should there be any significant, scientifically proven changes in the meantime,		3.9. Tuberculosis: How to screen for tuberculosis before and



	AGREE II-Domain 3: Rigour of development										
Guidelines	7. Systematic methods were used to search for evidence.	8. The criteria for selecting the evidence are clearly described.	9. The strengths and limitations of the body of evidence are clearly described.	10. The methods for formulating the recommendations are clearly described.	11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	12. There is an explicit link between the recommendations and the supporting evidence.	13. The guideline has been externally reviewed by experts prior to its publication.	14. A procedure for updating the guideline is provided.	Quality score (0%- 100%)	Chapters	
Treatment of Tuberculosis including LTBI Testing and Treatment of the German Central Committee (DZK) and the German Respiratory Society (DGP)								the guideline must be changed beforehand		during biologic treatment?	
	1	1	1	3	7	4	5	7	44%		
Smith et al. 2017 British Association of Dermatologists guidelines for biologic therapy for psoriasis 2017	Search strategy and database given. All searches for this draft version were completed between August and November 2015 depending on the review question and updated between August and	Each key question have the PICOS with relevant, population , study design, outcomes and a list of excluded studies with reasons	GRADe methodology was used also summary of findings tables are provided for each question	The consensus recommendations were agreed through discussions in the GDG. Unclear how consensus was reached and if disagreements occurred how it was handled.	The considerations for making consensus-based recommendations include the balance between potential harms and benefits, practical and economic considerations, current practices, recommendations made in other relevant guidelines, patient preferences and equality issues	Every key questions is linked with the evidence and the recommendation	The draft document was made available for a 1-month consultation to all relevant stakeholders including health care professionals, patient support groups and members of the pharmaceutical industry. Unclear how information gathered was used.	An annual literature review is planned for this fast-moving subject and the recommendations will be updated where necessary, in line with the BAD's recommended guideline development methodology. Unclear time interval and criteria for update.		3.11 Pregnancy: How should psoriasis patients with a wish for pregnancy in the near future or who are pregnant be managed?	



	AGREE II-Domain 3: Rigour of development										
Guidelines	7. Systematic methods were used to search for evidence.	8. The criteria for selecting the evidence are clearly described.	9. The strengths and limitations of the body of evidence are clearly described.	10. The methods for formulating the recommendations are clearly described.	11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	12. There is an explicit link between the recommendations and the supporting evidence.	13. The guideline has been externally reviewed by experts prior to its publication.	14. A procedure for updating the guideline is provided.	Quality score (0%- 100%)	Chapters	
	October 2016										
Rating	7	7	7	5	7	7	6	5	90%		
Warren et al. 2016 British Association of Dermatologists' guidelines for the safe and effective prescribing of methotrexate for skin disease 2016	Search strategy, database and time frame given	The abstracts for the shortlisted references were then reviewed by all members of the working group and the full papers of relevant material obtained no specific inclusion and exclusion criteria given.	This set of guidelines has been developed using the British Association of Dermatologists' recommended methodology, and with reference to the Appraisal of Guidelines Research and Evaluation (AGREE II) instrument. Unclear how it was done but at the end a scale of evidence is given	Recommendations were developed for implementation in the National Health Service using a process of considered judgement based on the evidence. No information on how consensus was done and disagreements were solved.	There is supporting information on benefits, harms and contraindications	Recommendations were presented with the evidence on text	Following further review, the finalized version was peer reviewed by the Clinical Standards Unit of the BAD (made up of the Therapy & Guidelines Subcommittee) prior to publication. No information on how recommendations gathered were used and how the external review was undertaken	The proposed revision date for this set of recommendations is scheduled for 2021; where necessary, important interim changes will be updated on the BAD website. No methodology of update given		3.11 Pregnancy: How should psoriasis patients with a wish for pregnancy in the near future or who are pregnant be managed?	
Rating	7	5	4	3	7	6	5	7	75%		



	AGREE II-Domain 3: Rigour of development										
Guidelines	7. Systematic methods were used to search for evidence.	8. The criteria for selecting the evidence are clearly described.	9. The strengths and limitations of the body of evidence are clearly described.	10. The methods for formulating the recommendations are clearly described.	11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	12. There is an explicit link between the recommendations and the supporting evidence.	13. The guideline has been externally reviewed by experts prior to its publication.	14. A procedure for updating the guideline is provided.	Quality score (0%- 100%)	Chapters	
WHO 2018 Latent tuberculosis infection: updated and consolidated guidelines for programmatic management	Seven new or updated systematic reviews were conducted for these guidelines. No search strategy provided, database and time	Each key question have specific PICO but inclusion and exclusion criteria not mentioned and how study selection was done	GRADE methodology was used	The guideline methodologist facilitated the discussions in order to reach consensus, which was defined as unanimous or majority agreement. Recommendations from existing WHO guidelines were initially assessed by the steering group and were later discussed and approved by the GDG.	Benefits, harms and risk were taken into account for recommendations	Each key question has specific PICO with evidence found and summary of findings table	Remarks from the external review group were evaluated by the steering group for incorporation into the final version of the guidelines. There was an external review group and also patient survey taken into account	WHO will update the guidelines 5 years after their publication or earlier if new evidence becomes available that necessitates a revision		3.10. Tuberculosis: how to manage psoriasis in patients with positive tuberculosis test results?	
Rating	3	4	7	6	7	7	6	7	81%		





APPENDIX 1

AGREE II Evaluation of this guideline

The development and reporting of this guideline were based on AGREE II. Below we included the checklist. This may help others when assessing the *EuroGuiDerm Psoriasis guideline*.

Domain	ltem		Comment	Section		
	1. The overall objective(s) of the guideline is (are) specifically described.	7	Clear descriptions of health benefits, outcomes and targets; item content easy to find	M: "Scoping and defining the purpose of the guideline" and following sections		
DOMAIN 1. SCOPE AND PURPOSE	2. The health question(s) covered by the guideline is (are) specifically described.	7	Clear written questions for every sub-goup; interventions and outcomes for target population defined and easy to find	M: Table 3 and 4		
	3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	7	Gender, age, clinical condition and stage of psoriasis clearly defined	M: "Population and health questions covered by the guideline"		
	4. The guideline development group includes individuals from all relevant professional groups.	7	All relevanant information listed (name, institution, location, role in group); methodology experts included in development group	M: "Involving stakeholders and forming the guideline subcommittee", Table 1		
DOMAIN 2. STAKEHOLDER INVOLVEMENT	5. The views and preferences of the target population (patients, public, etc.) have been sought.	2	Two patients nominated but further information on patients perspective missing	M: "Patient-perspective and needs"		
	6. The target users of the guideline are clearly defined.	7	Intended guideline audience (physicians from Europe e.g. dermatologists) and potential usage clear described and appropriate	M: "Population and health questions covered by the guideline"		



Domain	Item	Rating*	Comment	Section		
	7. Systematic methods were used to	6	General recommendations are based on the Cochrane Review, all methods described in full review	M: "Search methods and results, evidence selection and critical appraisal of evidence",		
	search for evidence.	Ü	Chapters in special patients population based on narrative review of systematic search with non systematic selection	Table 5		
DOMAIN 3.	8. The criteria for selecting the evidence are clearly described.	6	General recommendations are based on the Cochrane Review, all methods described in full review Psoriatcic arthritis – all methods described All other chapters of special patients population are consensus-based texts/recommendations	M: Table 5, Appendices		
RIGOUR OF DEVELOPMENT	9. The strengths and limitations of the body of evidence are clearly described.	6	General recommendations are based on the Cochrane Review, all methods described in full review Psoriatcic arthritis – all methods described All other chapters of special patients population are consensus-based texts/recommendations	M: Appendices Evidence to Decision Framework		
	10. The methods for formulating the recommendations are clearly described.	7	Detailed description of the recommendation development process (voting procedures, reaching of consensus, influence of final recommendation); formal process used	M: "Developing recommendations and the consensus process", Table 6 and 7		
	11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	7	Evidence to Decision Frameworks (2), Health benefits and potential harms described as research priorities	M: "Developing recommendations and the consensus process" GL: all drug chapters		





Domain	main Item Ratio		Comment	Section		
	12. There is an explicit link between the recommendations and the supporting evidence.		Evidence based recommendations refer to review results Supporting evidence not clearly linked in some chapters of special patients population, but these are not evidence-based per se	GL: "Recommendations", " Psoriasis Arthritis",		
	13. The guideline has been externally reviewed by experts prior to its publication.	7	Yes, methods clearly described	M: "Internal and external review"		
	14. A procedure for updating the guideline is provided.	7	Statement for update with methodology for updating and interval clear and easy to find	M: "Update and methods", Figure 1		
	15. The recommendations are specific and unambiguous.	7	Statements for recommended action, purpose of action and relevant population clearly and consistently described; uncertainty in recommendations stated and reflected	GL: all chapters		
DOMAIN 4. CLARITY OF PRESENTATION	16. The different options for management of the condition or health issue are clearly presented.	7	Statement for each option discussed and easy to find	GL: all chapters		
	17. Key recommendations are easily identifiable.	7	Summarized boxes with specific recommendations grouped together; use of colour to underline message	GL: all chapters		
DOMAIN 5.	18. The guideline describes facilitators and barriers to its application	4	Types of facilitators and barriers identified and description of how this influenced the guideline development process	M: "Dissemination and Implementation"		
APPLICABILITY	19. The guideline provides advice and/or tools on how the recommendations can be put into practice.	7	Description of additional publication of guideline summary	M: "Dissemination and Implementation", Table 8 flow chart & grid		



Domain	ltem	Rating*	Comment	Section
	20. The potential resource implications of applying the recommendations have been considered.	4	Statement of problems with not uniform costs for treatment in Europe;	M: "Cost and economic considerations", "Strengh and limitations"
	21. The guideline presents monitoring and/or auditing criteria.	7	Summary tables of recommended monitoring provided and easy to find	M: "Dissemination and Implementation", Table 8 GL: "Accompanying documents"
DOMAIN 6.	22. The views of the funding body have not influenced the content of the guideline.	7	Funding body named and statement that the funding body did not influence the content; clear and easy to find	M: "Declaration and management of conflicts of interest", " Funding", Table 2
EDITORIAL INDEPENDENCE	23. Competing interests of guideline development group members have been recorded and addressed.	7	Competing interests listed and described; description of how comparing interest influenced the guideline process provided	M: Table 2
OVERALL	1. Rate the overall quality of this guide	eline:	6*	
GUIDELINE ASSESSMENT	2. I would recommend this guideline fo	r use:	Yes	

M – Methods & Evidence Report, GL – main guideline text

1 Strongly Dis	agree 2	3	4	5	6	7 Strongly Agree
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* Rating in Agree II:

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