Implementation guide for recommendations of the Centre of Evidence of Dermatology

1. Funding and confidentiality

- ***Funding for the recommendations was provided by the Centre of Evidence of Dermatology (CDP, Centre de Preuves en Dermatologie) and the French Society of Dermatology (FSD, Société Française de Dermatologie), independently of the pharmaceutical industry.***
- ***Throughout the entire recommendation drafting process and until their final validation, the members of the working groups, the experts interviewed and the members of the review group are subject to a strict duty of reserve and the provisional documents remain strictly confidential.***

2. Choosing themes to be addressed

- ***The CDP proposes a list of themes and asks the representatives of the three constituent bodies (SFD/CEDEF/FFFCEDV) and CDP members to prioritise them.***
- ***Themes may be suggested by the thematic groups.***
- ***Health authorities such as the HAS, ANSM, INCa, DGS, etc., may need to refer matters to the CDP.***

3. Designating a working group chairperson and project manager

Designating authority: the working group chairperson and project manager are designated by the CDP, itself made up of three constituent bodies, according to candidates' competences and after considering possible conflicts of interest.

Project manager's duties:

- ***Drafting the framing note in conjunction with the CDP co-ordinator and chairperson.***
- ***Establishing bibliographic search rules.***
- ***Drafting the rationale for the recommendations and the summary.***
- ***Devising the publication policy.***

Chairperson's duties:

- ***Appointing members to the working group and ensuring that they have no vested interests.***
- ***Chairing the working group to ensure that each member of the group has a voice.***
- ***Liaising with relevant academic associations.***
- ***Ensuring the consistency of the final document and assisting in its dissemination/publication.***

4. Defining the scope of and drafting the framing note

Who: the CDP co-ordinator, chairperson and project manager

The framing note:

- ***is validated by the CDP and the thematic group concerned, if necessary;***
- ***defines the following points:***
    - ***the list of questions to be asked, each of which must be formulated as precisely as possible;***
    - ***the patients concerned;***

- *the professionals concerned;*
- *the literature search strategy;*
- *the budget;*

- *specifies the timeliness and relevance of a possible survey of practice.*

The framing note validated by the CDP is the mandatory pre-requisite for the issuing of any recommendation.

5. Carrying out the literature search

***Who**: the co-ordinator with the project manager, in collaboration with one or two members of the CDP or members of the working group (cf. point 5) and a documentalist if possible (HAS, for example).*

*The methodology for this literature search should follow the HAS proposals ("**Development of good practice recommendations**", updated January 2020: **www.has-sante.fr**) and in particular:*

the prior explanation of the article selection criteria: language, period, level of evidence accepted, position with regard to grey literature, conference summaries, etc.;

the highest levels of evidence will be preferred;

a flow chart will be appended to the final text.

Literature monitoring throughout the drafting of the recommendation should be planned with the help of the CDP co-ordinator.

6. Constituting a working group and a list of experts

***Who**: the chairperson in collaboration with the CDP members and co-ordinator.*

***The working group (10 to 20 people depending on the themes) is composed**:*
(NB to be done as soon as possible after validation of the framing note as the time to receive and analyse declarations of conflict of interest may be very long)

- *of one or more representatives of the professionals concerned (defined in the framing note);*
- *of one or more patients;*
- *by balancing methods and geographical distribution;*
- *and of one person qualified in methodology (the CDP co-ordinator can play this role if necessary).*

***In practice**:*

- *A list of academic societies and patient associations to be contacted is drawn up.*
- *The working group chairperson and the CDP chairperson draft a letter asking each academic society concerned to mandate one or more persons to sit on the working group, describing the context and the recommendation process, and specifying the absence of remuneration but that travel expenses can be reimbursed.*
- *A list of the academic societies that decline to participate is drawn up.*
- *Each person agreeing to participate is requested to fill in a declaration of interest form. The SFD and the CDP review the returned declarations and validate participants' enrolment.*
- *The working group members are people trained both in the critical reading of articles and in methodology.*
- *A list of experts to be interviewed will be drawn up in due consultation with the thematic groups.*

7. Organising the first working group meeting

***Who**: the CDP co-ordinator*

Plan a one-day programme (starting around 10 a.m. and ending around 4.30 p.m.) to allow people travelling a certain distance to make the round trip during the day, preferring physical presence to videoconferencing whenever possible.

***Place**: Maison de la Dermatologie*

Arrange for lunch to be served.

8. Selecting the studies to be analysed

***Who**: ideally the project manager and the CDP co-ordinator/methodologist, working in duplicate, independent roles.*

- ***Articles will be selected based on their title and then on the summary, according to the predefined inclusion criteria.***
- ***Systematic reviews and articles for each question will be grouped by type of comparison or molecule, type of epidemiological question, etc.***
- ***All selected articles will be collected in PDF format and then categorised by question in order to send them by Dropbox (or equivalent) to the working group members.***
- ***A flow chart of the articles retained and rejected will be drawn up as the process advances.***

9. Analysing articles

***Who**: working group members*

A critical analysis will be carried out according to the usual procedure using a validated GRADE scale (or equivalent) according to the international consensus of the moment.

The working group members involved in the article review will produce a summary in the form of one or more tables for each question. All reviewers will respect bibliographical analysis standards and use the same interpretative approach.

10. Drafting the rationale and recommendations (drafting need not necessarily be finalised for all issues at the first working group meeting)

***Who**: the project manager and the working group chairperson*

The rationale is drafted under the direction of the project manager and the chairperson, on the basis of contributions from the working group members. It will be validated by the whole working group.

The recommendations are drafted by the working group according to the data in the rationale.

11. Working group meetings

***Who**: working group members, project manager, working group chairperson.*

The chairperson will set out the context, issues and method at the first meeting.

The literature review and the draft rationale should be sent to the working group members at least 15 days before the meeting.

At each meeting the project manager and/or a member of the analysis group presents the evidence in the literature.

The working group chairperson leads the discussion on the recommendations arising from the literature review and according to the working group's opinion.

The opinion will be drafted during the meeting.

The chairperson and/or project manager will keep the CDP informed of the progress of the project and any issues related to the recommendations.

In general, three or four in-person meetings should be scheduled.

12. Seeking expert advice

Who: the working group members, the project manager and the working group chairperson

Experts will be chosen primarily from the members of the thematic group involved in the theme of the recommendation, but also among members of the academic societies concerned and other qualified experts.

Experts with related personal or professional interests may be interviewed, but they will be required to provide a declaration of conflict of interest.

The selected experts will be interviewed individually by the working group before its final meeting.

The text of the rationale and recommendations will be sent to them one month before the interview, together with a list of questions if necessary.

The interview of the experts will focus on questions that could not be answered by an analysis of the factual data or if the working group fails to reach agreement on the basis of these data. In the event of disagreement among the experts, the working group shall position itself in the best possible way, and the working group's opinion will prevail.

The experts' remarks should be recorded as accurately as possible.

These remarks will be summarised in the rationale, followed by an insert entitled "Remarks from the experts", and any changes to the recommendations following this hearing will be described.

13. Composition of the review group

Who: the working group chairperson and the project manager, in collaboration with the CDP members and co-ordinator.

Like the working group, the review group is made up of professionals from all the specialities involved and all the modes of practice concerned. The review group will comprise a minimum of 30 and a maximum of 60 members.

The letter requesting academic societies and user representatives to mandate representatives for the review group will be sent by the working group chairperson as early as possible after the penultimate meeting of the working group.

The thematic groups will be invited to nominate reviewers. Where appropriate, individual CDP members may be asked to participate in the review process.

A declaration of conflict of interest is not required for external reviewers.

14. Review group

Who: the project manager in collaboration with the CDP members and the CDP co-ordinator.

Reviewers' opinions will be collected by the GraAL system (HAS) or equivalent.

Reviewers' remarks must be substantiated by references. Expert opinions are not suitable references.

The GraAl tool (or equivalent) enables users to send the rationale, the recommendations and a questionnaire by e-mail, where each recommendation is rated on a scale from 1 to 9.

The tool automatically summarises the ratings and remarks.

If the threshold of 90% agreement between reviewers is not reached for a given recommendation, the recommendation must be reconsidered.

The working group will meet one last time in order to take into account the remarks and ratings of the review group and to integrate, as necessary, the reviewers' remarks into the recommendation.

15. Validation by the CDP

Once the document has been completed, it will be validated by the CDP, which will ensure that it complies with the framing note and respects its ethical and methodological requirements.

16. Formatting of final documents and online tools/organisation of communication

Who: the project manager in collaboration with CDP members/a graphic designer and webmaster/the CDP co-ordinator, in collaboration with the SFD, CEDAW and FFFCEDV.

The working group's output will be:

- *the rationale drawn up during the working sessions (long document);*
- *a summary of the recommendations (short document);*
- *a presentation in the form of an interactive algorithm implemented on the existing mini-site (https://reco.sfdermato.org/fr/).*

17. Promotion, publication policy and dissemination of recommendations

The promotion of the recommendations will be discussed by the CDP, in particular among its members representing the SFD.

18. Evaluating practice and conducting studies on the recommendations' impact

Depending on the themes, evaluating practice may be useful to assess the need for and impact of the recommendations in real-life circumstances.

Such an evaluation would be carried out through collaboration between the thematic group concerned and the CDP.

If a survey evaluating practice is carried out, an impact study on the recommendations issued should logically be carried out 12 to 24 months after their publication.

Respective roles of bodies and actors

1. The Centre de Preuves en Dermatologie (Centre of Evidence of Dermatology)

- *Proposes a list of themes, possibly on the advice of the thematic groups.*
- *Requests the prioritisation of themes from the three constituent bodies of the CDP.*
- *Appoints the working group chairperson and project manager.*
- *Validates the framing note.*
- *Participates in appointing the review group, with the chairperson and the project manager.*
- *Validates the recommendations.*
- *Draws up the promotion plan for the recommendations.*

2. The CDP co-ordinator

- *Defines the project area and writes the framing note with the project manager.*
- *Carries out documentary research.*
- *Organises working group meetings (logistics).*
- *Participates in working group meetings.*
- *Contacts the designated review group members and gathers opinions.*
- *Analyses reviewers' opinions.*
- *Participates in the formatting of the final document.*

3. The thematic groups

- *Suggest themes to the CDP.*
- *Participate in the choice of experts to invite.*
- *Are invited to participate in the designation of reviewers.*
- *Participate in the dissemination of recommendations.*

4. The working group chairperson

- *Is appointed by the CDP.*
- *Completes a declaration of conflict of interest.*
- *Participates in the drafting of the framing note with the project manager and the CDP co-ordinator.*
- *Appoints the members of the working group (in connection with the CDP) and participates in the selection of experts to invite.*
- *Chairs the working group to ensure that each member of the group has a voice.*
- *Liaises with relevant academic associations.*
- *Invites the members of the review group to participate.*
- *Ensures the coherence of the final document.*

5. The project manager

- *Is appointed by the CDP.*
- *Completes a declaration of conflict of interest.*
- *Writes the framing note in conjunction with the CDP co-ordinator.*
- *Establishes the rules for and participates in documentary research.*
- *Drafts the rationale for the recommendations and the summary.*
- *Devises the publication policy, in particular by participating in the drafting of the publication material for the recommendation.*

6. The members of the working group

- *Undertake to participate in all working group meetings.*
- *Participate in the analysis of the literature.*
- *Draft recommendations based on the data from the literature review.*
- *Include or reject proposals from experts.*
- *Include or reject the substantiated proposals from the reviewers.*
- *Validate the final document.*

7. The experts

- *Read the draft recommendations.*
- *Reply to questions put by the working group.*

8. Review group members

- *Review the entire document.*
- *Score each proposal from 1 to 9.*
- *Provide references supporting contested proposals.*

List of abbreviations

ANSM: National Agency for the Safety of Medicines and Health Products (Agence National de Sécurité des Médicaments et des Produits de Santé)

CEDEF: College of Teachers of Dermatology and Venereology (Collège des Enseignants en Dermatologie et Vénérologie)

CDP: Centre of Evidence of Dermatology (Centre de Preuves en Dermatologie)

DGS: Directorate General for Health (Direction Générale de la Santé)

FFFCEDV: French Federation for Continuing Education and Evaluation in Dermatology and Venereology (Fédération Française de Formation Continue et d'Evaluation en Dermatologie et Vénérologie)

HAS: High Authority for Health (Haute Autorité de Santé)

INCa: National Cancer Institute (Institut National du Cancer)

SFD: French Society for Dermatology (Société Française de Dermatologie)