



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C2 - Management of scientific committees; scientific co-operation and networks

Doc.SANCO/SCMPMD/2002/0005 Final

OPINION
ON

Revision of the scientific opinion on the effects of xylitol and other polyols on caries development adopted by the Scientific Committee on Medicinal Products and Medical Devices on 2 June 1999.

Adopted by
The Scientific Committee on Medicinal Products and Medical Devices
On 26 September 2002

Request for revision of scientific opinion on the effects of xylitol and other polyols on caries development, which was adopted by the Scientific Committee on Medicinal Products and Medical Devices on 2 June 1999.

Background

Question (1999)

The original question posed by DG XXI to the Scientific Committee on Medicinal Products and Medical Devices in 1999 was:

Can the Committee agree with the conclusions of the report "Assessment of the beneficial effects of xylitol and other polyols on caries development" as prepared by independent scientists on behalf of the Commission services and more in particular with the conclusion that, as to its properties regarding caries development, as of today, no clear data exists to support the concept that xylitol possesses specific effects in vivo which validate a superiority claim over other polyols? If not, can the Committee specify to what extent it disagrees?

Answer (1999)

The Committee has assessed the various reports on this matter provided by DG XXI and on the basis of these reports and their knowledge of the literature relating to dental caries, agrees with the conclusion that "there are, as of today, no clear data to support the concept that xylitol possesses specific effects in vivo which validate a superiority claim over other polyols."

Request for revision of the Opinion (2002)

DG SANCO forwarded to the SCMPMD a series of documents on 15 March 2002, sent by Danisco in support of their request for a revision of the scientific opinion on the effects of xylitol and other polyols on caries development adopted by the Scientific Committee on Medicinal Products and Medical Devices on 2 June 1999 (http://europa.eu.int/comm/food/fs/sc/scmp/out23_en.html).

The following documents were supplied by Danisco:

- a) Dental aspects of xylitol (a review of the literature regarding xylitol and caries prevention). A report to Danisco Sweeteners by Dr A Maguire and Professor AJ Rugg-Gunn, University of Manchester October 2001.
- b) List of 36 Xylitol Publications referred to in Medline from 1 January 1999 to 20 January 2002)
- c) Copies of 6 scientific articles listed in b) under numbers 1, 9, 19, 26, 28, 35

On its own initiative, the committee has also considered whether any additional publications available on Medline search from January 2002 to 6 June 2002 were of relevance to the present question.

Question (2002):

Does the committee see documented scientific evidence to suggest a revision of its Opinion of 2 June 1999?

Evaluation of additional documentation

1a) Dental aspects of xylitol (a review of the literature regarding xylitol and caries prevention). A report to Danisco Sweeteners by Dr A Maguire and Professor AJ Rugg-Gunn, University of Manchester October 2001.

This report is an extensive review of the current literature. It is similar in content with the reports supplied in this matter to the SCMPMD at the former evaluation in 1999, and refers to essentially the same literature. The main difference lies in the manner in which the literature is cited. The Maguire/Rugg-Gunn report mainly repeats and accepts the conclusions of most of the articles. The report does not consistently carefully evaluate the scientific basis of the studies, i.e. whether the study design(s) allow for the conclusions given by the original authors. The Executive Summary reiterates the positive statements of xylitol. It does not seem to be equally balanced in its presentation of other polyol's merit as compared to xylitol's. There are inconsistencies between the Executive summary and the text in aspects that directly address the original issues that were given to the SCMPMD:

Executive summary Point 2: "The anti-cariogenic effects of sugar-free gums containing xylitol (and sorbitol to a lesser extent) are proven and accepted. The anti-cariogenicity of xylitol used without chewing gum as a vehicle is strongly suggested but has not been stated with unanimity or conviction".

This is statement not quite consistent with equivalent section in the body of the text, section 7.5, page 70, lines 11-14: "From the strict scientific viewpoint, it is not possible to label xylitol as anti-cariogenic in humans - it is possible, though, as discussed earlier, to label xylitol chewing gum as anti-cariogenic".

1 b) List of 36 Xylitol Publications referred to in Medline from 1 January 1999 to 20 January 2002

The committee has evaluated the papers that directly address the clinical issues raised by DG XXI, in 1999:

Of the 36 papers the following 31 papers are reviews, or were evaluated at the time of the former Opinion, or are not directly of relevance in the present context:

1, 2, 3, 4, 5, 6, 8, 10, 11, 12, 13, 14, 15, 16, 17, 18, 20, 21, 22, 23, 24, 25, 27, 29, 30, 31, 32, 33, 34, 35, 36.

7, 9, 19, 26, 28 are discussed under 1 c)

1 c) Comments to papers #7, 9, 19, 26 and 28. The numbers refer to the List of 36 Xylitol Publications referred to in Medline from 1 January 1999 to 20 January 2002.

7 Machiulskiene et al (2001): This publication is of direct relevance in the present context, as it compares the clinical effect of two polyols in caries development. This study was designed to compare the effects of various sugar-substituted chewing gums on caries development over a 3-year period. The children were randomly allocated to receive one of the following interventions: Sorbitol/carbamide gum; sorbitol gum, xylitol gum, control gum and no gum. The children were reexamined clinically after 1, 2 and 3 years, and radiographically after 3 years. The conclusion of this well designed study is as follows: "The results indicate that the caries preventive effect of chewing sugar-free gum is related to the chewing process itself, rather than being an effect of gum sweetener or additive, such as polyols and carbamide.

9, 19 and 28 (Söderling et al., 2000, 2001; Isokangas et al.,2000) are various parts of the same main project: The Ylivieska study: The effects of the mothers' use of xylitol chewing gum (3 x per day) compared with single administration of chlorhexidine (CHX) varnish or fluoride varnish at 6, 12 and 18 months after delivery. The results indicate that the maternal use of xylitol chewing gum influences the mother-child transmission of Mutans Streptococci, the infants acquisition of them and that there is less dental decay at a 6-year follow-up. The findings are interesting, but the studies were not sufficiently controlled or designed for others to be able to draw the same conclusions that the authors did. Also, the study design does not allow for any comparisons with the effects of other polyols.

26: Alanen et al 2000: The results suggest that not only xylitol chewing gum but also xylitol candies are effective in caries prevention. The study design and allocation of experimental and control groups based on school districts is open for criticism in an epidemiological context. The study does not allow for comparison between different polyols.

2. The committee has also considered whether any additional publications available on Medline search from January 2002 to June 6th 2002 were of relevance to the present question. There were 3 additional publications related to xylitol, but none of direct relevance to the present opinion.

Answer (2002)

The Committee has evaluated the scientific evidence of the new documentation provided by DG SANCO. On its own initiative, the committee has also considered whether any additional publications available on Medline search from January 2002 to June 6th 2002 were of relevance to the present question.

The conclusion of the Committee is that the additional documentation does not contain documented scientific evidence to justify a revision of the Committee's Opinion of June 2nd 1999 at the present time.

Annex I

Opinion on the Effects of Xylitol and Other Polyols on Caries Development adopted by the Scientific Committee on Medicinal Products and Medical Devices on 2 June 1999 :
Read at http://europa.eu.int/comm/food/fs/sc/scmp/out23_en.html

7 Machiulskiene V, Nyvad B, Baelum V.: Caries preventive effect of sugar-substituted chewing gum. *Community Dentistry and Oral Epidemiology* 2001, 29: 278-288.

9: Söderling E, Isokangas P, Pienihäkkinen K, Tenovuo J, Alanen P: Influence of maternal xylitol consumption on mother-child transmission of mutans streptococci: 6-year follow-up. *Caries Research* 2001, 35: 173-177.

19: Isokangas P, Söderling E, Pienihäkkinen K, Alanen P: Occurrence of dental decay in children after maternal consumption of xylitol chewing gum, a follow-up from 0 to 5 years of age. *Journal of dental research* 2000, 79:1885-1889.

26: Alanen P, Isokangas P, Gutmann K: Xylitol candies in caries prevention: results of a field study in Estonian children. *Community Dentistry and Oral Epidemiology* 2000, 28:218-224.

28: Söderling E, Isokangas P, Pienihäkkinen K, Tenovuo J: Influence of maternal xylitol consumption on acquisition of mutans streptococci by infants. *Journal of dental research* 2000, 79: 882-887.