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A pan-European research network for Complementary and Alternative Medicine

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Deliverable 7*

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This report includes an updated version of Deliverable 2 and replaces the version submitted to EC in January 2011.

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Executive summary

Introduction and objectives: There is an emerging notion that research into complementary and alternative medicine (CAM) should be strategically developed. A major aim of the CAMbrella project is to create a sustainable structure and policy for CAM research and development (R&D) in the EU. The specific objective of Work Package 6 (WP6) is to analyse the global R&D situation for CAM in order to inform the EU roadmap, facilitate harmonization and learn from previous and on-going CAM research initiatives across the world.

Method: Fifty-two CAM R&D representatives within the wider CAMbrella consortium were asked to nominate key CAM R&D stakeholders world-wide. Forty-three stakeholders (individuals and organizations) were nominated. The nominees were prioritized based on e.g. their international relevance as indicated by the number of publications, funded research projects and financial research allocations. Fourteen stakeholders were appointed first priority. A protocol for data collection was developed, partly based on structure, process, and outcome indicators published by the WHO. Main topics in the protocol included the mission statement, R&D activities, and explicit or implicit R&D strategies. In line with this protocol, information from policy documents and personal interviews was collected from prioritized stakeholders. Data of both descriptive and explorative character was analysed using principles of content analysis.

Results: The activities of key stakeholders vary greatly in terms of capacity, mission, and source of funding (private/public). R&D activities among selected stakeholders ranged from only providing research funding to having a comprehensive R&D and communication agenda. R&D strategies could be categorized into five different strategies, namely: 1) Context, paradigms, philosophical understanding and utilization; 2) Safety status; 3) Comparative effectiveness; 4) Component efficacy; 5) Biological mechanisms. An apparent shift in R&D focus among the stakeholders over the recent years was found from a narrow focus on efficacy and mechanism studies, to recent CAM R&D focusing on the whole spectrum of research including context, comparative effectiveness, efficacy and mechanisms. This broad range of R&D strategies and activities, including a health systems research perspective, engage the whole range of qualitative and quantitative research methodologies. This broader approach was in line with the views of the World Health Organization. Priority setting of strategic CAM R&D was recommended by some stakeholders to be in line with the *popularity of a certain CAM therapies* and the *disease and public health burden*. It was also found that the issue of strategic CAM R&D was a rather difficult topic to discuss with the informants for various reasons including the inherent political nature of the CAM in most countries.

Discussion and EU recommendations: Despite major differences among the stakeholders, including the size of the organizations, the mission statements and the level of funding there

was an emerging trend of both mission statements and financed projects supporting a broad CAM R&D focus, including qualitative and comparative effectiveness research. This change in agenda setting should be considered in the EU CAMbrella roadmap given the long experience and large size of research funding committed by our analysed stakeholders. Given the inherent political nature of CAM worldwide it is also our recommendation to EU to safeguard the feasibility and sustainability of the overall CAMbrella roadmap recommendations. This may imply the formation of a centralized EU CAM center with the responsibility to operationalise the CAMbrella recommendations within the wider EU context in collaboration with selected EU member states and qualified appropriate academic institutions. Such an EU wide authoritative centre could facilitate collaborative efforts with leading stakeholders internationally and capitalize on their previous experiences and hence minimize risk of duplication and investment failure. The main objective would be to allow for a high output of evidence based recommendations for health sector reform with appropriate CAM based interventions in the EU.

1. Introduction

The present report constitutes Deliverable 7 of the CAMbrella project and is provided by Work Package (WP) 6 'The global perspective'. Unlike it is written in the 'Description of Work' (Annex I of Grant Agreement No. 241951) this report comprises the contents of Deliverable 2 as an updated version which replaces the previous document. While elaborating the overall goal of Work Package 6 the separation into two parts turned out to be disadvantageous. The additional parts of the present report refer mainly to an extended information basis, a more comprehensive analysis of the data, and a discussion on the implications of a European research road map.

The overall objective of WP6 is to map the **international position and status of Complementary and Alternative Medicine (CAM) within health care policy** so the EU situation can be viewed in context. Its rationale is founded on the WHO Global strategy for Traditional Medicine (TM)/CAM; and the main objectives are:

- Incorporate experiences from countries in which CAM Research & Development (R&D) is integrated and publicly supported (US/Canada), while exploring its use as TM in developing countries (China/India).

- Understand the pros and cons of CAM R&D internationally, addressing issues of patient rights and need, cost, regulation (of practitioner and product), evidence base and research policy/strategy.

- Consider risks of over-harvesting medicinal plants, and protection of traditional inherited knowledge of traditional medicine used within CAM.

- Identify the strategies that we need to address from a EU perspective and gain understanding of how the EU might relate to international developments.

WP6 will reflect on the international complexity of CAM and facilitate future implementation of an EU roadmap and regulatory framework for harmonisation of procedures and provisions concerning medicinal products and natural remedies in EU member states.

2. Aim

The specific objective of this Deliverable 7 report is to explore global trends in TM/CAM policy related to research and development (R&D). Based on the global trends for TM/CAM R&D, this report will provide recommendations to the European Union on the future research investments and policy on TM/CAM. Deviations from the original plan for WP6 will be discussed as well as implications for the EU roadmap.

3. Methods

In order to identify global key stakeholders within TM/CAM R&D we sent out requests via e-mail asking for nominations of such individuals or organizations (see Attachment 1, letter to invite nominations). Fifty-two persons from the CAMbrella consortium and a selected group of external experts were contacted and asked to contribute nominations of individuals or organizations outside the EU playing a key role in TM/CAM R&D.
Forty-three stakeholders (individuals and organizations) were nominated. The nominees were prioritized based on their international relevance as indicated by the number of publications, funded research projects and financial research allocations. Fifteen stakeholders were given first priority status (see Textbox 1). These stakeholders could be grouped into four different organisational types: 1) State funded departments or institutes; 2) Research organizations; 3) Research associations (with networking as primary goal); 4) Global health organizations.

The analysis of the TM/CAM policy of these stakeholders' were analysed in two main steps. The first step involved the collection and analysis of data regarding stakeholders' mission statements, R&D policies and, R&D strategies. Step two in the data collection and analysis involved self-reported data involving stakeholder activities. In the first step we explored what stakeholders *want to do* and in the second step we explored what they *report to have accomplished*.

Textbox 1. Stakeholders and the type of organization they represent

15 STAKEHOLDERS WITH FIRST PRIORITY STATUS	
NAME OF STAKEHOLDER	**TYPE OF ORGANIZATION**
Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy (AYUSH), India	State funded department/ institute
Central Council for Research in Ayurveda & Siddha (CCRAS), AYUSH, India	State funded department/ institute
China academy of Traditional Chinese Medicine, China	State funded department/institute
The Consortium of Academic Health Centers for Integrative Medicine (here referred to as IM consortium) (CAHCIM), North America	Research association
Federal Ministry of Health/Complementary and Alternative Medicine, Brazil	State funded department/institute
International Society for Complementary Medicine Research (ISCMR), International	Research association
Japan Society of Oriental Medicine, Japan	Research organization
Korean Institute of Oriental Medicine, Korea	State funded department/ institute
National Center for Complementary and Alternative Medicine, National Institutes of Health, USA	State funded department/ institute
National Institute of Complementary Medicine (NCIM), Australia	Research organization (partly state funded)
Natural Health Product Directorate, Health Canada, Canada	State funded department/ institute (time limited initiative)
Osher Program for integrative medicine, located centers in USA & Sweden	Research organization
Research Council for Complementary Medicine, international, UK based	Research association
Samueli Institute, USA	Research organization
World Health Organization, Traditional Medicine, international	Global health organization

3.1 Step 1: Mission statements, R&D policy and R&D strategies of the 15 stakeholders

A research protocol for data collection was developed, partly based on structure, process, and outcome indicators published by the World Health Organization to facilitate the development of evidence based national drug policies (WHO/DAP 1995). Main topics in the protocol included the mission statement, R&D activities, and explicit or implicit R&D strategies (see Attachment 2, Data collection protocol).

With guidance from the research protocol, in May 2010[1] we conducted pilot interviews with four individual stakeholders holding key positions within the global TM/CAM research community but not representing the 15 prioritised stakeholders, to test the relevance of the questions in the protocol and in order to understand the essential issues to be discussed with the prioritised stakeholders. After that, with guidance from the research protocol, we conducted interviews with six strategically selected individual stakeholders. The interviewees were selected on the basis of their representation of different types of organizations across the globe and their willingness and ability to participate in a face-to-face interview.

The original plan including the stated tasks, as presented in the Description of Work (Annex I to the CAMbrella Grant Agreement) was to conduct focus group discussions with all the prioritized stakeholders through telephone conference calls with 4-5 stakeholders at a time in fall 2010. From the pilot interviewing however, it became clear that the discussions around TM/CAM R&D are of such complex nature that it is very difficult to discuss these issues on the phone and even more so in the form of conference calls. The method of data collection therefore needed to be adjusted to suit the topic of investigation. Face-to-face and/or individual telephone interviews were found to be better solutions for collecting this type of data without compromising on the quality and accuracy of the data.

Interviews were conducted with representatives of the following stakeholders:

- The Central Council for Research in Ayurveda & Siddha (CCRAS) that is an autonomous body of the department of AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy), Ministry of Health Family Welfare, Government of India (Interview with CCRAS Director Dr. Ramesh Babu Devalla)
- Korean Institute of Oriental Medicine (KIOM) (Interview with Myeong Soo Lee, Director of Brain Disease Research Center, KIOM & Jong-Yeol Kim, Director Constitutional Medicine Research Division (KIOM)
- National Center for Complementary and Alternative Medicine (NCCAM), National Institutes of Health (NIH), USA (Multiple interviews with director Dr. Josephine Briggs and selected NCCAM staff)
- National Center for Integrative Medicine (NICM), Australia (Interview with Professor Alan Bensoussan)
- Samueli Institute (Interview with director Professor Wayne Jonas)
- World Health Organization (Interview with director Dr. Zhang Qi & Ms. Yukiko Maruyama)

[1] 1. Jianping Liu, at The National Research Center in Complementary and Alternative Medicine (NAFKAM) which is organized as a center at the Faculty of Medicine, the University of Tromsø, Norway, and it is funded by the Norwegian Ministry of Health and Care Services & the Beijing University of Traditional Chinese Medicine, China; 2. Professor Barrie R. Cassileth, Director of the Integrative Medicine Service at the Memorial Sloan-Kettering Cancer Center; 3. Claudia Witt, The Institute of Social Medicine, Epidemiology and Health Economics, Charité Universitätsmedizin Berlin, Germany; 4. Heather Boon. Leslie Dan Faculty of Pharmacy, University of Toronto, Canada.

The collection of documents on CAM R&D policy by the prioritized stakeholders was conducted in parallel to the interview process. Documents were selected on the basis of their relevance in answering the questions in the research protocol and included policy documents and information on websites. Although documents could be collected from all prioritized stakeholders independent of the interviews, the interviews proved to be very valuable for finding the most relevant, accurate and updated documents.

Interview data and data from various documents played a complementary role in answering the questions posed in the research protocol. Data from interviews and documents of both descriptive and explorative character are analysed using principles of content analysis (Graneheim & Lundman 2004, Patton 2002). Data of descriptive character includes: budget, source of funding, number of funded research projects, focus area (e.g. TM/CAM vs. specific therapies). The explorative analysis includes data from both documents and interviews concerning mission statements and R&D strategies.

3.2 Step 2: Exploration of stakeholders' self-reported R&D activities

The analysis of the stakeholders' R&D strategies aims to show how stakeholders wanted their R&D practice to be implemented. Hence, an analysis of stakeholders' self-reported practice of CAM R&D would demonstrate their explicit R&D *practice,* in contrast to their stated mission.

Self-reported activities were here defined as projects and publications that were mentioned by the stakeholder either on their website, in key R&D documents or listed as publications in *Pubmed*. Both completed and on-going projects were included. The websites as well as key R&D documents of each stakeholder were extensively searched for any possible listings of research studies/publications (containing abstracts, titles etc.). The goal was to find an abstract for each study. However, when this was not possible the title served as a basis for analysing the nature of the project. In order to explore the content of the self-reported R&D activities, a manifest, deductive content analysis with the abstracts and titles as a basis, was conducted with the use of the five categories of research approaches to CAM described by Fønnebø et al (2007), namely: 1) Context, paradigms, philosophical understanding and utilization; 2) Safety status; 3) Comparative effectiveness; 4) Component efficacy; and 5) Biological mechanisms.

4. Results

Briefly, our findings indicate that activities of key stakeholders vary greatly in terms of capacity, mission, and source of funding (private/public). The analysis of the mission statements of the selected stakeholders indicates that the R&D activities of the selected stakeholders range from providing a platform/network for CAM researchers to having a comprehensive R&D policy and communication agenda. This heterogeneity, albeit with some common trends, are described in detail below.

4.1 Descriptive measures: Capacity and funding

The fifteen stakeholders vary greatly in geographical location, capacity and funding (see Table 1 and Figure 1). Some Asian stakeholders were inaugurated as early as in the 1950's while a number of stakeholders, mainly in high-income countries in North America and the Pacific region, were initiated in the 1990's or 2000's.

All together, the majority of financial support comes from public sources. Due to differences in the way budget figures are presented it is difficult to compare budget figures between stakeholders. For example, fiscal budgets 2010 (for stakeholders with an official research budget) range from almost €100 million to approximately €5 million. The majority of stakeholders that conduct research also finance external research. Some stakeholders serve as network associations (in Textbox 1 referred to as Research organizations) and do not have their own research budgets.

Table 1. Descriptive measures for the included stakeholders (figures are based on official documents and website information of the stakeholders)

Stakeholder	Date Established and Time of Operation	Budget estimates**	Financial support	Finances external research	Performs own research
Federal Ministry of Health (MoH), Brazil	1953-	Total CAM investment (2003-2008): €4,740,596	Federal	Yes	Yes
Natural Health Products Directorate (NHPD), Health Canada	2003-08	Total investment (2003-2008): €2,378,010 [NHPD, 2008]	Federal	Yes, ~11.5% of budget for partner-ship	No
Samueli Institute	2001-	€12,582,080 (2010) €10,437,973 (2009) €9,479,370 (2008)	Private. Not-for-profit.	Yes	Yes
Osher Centers	Centers in US: Harvard, 2001 & UCSF, 1998 and Sweden KI, 2005	Official budget figures not found.	Private. Not-for profit.	Yes	Yes
The Department of Ayur-veda, Yoga & Naturopathy, Unani, Siddha and Homoeo-pathy (AYUSH)	1995-	€142,645,082 (2010-11) €127,699,902 (2009-10)	Federal	No	Yes
CCRAS (AYUSH)	1978-	€19,574,744 (2010-11) €20,342,381(2009-10)	Federal	No	Yes
World Health Organization (WHO), Traditional Medicine (TRM)	Date of establishment not found	Not found	Member State support; private/ public funding	Not been found	No
Research Council for Complementary Medicine (RCCM)	1983-	N/A	Charity	No	No
Korean Institute of Oriental Medicine (KIOM)	1994-	€29,149,799 (2011) €19,944,599 (2010) €15,341,999 (2009)	Federal	Yes, ~10% budget goes to external research projects	Yes
National Center for Comple-mentary and Alternative Medicine (NCCAM), National Inst. of Health NIH	1998-	*)€101,260,265 (2011 plan) €98,795,573 (2010); €93,352,232 (2009)	Federal	Yes	Yes
Integrative Medicine (IM) Consortium	1999-	N/A	Memberships and philanthropic support	No	No
International Society for Complementary Medical Research (ISCMR)	2003-	N/A	Non-profit organiza-tion, with member-ship finances	No	No
Japan Society of Oriental Medicine (JSOM)	1950-	Official budget figures not found	Non-profit organization	Not found	Yes
China Academy of Trad Chin Medicine (CATCM)	1955-	Official budget figures not found	Federal	Not found	Yes
National Institute of Complementary Medicine (NICM)	2007-09	€6,044,748 (2009)	2009: €1,380,780 (federal support), €4,663,968 (univer-sities, other collab. Partners)	No	Yes

*) This represents approximately half of the budget of research into CAM. The other half is primarily represented by the National Cancer Institute (NCI).

**) Budgets are estimates derived from electronic sources which have not been confirmed by the stakeholders, and hence should be taken as pointers of investment and not be misinterpreted as actual spending.

Figure 1. Geographical representation of the selected 15 stakeholders

4.2 Mission statements

By analysing the mission statements of 15 stakeholders, we have identified four main themes, namely: *The development of health care practice*; *The scientific exploration of TM/CAM; Communication of TM/CAM related research and; TM/CAM focus area*. These themes represent both the expressed goals of the selected stakeholders and the means for achieving those goals. Although these themes overlap and are not contradictory to each other they have distinct features and are hence presented under separate sub-headings below. The excerpts presented in the results are used to illustrate the analytical points in each theme. The full mission statements of the stakeholders can be found in Attachment 3.

4.2.1 Development of health care practice

The mission statements of a few stakeholders disclose a general goal, not specific to CAM or TM, of transforming and improving health care and health of citizens. The two most explicit examples are the mission statements of the Samueli Institute, USA:
"The mission of Samueli Institute is to transform health care..." (Samueli Institute)

Other stakeholders express a similar goal slightly differently in terms of promoting integration between conventional health care systems and TM/CAM. The Osher Program for Integrative Medicine and AYUSH are two such examples:

"…A third goal is to establish clinical treatment programs in which the knowledge and resources of integrative medicine can be used directly to help people as well as furnish training opportunities for medical students." (Osher Program for Integrative Medicine)
"To mainstream AYUSH at all levels at the health care system…" (AYUSH)'

4.2.2 The scientific exploration of TM/CAM

The most general and prevalent theme found in the mission statements concerns the scientific exploration of TM/CAM. To some stakeholders the priority is set on increasing the academic influence and interest in CAM as well as extending the evidence base and conducting rigorous science. This can be exemplified by the mission statement by the Research Council for Complementary Medicine (RCCM), NCCAM and the North American Integrative Medicine (IM) Consortium:

"Our aim is to develop and extend the evidence base for complementary medicine…" (RCCM)
"We are dedicated to exploring complementary and alternative healing practices in the context of rigorous science…" (NCCAM)
"The mission of the Consortium is to advance the principles and practices of integrative healthcare within academic institutions…" (IM Consortium)

From another angle, the mission statement of the Osher Program for Integrative Medicine suggests that the conduct of basic research is one of the primary goals:

"*One of the primary goals of these centers is to conduct basic laboratory research on integrative medicine remedies, to examine their consequences, and to build an empirical case for their application…." (Osher Program for Integrative Medicine)*

An aspect that is covered explicitly by the mission statement of only one of the selected stakeholders is the need for strategic investment in TM/CAM R&D as expressed by NICM, Australia:
"…provide leadership and support for strategically directed research into complementary medicine…" (NICM)

4.2.3 Communication of TM/CAM related research

In line with the above excerpts from mission statements, another overarching goal expressed in the mission statements of many included stakeholders is to provide a communication platform for TM/CAM and TM/CAM research. The specific focus of such communication activities range from *research translation and dissemination* (e.g. NCCAM, NICM) to providing a *platform for information exchange* (e.g. ISCMR). NCCAM, USA and the

Osher program are examples of stakeholders aiming towards providing information about CAM both to the public and professionals:
"…and disseminating authoritative information to the public and professional communities." (NCCAM)

"A second goal is to reach out to the larger community with an emphasis on preventive care. The centers seek to educate both medical practitioners as well as the general public. (The Osher program)

Other organizations, such as ISCMR, focus on providing a platform for exchange of CAM information:
"…a platform for knowledge and information exchange to enhance international communication and collaboration." (ISCMR)

4.2.4 TM/CAM focus area

Some stakeholders focus their mission statements on specific areas of TM/CAM such as a specific type of traditional medicine or natural products. Among the selected stakeholders there are four examples of government-funded institutions focusing specifically on the traditional medicine of their respective country. These countries are China, India, Japan and Korea. Interestingly, the mission statements seem to indicate two lines of development, one most clearly expressed through the mission statement of Korean Institute for Korean Traditional Medicine and the other by the mission statement of AYUSH in India. While the Korean institute strives towards modernization and industrialization of Traditional Korean Medicine, the mission statement by AYUSH in India indicates that they rather aim for TM to take a larger role within the general health care system in its present form:

"…to contribute to the improvement of human health through modernization and industrialization of TKM (Traditional Korean Medicine)." (Korean Institute for Korean Traditional Medicine)
"To mainstream AYUSH at all levels at the health care system; To improve access to and quality of health care delivery…" (AYUSH)

Interestingly, the Natural Health Products Directorate (NHPD) is the only one of the selected stakeholders that explicitly emphasises the safety aspect in its mission statement:
"The mission is to contribute to improved knowledge of NHPD to enable Canadians to make informed choices about their safe and effective use." (Health Canada)

4.3 Stated R&D strategies and self-reported actual R&D activities

As indicated above, specific R&D strategies were rarely expressed in the mission statements of the selected stakeholders (with the exception of NICM, Australia). However, we have conducted an analysis of R&D strategies as expressed in collected policy documents and interviews with the following six stakeholders: KIOM (Korea), NCCAM/NIH (USA), NICM (Australia), CCRAS/AYUSH (India), Samueli Institute (USA), NHPD/Health Canada (Canada) (see Attachments 4 and 5 for detailed information including data sources). Through this analysis we found that three main types of factors seem to direct the R&D strategies: *Type of research; Utilization and; Impact on society.*

4.3.1 Type of research: Stated R&D strategies

When analysing the type of research prioritised by the selected stakeholders we used the division by Fønnebø et al (2007) who propose the following five different types of research areas: 1) Context, paradigms, philosophical understanding and utilization; 2) Safety status; 3) Comparative effectiveness; 4) Component efficacy and; 5) Biological mechanisms, abbreviated as 1) Context; 2) Safety; 3) Effectiveness; 4) Efficacy and; 5) Mechanisms.

A strong trend revealed by the analysis is a development over time from a R&D focus on biological mechanisms and component efficacy to a broader focus on all 5 research areas (1-5) mentioned above (e.g. NCCAM and CCRAS). The director of CCRAS for example, refers to this trend as *"reversed pharmacology".* This broad focus on research areas 1-5 also applies to the newly established center NICM. NCCAM also emphasize a broader research focus including translational research. One exception to this trend is KIOM, Korea whose focus is mainly on component efficacy and biological mechanisms. This is partly expressed by the three main goals of their research program: *"1) Scientification of Traditional Korean Medicine (TKM) technology; 2) Standardization of TKM technology; 3) Globalization of TKM technology" (KIOM)."*

4.3.2 Type of research: Self-reported R&D activities

In contrast to the stated R&D strategies the analysis of R&D activities carried out aimed to show what the stakeholders actually do engage in. The analysis of stakeholders' self-reported activities reveals that their R&D activities largely depend on their organisational type (see Attachment 5). Firstly it was found that state funded departments or institutes as well as research organizations did openly report most of their explicit R&D activities. Research associations with networking as primary goal and Global health organizations did not report having R&D activities on their own. Secondly, it seems that the type of reported R&D activities that is prioritised by State funded departments and research organisations cover the whole range of research categories. Thirdly, it was found that among the stakeholders that did have R&D activity, their mission statement were by large coherent

with the reported R&D self-reported activities identified in this analysis. Hence, we could conclude that there was no apparent theory-practice gap among the analysed stakeholders.

4.3.3 Utilization

The analyses indicate that to some stakeholders, utilization is an important factor directing R&D strategies whereas to others, utilization does not seem to explicitly direct R&D policy. In general, this seems to be a difference between the included stakeholders with a focus on CAM and those focusing on TM. Stakeholders with a focus on CAM (e.g. NCCAM, NICM, NHPD) seem to include utilization figures in some way or the other in their R&D strategy. On the other hand, stakeholders such as CCRAS and KIOM that have a focus on TM do not explicitly mention utilization as directing their R&D strategy. The distinction based on utilization is in line with the terminological pluralism that characterizes the current status and the historical developments of terminology issues in Europe (for details see the findings reported in WP1 Deliverable 1).

According to our analysis, utilization of TM/CAM may influence R&D strategies in two different ways through: 1) the *popularity of a certain TM/CAM* and; 2) the *disease burden* related to the condition for which TM/CAM is used. These two different ways in which utilization influence CAM R&D may be exemplified by the following statements from NICM and NCCAM:

"…high burden of disease where preliminary evidence is strong and demonstrates likelihood of positive impact." (NICM, Australia)
" Extent and Nature of Practice and Use…" (NCCAM, USA)

4.3.4 Impact on society

According to our analysis, for some stakeholders, also the potential impact of TM/CAM R&D on society seems to be an important factor in R&D policy. Two such examples involved collaboration with regulatory authorities and the natural health products industry. Many research initiatives funded by the NHPD were for example connected to the development of regulatory functions. Moreover, NICM prioritize research projects that involve collaboration with the natural health products industry.

For stakeholders focusing on TM (e.g. CCRAS), the issue of intellectual property rights was mentioned in relation to R&D policy but not considered to be a hindrance, thanks to different initiatives including the Traditional Knowledge Digital Library where ancient manuscripts containing old remedies have been translated and published in electronic form. The Traditional Knowledge Digital Library was set up by the Government of India in 2001 as a repository of 1200 formulations of various systems of Indian medicine, such as Ayurveda, Unani and Siddha.

5. Discussion

5.1 Directing the research - types of research and prioritization

From the interviews it is clear that there has been a shift in R&D focus in recent years. While the research in the 1990's was largely focused on efficacy and mechanism studies, the recent R&D activities analysed here indicate a shift in research focus towards covering the whole spectrum of research methodologies including Context, Effectiveness, Safety, Efficacy and Mechanisms. It became also clear from the interviews however, that the issue of strategic CAM R&D financing is not an easy topic to discuss with the informants. This is probably due to the inherent political nature of the CAM area in most countries. For example, there has been a spectrum of critical opinion regarding the NCCAM-funded research enterprise in the USA. At one end of the critical spectrum are claims that CAM approaches are inherently implausible and justified only by "pseudoscience," that peer-review processes are inferior and that NCCAM funds proposals are of dubious merit, that the field suffers from insularity, and that the research agenda is driven by political pressures rather than scientific considerations. At the other end of the spectrum are claims that NCCAM research fails to evaluate CAM as it is actually used in "real-world" CAM practice settings, that there is insufficient support of CAM practitioner involvement in the research process, that the field is dominated by reductionist scientific approaches or inappropriate methodology, that the peer-review process is biased against CAM, that most NCCAM research is designed or conducted with a goal of "debunking" or disproving value, and that there has been insufficient focus on health and wellness.

In general, such contrasting views and opinions are likely to be common in most countries, also among the EU member states, and may hence impact substantially on any CAM R&D initiative. Possibly as a consequence of this, several of the mission statements collected from the prioritized stakeholders aim to achieve a balance between the many divisions. This was also confirmed by our analysis of the actual CAM R&D projects carried out. This seems to apply to several initiatives in high-income countries including NCCAM, NICM, and the Samueli & Osher centers. In contrast, in China and South Korea, both the theoretical and practical focuses appear to be predominately on component efficacy and biological mechanisms. However, India deliberately seems to argue for a shift of focus from efficacy towards "real world" general effectiveness research, or as stated by the director of CCRAS, for a *"reversed pharmacology"* approach to evaluation of TM. This shift was also obvious from the analysis of the CCRAS funded research projects scrutinized.

Despite the aim of many stakeholders to cover all divisions of research, priority setting is vital for any organization given the limited R&D funding available in most countries. Priority setting was suggested to occur in two ways by NICM and NCCAM, with the *popularity of a certain CAM* and the *disease burden* as potential influences on prioritization. For other stakeholders, to which TM utilization is predominant, prevalence information seems not to be as important.

In addition, the enquiry with our informants did not reveal that general effectiveness research should precede efficacy evaluation where efficacy studies would be only financed provided that they promise research results on general effectiveness. Rather, a broad CAM R&D agenda was favoured by most stakeholders. This broad range of R&D strategies and activities covering the whole range of qualitative and quantitative research methodologies were also supported by data from the interviews with the representatives of the World Health Organization. This finding, attested by a majority of the stakeholders, gives an important recommendation of direction of the EU CAMbrella roadmap for R&D strategic financing, given the experience and size of research funding committed by our analysed stakeholders.

In addition, the lack of focus on R&D regarding CAM safety by most stakeholders indicates that this is a topic for further investigation to detail our understanding of the reasons or lack of reason behind this fact. However, indication from Health Canada (personal communication) is pointing towards governmental constraints in financing of costly comprehensive legislation and regulation of CAM products and therapies that have a large therapeutic index and that have been used extensively among the population for many years. Nevertheless CAM research is challenged to find a justifiable balance between costs and benefits of exploring safety issues.

5.2 Impact on society & intellectual property rights

A few stakeholders aim for health care reform to include CAM where this is compatible with their national health care law and legislations. The Korean institute strives towards modernization and industrialization of Traditional Korean Medicine whereas CCRAS/AYUSH in India aims for TM to take a larger role within the general health care system in its present form. Notably, Health Canada was the only stakeholder who explicitly referred to the safety aspect in their mission statement. Variations in national law and legislation among the EU countries, safety aspects, as well as the impact of CAM on health sector reform, are issues which need to be considered on an EU-wide level in relation to the CAM roadmap.
For stakeholders focusing on TM, the issue of intellectual property rights was raised by e.g. the WHO as an obstacle to R&D efforts. This is because most TM modalities cannot be patented, and indigenous knowledge may hence be exploited for commercial purposes without any benefit to the nation or indigenous population. CCRAS informed that in response to biopiracy threats, the Government of India had ancient manuscripts containing old remedies translated and published in electronic form: in 2001, the Traditional Knowledge Digital Library was set up as repository of 1200 formulations of various systems of Indian medicine, such as Ayurveda, Unani and Siddha. How this may translate to the role of CAM in

Europe is an under-researched area that needs to be addressed in the EU context in order to facilitate industrialization of the CAM area.

5.3 Deviations & Methodological limitations

5.3.1 Deviations from the original tasks for WP6

The data collection methods in this study had to be revised due to the inherent complexity and the challenging nature of the topic for exploration. In addition, the lack of availability of the involved stakeholders contributed to the revision of methodological means for investigation. Hence, instead of as originally stated, building this work package predominantly on broad telephone/video conferences was not deemed feasible. The implication of this was that the procedures described in tasks 6.2 & 6.3 as presented in the 'Description of Work' (Annex I of Grant Agreement No. 241951) had to be revised as described in more detail in previous WP6 progress reports. Notably, this did not mean that the objectives of WP6 where revised but rather that the means to meet the objectives were changed. However, it is likely that the change from a participatory approach, using international group video conferences, to a comprehensive web based study of policy documents, home pages and scientific publications in combination with strategically selected in depth face-to-face interviews with individual stakeholder representatives may have impaired on our ability to meet some of the WP6 objectives. Clearly, the aim to build a group of key international stakeholders who could jointly work with WP6 members towards developing WP6 global guidelines for CAM R&D would have been a great achievement. Some of the planned workshops described in the tasks were as a consequence either omitted or changed in time and scope to accommodate for the revised tasks.

5.3.2 Methodological limitations

The tasks increasingly included data gathering that is presented on websites and policy documents. Subsequently, a number of selected and strategic interviews with individuals representing experienced organization in CAM R&D were carried out to validate the electronic information and describe possible reasons for deviations from the electronic sources. This was one way to ensure member check by minimizing the risk for misinterpretation and inaccuracies in original data from websites and policy documents. The data on which these results are based are also dependent on the level of transparency of the organization. Moreover, the views of individuals representing an organization may sometimes differ from the organization as a whole (although the individuals have been explicitly asked to represent the organization during the interview). However, the triangulation of different data sources (website information, policy documents and personal interviews) is one way of reducing misunderstandings that may be due to inaccuracies in one data source. The limitations of drawing conclusions from mission statements should also be

considered, since mission statements may not reflect current thinking and activities of the stakeholders. In addition, our approach to review actual practice by the stakeholders financing CAM R&D by analysing reported projects through *Pubmed* and/or websites might not accurately reflect the totality of the stakeholders' engagement, which may not be reported through such sources. However, the lack of discrepancy between theoretical and practical R&D activities indicates that this was not the case. Finally, we have not been able to include stakeholders from the African continent, and this provides a limitation to our generalizations (Figure 1).

6. Implications for the EU research roadmap

6.1 WP6 objectives in relation to the EU roadmap

In WP6 we have aimed to incorporate experiences from countries across the world in which CAM R&D is integrated and publicly supported (e.g. USA, Canada, China, and India) in accordance with the objectives of WP6. In the data collection we have addressed a wide range of CAM related issues including patient rights and needs, cost, regulation (of practitioner and product), the risks of over-harvesting medicinal plants, and protection of traditional inherited knowledge of traditional medicine, evidence base and research policy/strategy. It was found that the acknowledgement and prioritization of these issues vary to a great extent among the selected stakeholders. In order to meet the overall aim of WP6 "To identify the strategies that we need to address from an EU perspective and gain understanding of how the EU might relate to international developments" we have come to the conclusion that the best basis for generalization is to capitalize on issues that are explicitly addressed by several stakeholders. Such issues were found to be primarily related to strategies for a) how to set priorities for CAM R&D and b) how to conduct CAM R&D. This analysis of the international position of CAM research is important for the EU to acknowledge and incorporate in its own strategies for the EU roadmap and is what WP6 highlights to a large extent as *recommendations* in this final report (see Textbox 2).

6.2 Recommendations for the EU roadmap

Firstly, an apparent shift in R&D focus among the stakeholders over the recent years was found. While the research in the 1990's was largely focused on efficacy and mechanism studies, the recent R&D activities analysed here indicate a shift in research focus towards covering the whole spectrum of research including a focus on context, effectiveness, efficacy and mechanisms. This broad range of R&D strategies and activities including a health systems research perspective engage the whole range of qualitative and quantitative research methodologies and their theoretical and conceptual underpinnings. This broader

approach was much in line with the views on CAM R&D strategic research by the representatives of the World Health Organization. This finding, attested by a majority of the stakeholders, gives an important recommendation of direction of the EU CAMbrella roadmap for R&D strategic financing, given the experience and large sizes of research funding committed by our analysed stakeholders.

1. Based on current worldwide strategies we recommend that a broad range of mixed methods research strategies should be used to investigate CAM within the EU. The choice of method(s) for any particular project or experiment should be based on the specific scientific question and should focus on delivering safe and effective health interventions to EU citizens.

Secondly, despite the aim of many stakeholders to cover all divisions of research, priority setting is however vital for any organization given the limited R&D funding available in most countries. Priority setting was recommended by some to be in line with the *popularity of a certain CAM* and the *disease burden* as potential influences on prioritization, which have bearing also for the CAMbrella roadmap priorities. However, it should also be considered that a lot of CAM research attest to the benefits of CAM to improve the abilities of individuals' quality of life as well as maintenance of health where a *caring* perspective is more relevant compared to a *curing* perspective (i.e. where diagnosis often lead the way).

2. CAM research strategy should be based on the popularity of a specific intervention and related to the national or regional public health needs and disease burden.

Thirdly, the finding that the issue of strategic CAM R&D was not an easy topic to discuss with the informants, which is likely due to the inherent political nature of the CAM area in most countries, is important to consider. The complexity of CAM may impact substantially on any CAM R&D initiative in general and on the EU roadmap in particular. As a consequence of this, and in the light of the stakeholders, which have been successfully active over a long period of time with substantial funding, it is our recommendation to EU to ensure by various means the feasibility and sustainability of the overall CAMbrella roadmap recommendations. Such means may include the formation of an EU centralized CAM center with the responsibility to operationalize the CAMbrella recommendations in collaboration with selected EU members states and academic institutions. Here NCCAM at NIH in the USA may serve as a model for a successful strategic CAM R&D programme and structure. The establishment of such an EU based authoritative CAM center would facilitate collaborative efforts with leading stakeholders internationally which would increase synergies and minimize the risk of duplication of R&D investments (on the national levels). The main objective would to allow for a high output of evidence based recommendations for health sector reform with appropriate CAM based interventions.

3. We suggest the formation of a centralised EU CAM centre with the responsibility to operationalise the CAMbrella recommendations in collaboration with selected EU member

states and appropriate (worldwide) academic institutions to enable evidence based health sector reform with appropriate CAM interventions in the EU.

Textbox 2. General recommendations for EU based on the global analysis of the CAM R&D situation

WP6 RECOMMENDATIONS FOR STRATEGIC CAM R&D IN EUROPE

- ***A broad range of mixed methods research strategies should be used to investigate CAM within the EU. The choice of method(s) for any particular project or experiment should be based on the specific scientific question and should focus on delivering safe and effective health interventions to EU citizens.***
- ***The CAM research strategy for Europe should be based on the popularity of a specific intervention and related to the national or regional public health needs and disease burden.***
- ***We suggest the formation of a centralised EU CAM centre with the responsibility to operationalise the CAMbrella recommendations in collaboration with selected EU member states and appropriate (worldwide) academic institutions to enable evidence based health sector reform with appropriate CAM interventions in the EU.***

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Attachment 1: Letter to invite nominations

Stockholm June 23, 2010

Dear Professor/Dr. X,

We are writing to you as partners of the pan-European project CAMbrella established under the Seventh Framework Program in January 2010. Sixteen partner institutions from 12 European countries are working together to develop the first roadmap for European research in CAM. The main objective of this coordinating and networking project is to develop a roadmap for future European research in Complementary and Alternative Medicine (CAM) that is appropriate for the health needs of European citizens and acceptable to their national research institutes and health care providers both public and private.

In order to understand the role of the EU in relation to strategic international CAM research, a dialogue with institutions such as X is of outermost importance. As coordinators of Work-Package 6 focusing on the global situation of CAM research within CAMbrella we would therefore like to ask for your views and experiences and/or policy documents related to essential CAM research within your organization/institution.

If this is acceptable to you, please send us relevant policy documents/views or references before **August 30, 2010**.

Based on our review of the material we might contact you again to suggest a time and date in fall 2010 when you could participate in a telephone interview. For such an interview, we will in advance provide you with questions that we intend to discuss.

For more information about CAMbrella, please visit the website www.cambrella.eu

We are looking very much forward hearing from you!

Best regards,

Torkel Falkenberg, Assoc. Prof., Johanna Hök, Ph.D.
Coordinator of Work Package 6 *Associate coordinator*
CAMbrella, Work Package 6: The Global Position and Status of TM/CAM
Karolinska Institutet

Attachment 2: Data Collection Protocol

Probing research financing and priority setting in relation to safety, quality, effective and appropriate use of CAM.

The following questions have been developed and structured on the basis of the process, structure and outcome indicators developed by WHO/DAP for a comparative analysis of national drug policies (WHO/DAP/97.6).

GENERAL QUESTIONS

1. The experience when it comes to strategic financing of CAM research – how do you see that the best financing is done, e.g. what is financed, how is it financed, who is financed?
2. What are the lessons learned (from the horizon of your institution) when it comes to aiming for successful financing?
3. What is successful financing for your organization?
4. Who are the beneficiaries of your organization?

SPECIFIC QUESTIONS

STRUCTURAL ISSUES

1. How is current law and legislation of CAM taken into account regarding priority setting of research areas?
2. Research priority setting in relation to products and practitioner regulations (e.g. chiropractors). Level of alternativeness?
3. Budget requirements for vital research financing, how little, how much?
4. Administration experience, and financing of core facilities, etc. How should the EU do this, need to build separate structure, why – why not?
5. Advise regarding structures for quality assurance of research financing allocation.
6. Information, education and communication strategies useful for EU, what do you recommend in outreach and structures necessary for this?
7. Collaboration with other authorities, such as the national food and drug administration?

PROCESSES ISSUES

1. How has the financing developed over time, and what are the lessons learned relevant for the EU?
2. Organisation (size, budget, personnel, etc.) – how has it developed over time, and what are your recommendations to the EU?
3. What proportion of the total CAM activity in your country does your organization actually cover through research activity? What are the excluded areas, what are priority areas, what do you recommend to start with as essential areas for the EU?
4. Cost-benefit of research financing provided by your institution- how is research money used most successfully? What are the risks, the potential benefits, and how is benchmarking done?
5. Turn-over of research project funding; what are the best project cycles, length of project financing, motivate the answer.
6. International collaboration experience among CAM researchers, and/or interdisciplinary research efforts, e.g. wide collaborative consortia? What is your experience of best practice here.

7. What forms of IEC are produced, and what are the essential priorities of content and target groups receiving IEC?
8. How do you ensure, work with TRIP rights, for example traditional knowledge?
9. Meetings with national food and drug administration or equivalent, Government, etc.

OUTCOMES ISSUES

1. Number of considered successful research projects per year and over the years (in your organization). What are the lessons learned, for example in relation to level of funding and success?
2. Quality assurance indicator results of research projects at your institution?
3. Total cost of your institution today and the future? What is the prognosis, i.e. financial resources?
4. Number of patents as part of result of project financing?
5. Number of CAM technologies/procedures within the national health system as a consequence of proven efficacy due to project financing of the actual organization?
6. Improved patient safety thanks to financed research projects?
7. Improved quality and appropriate use of CAM thanks to funded projects?

Attachment 3: Mission statements

AYUSH, India

1) To mainstream AYUSH at all levels at the health care system; 2) To improve access to and quality of health care delivery; 3) To focus on promotion of health and prevention of diseases

CCRAS/AYUSH India

To enhance the capability of the Council as a premier institution for research in Ayurveda and Siddha, and to forge strategic alliances with similar establishments and constantly strive for excellence in basic and applied knowledge for efficient understanding of the cause and prevention of human diseases and their management.

China Academy of Chinese Medical Sciences, China

To carry out the scientific research on TCM is the leading mission of the Academy.

At present, China Academy of Chinese Medical Sciences is the largest research organization on TCM throughout the country (in China), which has all the necessary disciplines of TCM, advanced equipment and solid scientific research strength. In the Academy, there are 13 institutes, 6 hospitals, as well as the Graduate School, the Publishing House of Ancient Chinese Medical Books and the Journal of TCM, etc. The staff of CACMS, in total, is over 4,000, including 3,200 professionals in various fields.

IM Consortium, International

The mission of the Consortium is to advance the principles and practices of integrative healthcare within academic institutions. The Consortium provides its institutional membership with a community of support for its academic missions and a collective voice for influencing change.

Ministry of Health, Brazil, PNPIC - National Policy on Integrative and Complementary Practices of the SUS (Unified Health System)

OBJECTIVES

1) To incorporate and to implement the Integrative and Complementary Practices in SUS, in the perspective of injury prevention and the promotion and recovery of health, with emphasis in the basic attention, for the continuous humanized and integral health care.

2) To contribute for the increase of the System resolubility and broader access to the Integrative and Complementary Practices, ensuring quality, effectiveness, efficiency and safety in its use.

3) To promote the rationalization of health actions, stimulating innovative and socially contributive alternatives to the sustainable development of the communities.

4) To stimulate actions regarding the social control/participation, promoting the responsible and continuous involvement of the users, managers and professionals in the different instances of health policies effectiveness.

ISCMR, international

ISCMR is an international scientific organization of researchers, practitioners and policy makers that fosters Complementary and Integrative Medicine research and provides a platform for knowledge and information exchange to enhance international communication and collaboration.

Japan Society of Oriental Medicine, Japan

The intention of the society is to hold research presentations and seek communication, tie-up and promotion concerning oriental medicine and contribute to the progress and dissemination of oriental medicine, and thus contributing to the development of scientific culture.

Korean Institute for Korean Traditional Medicine, South Korea

"…to contribute to the improvement of human health through modernization and industrialization of TKM (Traditional Korean Medicine)."

National Center for Complementary and Alternative Medicine, NCCAM, USA

We are dedicated to exploring complementary and alternative healing practices in the context of rigorous science, training CAM researchers, and disseminating authoritative information to the public and professional communities.

National Institute for Complementary Medicine, NICM, Australia

The National Institute of Complementary Medicine (NICM) was established to provide leadership and support for strategically directed research into complementary medicine and translation of evidence into clinical practice and relevant policy to benefit the health of all Australians.

Natural Health Products Directorate (NHPD)/Health Canada, Canada

"The mission is to contribute to improved knowledge of NHPD to enable Canadians to make informed choices about their safe and effective use."

Osher Program for Integrative medicine (overarching the three centers), USA & Sweden

1) One of the primary goals of these centers is to conduct basic laboratory research on integrative medicine remedies, to examine their consequences, and to build an empirical case for their application. In the case of the American institutions, third-party reimbursement will likely depend upon persuasive cases being made to insurers that integrative medicine offers effective remedies.

2) A second goal is to reach out to the larger community with an emphasis on preventive care. The centers seek to educate both medical practitioners as well as the general public. Seminars and conferences help educate people about the benefits of such "non-traditional" approaches to good health and medical care.

3) A third goal is to establish clinical treatment programs in which the knowledge and resources of integrative medicine can be used directly to help people as well as furnish training opportunities for medical students.

Research Council for Complementary Medicine, RCCM, UK

Our aim is to develop and extend the evidence base for complementary medicine in order to provide practitioners and their patients with information about the effectiveness of individual therapies and the treatment of specific conditions.

Samueli Institute, USA

"The mission of Samueli Institute is to transform health care through the scientific exploration of healing."

The World Health Organization (WHO), international

WHO Traditional Medicine Strategy 2002-2005

In terms of TM/CAM, WHO carries out these functions by:

- *Facilitating integration of TM/CAM into national health care systems by helping Member States to develop their own national policies on TM/CAM.*

- *Producing guidelines for TM/CAM by developing and providing international standards, technical guidelines and methodologies for research into TM/CAM therapies and products, and for use during manufacture of TM/CAM products.*

- *Stimulating strategic research into TM/CAM by providing support for clinical research*
- *projects on the safety and efficacy of TM/CAM, particularly with reference to diseases such as malaria and HIV/AIDS.*

- *Advocating the rational use of TM/CAM by promoting evidence-based use of TM/CAM.*

- *Managing information on TM/CAM by acting as a clearing-house to facilitate information exchange on TM/CAM*

Attachment 4: Stated R&D strategies

In this analysis we have identified three main types of factors that seem to direct the R&D strategies of 6 selected stakeholders: *Type of research; Utilization; and Impact on society.* Below follows a brief description of the data sources used in the analysis of R&D strategies.

CCRAS/AYUSH, India

Data sources on CCRAS/AYUSH R&D policy include transcript from interview with CCRAS Director Dr. Ramesh Babu Devalla.

Summarized interpretation of CCRAS/AYUSH R&D strategy: Dr. Ramesh Babu Devalla is the new director of the institute since April 2010 and, according to a personal interview in December 2010, is currently reforming the institute's R&D strategy. They are currently working on a new R&D strategy document. While CCRAS previously focused on research on biological mechanisms and component efficacy, there is now a strong focus on *"reverse pharmacology research"* (citation from interview), which we interpret to be in line with the reverse order of research discussed in the article by Fønnebø et al. (2007). According to Dr. Devalla, the institute is now focusing on whole systems research in order to investigate traditional individualization of treatments according to Ayurvedic principles.

Utilization and impact of CCRAS's activities on society are not explicitly mentioned, but the focus on Ayurveda is in itself an indicator of the importance of this focus. The institute is currently putting resources into educating university staff in Ayurvedic principles.

KIOM, Korea

Data sources include transcript of interview with Director Dr. Kim Ki oK & Dr. Myeong Soo Lee at the Korean Institute of Oriental Medicine (KIOM) and R&D policy documents from KIOM website.

KIOM website regarding R&D strategy:
Scientification of TKM technology; 2) Standardization of TKM technology; 3) Globalization of TKM technology

Summarized interpretation of KIOM R&D strategy: Main R&D focus is on research areas 4 & 5 (according to Fønnebø et al. (2007)). Utilization and impact of KIOM's activities on society are not explicitly mentioned, but the focus on Korean traditional medicine is in itself an indicator of the importance of the prevalent use of Korean traditional medicine.

NCCAM/NIH, USA

Data sources include transcript of interview with Director Dr. Josephine Briggs and her colleagues at NCCAM and R&D policy documents from NCCAM website.

NCCAM website regarding R&D strategy:
Four factors will be used in research prioritisation: 1) Scientific promise; 2) Extent and Nature of Practice and Use; 3) Amenability to Rigorous Scientific Inquiry; 4) Potential to change health care practice

Summarized interpretation of NCCAM R&D strategy: Research strategy has developed over the years from a focus on biological mechanisms and component efficacy (4 & 5) to encompass the broader scope of R&D areas 1-5. Priority is also given to areas that are used by a large percentage of the population and therapies/areas that shows ”great scientific promise”.

Natural Health Product Directorate/Health Canada, Canada

Data sources on Natural Health Product Directorate (NHPD) (Health Canada) R&D policy include e-mail correspondence with Dr. Loretta Wong (current position) and from the publication ”Natural Health Products Research Program, Five -Year Performance Report 2003/04 - 2007/08”.

Funding allocation in Five-year performance report:

Product quality, safety and efficacy	25.0%
Information and knowledge transfer	21.8%
Health systems and health services research	18.8%
Clinical areas and population groups	14.0%
Bioethics, policy and regulatory issues	12.5%
Issues related to the conduct of research and methodologies	7.8%

Summarized interpretation of NHPD R&D strategy: Research strategies have an explicit broad scope in the NHPD field seemingly covering areas 1-5 (see table on funded research above). Many of funded research initiatives were connected to development of regulatory functions.

NICM, Australia

Data sources on NICM R&D policy include transcript of telephone interview with Director Prof. Alan Bensoussan and R&D documents from NICM website.

NICM website regarding R&D strategy:
“Has the potential to impact positively on the health and wellbeing of all Australians. Emphasis will be given to those areas of high burden of disease where preliminary evidence is strong and demonstrates likelihood of positive impact. 2) Elucidates safety, efficacy and cost effectiveness of complementary medicine and translates this into policy and practice. 3) Investigates methodological issues relevant to the complex nature of complementary medicine. These include the development of methodological tools, such as measurement instruments, trial designs and pharmacological approaches which may impact on our understanding of the whole practice, concepts and mechanisms underpinning complementary medicine.”

Summarized interpretation of NICM R&D strategy: In their mission statement NICM explicitly state the need for *”strategically directed research”*, stressing the need for research in all 5 areas with a particular focus on the impact on our *“understanding of the whole practice, concepts and mechanisms underpinning complementary medicine”.* Priority is given to areas of *”…high burden of disease where preliminary evidence is strong and demonstrates likelihood of positive impact.”* According to the interview with Professor Alan Bensoussan, prioritization is also given to joint research projects between academic institutions and CAM-associated industry (e.g. Natural Products Industry).

Samueli Institute, USA

Data sources on Samueli Institute R&D policy include transcript from interview with Director Dr. Wayne Jonas and R&D documents from Samueli Institute website. The Institute's mission is to explore the scientific foundations of healing and to apply that understanding in medicine and health care. The Institute conducts research on all types of health care practices. The Samueli Institute supports scientific exploration together with partners, collaborators and its own scientists with the aim of cultivating research on healing and its evaluation in mainstream health care. In developing these initiatives, the Institute seeks opportunities that will:

- Build the scientific tools and capacity for the evaluation of healing practices
- Use multi-disciplinary evaluation models of science
- Develop effective research services on healing practices for use by the public and private sectors
- Increase its grants, contracts and joint ventures in research
- Transfer knowledge and technologies that facilitate healing to the public sector

Summarized interpretation of the Samueli research strategy: The research strategy includes all research areas, with an increasing focus on whole systems research with a pragmatic clinical trials approach that uses mixed methods (areas 1,3 & 5). Such investigations aim to facilitate the transfer of knowledge and technologies to include healing services practices in the public sector.

Attachment 5: Summary of stated R&D strategies and self-reported actual R&D activities

1. Central Council for Research in Ayurvedic Sciences (CCRAS) [AYUSH]

Stakeholder type: Research organization	Budget (2010-11 fiscal): €19,574,744
Financial support: Federal	Finances external research: No
R&D statements and prioritized research: While CCRAS previously focused on research on biological mechanisms and component efficacy, there is now a strong focus on *"reverse pharmacology research"* (interview), which we interpret to be in line with the reverse order of research discussed in the article by Fonnebo et al. (2007). According to Dr. Devalla, the institute is now focusing on whole systems research in order to investigate traditional individualization of treatments according to Ayurvedic principles. Utilization and impact of CCRAS's activities on society are not explicitly mentioned, but the focus on Ayurveda is in itself an indicator of the importance of this focus. The institute is currently putting resources into educating university staff in Ayurvedic principles. Self-reported activities: From the preliminary interview, it is understood that CCRAS focuses on a "reversed pharmacology" approach. This is apparent from content analysis from the CCRAS website. Most activities were found within the categories *Context*, *Safety and, Effectiveness.* Official policy vs. self-reported activities: According to the analysis of CCRAS self-reported activities, they seem to follow the order of the Fonnebo categories. The prioritization according to an analysis of a pubmed search is: *Context, Safety and Effectiveness*.	

2. Korea Institute of Oriental Medicine (KIOM), South Korea

Stakeholder type: Research organization/National research institute	Budget (2011): €29,149,799
Financial support: Federal	Finances external research: Yes (10% budget)
R&D statements and prioritized research: Main R&D focus is on research areas 4 & 5. Utilization and impact of KIOM's activities on society are not explicitly mentioned, but the focus on Korean traditional medicine is in itself an indicator of the importance of the prevalent use of Korean traditional medicine. Self-reported activities: According to an analysis of the published studies found on Pubmed by KIOM the focus is on 5) *Mechanisms*, 4) *Efficacy*, and 3) *Effectiveness*. Official policy vs. self-reported activities: KIOM matches their official policy with their self-reported activities. Biological mechanisms have first order of priority. This matches their R&D statements to scientifically explore and communicate TKM with technology.	

3. National Center for Complementary and Alternative Medicine (NCCAM), National Institutes of Health (NIH), USA

Stakeholder type: Research organization/National research institute	Budget (2011): €101,260,265
Financial support: Federal	Finances external research: Yes
R&D statements and prioritized research: Research strategies have developed over the years from a focus on biological mechanisms and component efficacy (5 & 4) to encompass the broader scope of R&D areas 1-5. Priority is also given to areas that are used by a large percentage of the population and therapies/areas that show "great scientific promise." Self-reported activities: The majority of the self-reported activities were categorized in the three areas *Effectiveness*, *Efficacy*, and *Mechanisms*. A significant body of funding however, also covered activities within the field of context and safety. Official policy vs. self-reported activities: Given the amount of funding given to respective research areas, effectiveness studies seems to receive more funding compared to efficacy studies (which is the category that receives the second largest funding within the five categories. Context and safety received a comparative significant funding, although smaller than the other three categories. It appears thus that NCCAM follows a broad approach while searching both for external and internal validity -- thus also matching their far-reaching R&D statements.	

4. Natural Health Products Directorate (NHPD)/Health Canada, Canada

Stakeholder type: Regulation association	Total investment (2003-2008): €2,378,010
Financial support: Federal	Finances external research: Yes (11.5% funds)
R&D statements and prioritized research: Research strategies have an explicit broad scope in the NHPD field covering all areas 1-5 [5-year Performance Report]. Many of funded research initiatives were connected to natural health products and development of regulatory functions. Self-reported activities: According to the final performance report (ref), safety studies play a major role while also studies on efficacy, mechanisms and, effectiveness are prevalent. Official policy vs. self-reported activities: Official policy and self-reported activities both come from the National health Products Research Program – Five-Year Performance Report (2003-2008). The official policy indicates that all strategies are generally covered. The reports of the finished projects however indicate a particular strong focus on safety, a relevant focus on effectiveness, efficacy and mechanisms while context is least prevalent in the report of finished projects.	

5. National Institute of Complementary Medicine (NICM), Australia

Stakeholder type: Parent research org.	Budget (2009): €6,044,748
Financial support: Federal	Finances external research: No, only NICM branches
R&D statements and prioritized research: In their mission statement NICM explicitly state the need for *"strategically directed research,"* stressing the need for research in all 5 areas with a particular focus on the impact on our *"understanding of the whole practice, concepts and mechanisms underpinning complementary medicine."* Priority is given to areas of *"…high burden of disease where preliminary evidence is strong and demonstrates likelihood of positive impact."* According to the interview with Professor Alan Bensoussan, prioritization is also given to joint research projects between academic institutions and CAM-associated industry (e.g. Natural Products Industry). Self-reported activities: An analysis of the published reports revealed a strong focus on *Effectiveness*. Official policy vs. self-reported activities: The preliminary interview identified a "reversed pharmacology" approach – which is verified by the content analysis. However, the analysis was made shortly after the center was established. If more projects could be found and analyzed, a more accurate conclusion could be made. Nonetheless, a general pattern that mildly reflects actual activities has been found mostly centered around effectiveness – with all other strategies partially explored as well.	

6. Samueli Institute, Europe/USA

Stakeholder type: Research organization	Budget (annual): €12,580,440
Financial support: Non-profit organization with private support from various sources	Finances external research: Yes
R&D statements and prioritized research: The research strategy includes all research areas, with an increasing focus on whole systems research with a pragmatic clinical trials approach that uses mixed methods (context, effectiveness & mechanisms). Such investigations aim to facilitate the transfer of knowledge and technologies to include healing services practiced in the public sector. Self-reported activities: From an analysis of published papers in association with Samueli Institute, R&D activities deal with areas Context, Effectiveness and Efficacy. More specifically there is a strong focus on CAM pragmatic clinical trials with mixed methods, but also explanatory trials. Official policy vs. self-reported activities: Samueli appears to match their official policy with their self-reported activities, aiming to pool resources to understand how to use CAM properly with an outreaching impact.	