

CONSENSUS STATEMENT

Summary Consensus Statement of the PEK Review Board Regarding the PEK Process and the PEK Products

The international review board was set up as the scientific advisory body of the Swiss program for the evaluation of complementary medicine (PEK) in 2002. It has met several times and has given advice with respect to the most important aspects of the program. It would have been the normal procedure that the review board would have had the opportunity to comment on the drafts of the final scientific products as well as the draft of the summary report in order to advise on them before the documents became publicly available and formed the basis for political decision making. The respective authorities have changed this process. In the following, the review board is going to comment both on this process and on the products:

1. PROCESS

There is a consensus among the review board members that the final PEK process deviated from what would have been expected by conventional standards. Especially disconcerting was the fact that the products of the PEK process—health technology assessment (HTA) reports, single description of studies, publication manuscripts, and the final condensed report—were sent to the board members but no discussion, commenting, or reviewing was solicited by the responsible agencies. In fact, those responsible even cancelled the final review board meeting. It was only through a public opinion campaign that the responsible agency reconvened the review board for a last discussion, but only after the political decision on public insurance coverage in relation to complementary medicine had been taken.

Ideally, the reviewing process of the whole study would have been a two-step procedure: After some intermediate reporting, feedback should have been given to the research agents in order to give them a chance to adjust and improve their research products. However, this was impossible due to the narrow time constraint which in turn was a consequence of a loss of valuable time in the first part of the project. During that initial period a cumbersome process of consensus-seeking between different stakeholders took more time than anticipated. It is likely that this process could have

been accelerated by commissioning a completely independent organization with research experience far off the reach of any political agency to conduct the whole program. Thus, the time left for the actual evaluation studies was too short to produce really definitive results. Unfortunately, the time left for finalizing the research projects that initially were expected to be prolonged was again cut back at a very late stage of reporting.

It is unfortunate that comparative longitudinal studies, the phase 3 studies of the original PEK setup, could not have been conducted due to prohibitive statements of the ethics committee of the Canton of Bern. This negative decision of the ethics committee Bern has certainly been due at least in part to deficits in the protocol submitted. Some further consultation and advice might have been helpful at this stage, which was not carried out to a full extent again due to time constraints. However, individual members of the review board expressed the concern that there also may have been other reasons motivating the negative decision of the ethics committee.

For a fully informed political decision it would have been desirable that there had been a discourse between the researchers, the political agencies, and the review board concerning the interpretation, the methodological strength, and the content of the data provided by PEK. This could then have gone into a public discussion process, which would then have had an informative character for a political decision. As it happened, this process was reversed. The review board unanimously disapproves of this reversal of normal procedures.

What is especially disconcerting is the fact that part of the decision seems to be due to analyses of the federal office of health (BAG), which rest on data and procedures, which cannot be publicly checked.

2. CONTENT

There are three categories of primary PEK products and one final report which synthesizes all PEK products into one document: there are health technology (HTA) reports on all

five complementary methods; there are meta-analyses on three methods for which enough data were available, namely homeopathy, phytotherapy, and Traditional Chinese Medicine; and there are primary studies evaluating structural aspects of complementary and conventional care in the Swiss setting.

In the last meeting of the review board mainly the final report was discussed. While most experts were satisfied with the quality of the final report, it is most plausible that the discussion would have been more critical if political decisions had not yet been taken and the experts would have had the feeling of being able to contribute to the quality of the scientific products in order to inform political decisions.

It was observed that the HTA reports have been conducted up to a high standard and present solidly the evidence base inasmuch as it is available. Doubts were raised about some of the very positive evaluations given in the original HTA reports, a fact which had already been noted in the final report. Thus, the final report condenses the findings of the HTA reports in a correct and justifiable manner.

Some doubts were raised with respect to the methodology of the primary care studies. Response rates of questionnaires were generally low, and reservations with respect to the validity and reliability of the questionnaire data were formulated. Most probably, the response rate among doctors remained low as they perceived the study as being guided by health authorities. This should be a lesson for future studies indicating that political and regulatory authorities should not be directly involved in research. In general, the validity of the data would have been greatly improved through additional research methods such as interviews. It was emphasized that the economic analyses, although conducted with crude data, did not point towards the expected rise in costs. If at all possible, a more detailed analysis accounting for ICD diagnosis would be desirable to clarify and control for the influence of costly diagnosis.

It was observed that an important research question arising out of the data structure of the primary care studies is why so many patients prefer complementary therapies in the face of their lack of superior efficacy over and against placebo.

There was a consensus that the primary data and studies should be made publicly available. A solution should be found for making the cost analysis data and the primary care

studies publicly accessible without burdening the researchers who conducted the study with data handling.

It was observed that more work was needed to finalize some of the manuscripts, to finish primary analyses, and to bring manuscripts into a publishable form. This would need further support, and the experts were in agreement that this support should come from the sponsor of the whole evaluation program, the Federal Office of Health (BAG).

There was no agreement as to whether the political decision was backed by the data and the results of the PEK process. If the final report of all PEK products is considered valid, then the decision made is not backed by the PEK outcome. However, if one considers some of the elements of the PEK process and data as invalid, one could also agree with the decision. It is unlikely that any final consensus can be reached on this issue since such a consensus is highly dependent on the primary presuppositions made.

It was declared publicly that the PEK process and the political decisions derived thereof should form the basis for further and similar processes to evaluate other elements of the health system. The review board generally supports any move towards evidence-based medicine and health technology assessment without distinction between conventional and complementary medicine.

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