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Committee for Medicinal Products for Human Use (CHMP)

Concept paper on the need for revision of the guideline on the development of medicinal products for the treatment of smoking

Agreed by CNS Working Party	19 February 2026
Adopted by CHMP for release for consultation	11 May 2026
Start of public consultation	29 May 2026
End of consultation (deadline for comments)	30 August 2026

The proposed revision will replace the current version of the Guideline on the development of medicinal products for the treatment of smoking (CHMP/EWP/369963/05).

Comments should be provided using this EUSurvey form. For any technical issues, please contact the EUSurvey Support.

Keywords	smoking cessation, Guideline, Confirmatory trials, nicotine dependence

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1. Introduction

The current guideline (CHMP/EWP/369963/05) came into effect in July 2009. The scope of the guideline is to provide guidance in the definition of treatment goals, study design, outcome measures, and data analysis for new medicinal products that will be developed to treat nicotine dependence in support of an indication for the treatment of tobacco smoking.

There has been a rapid development of essentially tobacco-free recreational products containing nicotine for inhalation (e.g. electronic cigarettes) and oromucosal use (e.g. snuff) in the EU. Addiction to tobacco-free nicotine products has become an increasing problem, especially in the adolescent and young adult populations.

The current guideline is not intended for and is neither completely applicable for development of medicinal products for the treatment of the addiction to non-smoking nicotine products. Nevertheless, as no other guideline applies in those cases, the guideline for smoking cessation is still the most relevant. To meet the treatment needs arising from the new types of nicotine addiction, adjustments of this guideline are proposed for the document to be fully applicable for all types of nicotine dependence.

2. Problem statement

In recent years, a variety of products containing nicotine such as electronic cigarettes and tobacco - free snuff have appeared in the EU, including different types of devices, different concentrations of nicotine as well as different kind and amounts of flavours and other excipients. Toxicity of these different nicotine containing products is still under discussion, compared to the long-term experience and vast knowledge of tobacco smoking toxicity. Achieving smoking cessation is known to be associated with large health-gains, but the situation is not as clear for other forms of nicotine use as their long-term negative effects are not as well-known.

Furthermore, dependence to substances is characterised by a cluster of physiological, behavioural, and cognitive phenomena. The target population for pharmacological treatment of nicotine dependency from other sources than tobacco cigarettes is not a homogenous group and could be difficult to define for a study.

Overall, the main objective of treating nicotine dependency is to reach nicotine abstinence. However, the current guideline does not address addiction to nicotine containing products other than smoked tobacco. There is a gap in guidance in the definition of treatment goals, study design, outcome measures, and data analysis for new medicinal products to be developed to treat nicotine dependence from other sources than tobacco cigarettes.

3. Discussion (on the problem statement)

The lack of guidance for developing treatment for nicotine addiction beyond smoking is proposed to be addressed by an update of the current guideline. An update could consist of additions intended to apply specifically to the treatment of addiction to smoke-free nicotine products. The following aspects are foreseen to be addressed in the update of the guidance document:

- Widening of the scope of the guideline to treatment of nicotine dependency irrespective of the source of nicotine.
- Criteria for adequately selecting a study population reflecting the target population intended for treatment of nicotine dependency from other sources than tobacco smoking. For example, the

handling of a population including mixed users i.e., patients using both tobacco and tobacco-free or smoke-free nicotine products should be addressed.

- Aspects on nicotine addiction in special populations, particularly in adolescents and the different risk behaviour in this age group, and in pregnant and breast-feeding women.
- The long-term abstinence from nicotine and the definition of an appropriate treatment goal, defining acceptable primary study endpoints.
- Guidance on relevant biomarkers and relevant time-points to establish support to the primary endpoint(s).
- Guidance on requirements for data package supporting assessment of benefit/risk balance of the medicinal product for the treatment of nicotine dependence in relation to recreational products causing addiction.
- The relevance of nicotine replacement therapy for the treatment of nicotine dependency from tobacco-free nicotine recreational products with similar delivery methods.

4. Recommendation

The Central Nervous System Working Party (CNSWP) recommends drafting a revision Guideline on the development of medicinal products for the treatment of smoking to also include treatment of nicotine dependency. As a consequence, also the title of the guideline needs to be revised.

5. Proposed timetable

It is planned to release for consultation a draft CHMP guidance document not later than Q1 2027.

6. Resource requirements for preparation

The preparation of this guideline will involve the CNSWP. Drafts of the document will be discussed with the SAWP, MWP, PDCO and other relevant WPs and committees.

7. Impact assessment (anticipated)

It is aimed that this guideline will be helpful to achieve consensus in the evaluation and standardisation of the clinical development plan for medicinal products evaluated for nicotine dependency.

8. Interested parties

The interested parties in the guidance document include academic networks and learned societies within the EU, patients and health care professional representatives.

9. References to literature, guidelines, etc.

1. WHO global report on trends in prevalence of tobacco use 2000–2024 and projections 2025–2030; ISBN 978-92-4-011627-6 (electronic version)

2. Kavousi et.al., (2020). Electronic cigarettes and health with special focus on cardiovascular effects: position paper of the European Association of Preventive Cardiology (EAPC). European Journal of Preventive Cardiology, 28(14), 1552–1566. https://doi.org/10.1177/2047487320941993