Comments received by the National Vaccine Program Office from International Sources on the draft strategic National Vaccine Plan through January 30, 2009.

General Comments:

European CDC (Dr. Lsuzsanna Jakab, Director)

1) *Comments on priorities for the National Vaccine Plan for* a *ten-year period and Comments on the goals, objectives and strategies for the National Vaccine Plan for* a *ten-year period:*
ECDC supports the five broad goals that the Plan is built around. The goals in the Plan fit well with the aims of the programme on Vaccine-Preventable Diseases at ECDC concentrating on 1) *safety* of *vaccines and vaccination practices* having developed self-assessment tools for Member States to evaluate their systems for reporting AEFIs and causality assessment tools, 2) *informed vaccine decision-making by the public, providers and policy-makers* by establishing a new permanent Scientific Panel of Experts on Vaccinology (EVAG, 15 members) and developing educational tools to be used for training of nursing and medical students, and information to the public, and produce evidence-based guidance on introduction of new vaccines, 3) *achieving better use* of *existing vaccines to prevent disease, disability and death,* specifically measles and rubella vaccines through preparing a selfassessment tool for Ministries of Health in Member States to evaluate their measles and rubella programs with the aim of eliminating measles and rubella from the European region, but also pneumococcal, Hib, HPV, varicella and rotavirus vaccines, and 4) *increase global prevention* of *death and disease through* safe *and effective vaccination,* by looking into the possibilities for the ECDC and the European Member States to participate in to the proposed Global Safety DataNet

United Kingdom (Dr. David Salisbury, Director, Immunization)

This is an extraordinarily ambitious set of goals and targets. What resources are going to be set aside? Even monitoring these multiple targets and outcomes is going to be hugely labour intensive, even if no new funds are provided for the activities themselves.

In all, the plan provides a very large number of process and outcome indicators. These are laudable objectives but there are no indications of how the resources are going to be identified and mobilised to achieve these goals.

On page 23, the responsibilities of NVPO in coordinating activities of other agencies are described. But, missing from the document is where the responsibility for programme implementation and management lies and how this will be done. Who has responsibility for performance management and where is the output – feedback – output cycle that oversees the national programme?

(1) *Comments on priorities for the National Vaccine Plan for a ten-year period:* What do you recommend be the top priorities for vaccines and the immunization enterprise in the United States and globally? Why are those priorities most important to you?

These priorities are not incorrect: the problem is how attainable they are, who has the resources to take each forward and who has the resources to coordinate all of the disparate activities. My comments on global activities are as above.

(2) *Comments on the goals, objectives, and strategies for the National Vaccine Plan for a ten-year period:* Please comment on the existing goals, objectives, and strategies in the draft Plan, and suggest specific goals, objectives, or strategies to be added to it, if the existing ones do not address your concerns. Are there any goals, objectives or strategies in the draft strategic Plan that should be discarded or revised? Which ones, and why?

Please see my comments above. Overall, I think there are too many targets for too many people – some are measurable and some are aspirational. Where numerical targets are set, there will need to be explicit criteria that justify the figures that are chosen.

(4) *Comments on stakeholders' roles in the National Vaccine Plan:* Please identify which stakeholders you believe should have responsibility for enacting the objectives and strategies listed in the draft Plan, as well as for any new objectives and strategies you suggest. Specifically identify roles your organization can play in the Plan.

My concern is not the roles and responsibilities of individual agencies or stakeholders but the identification of how this project will be managed and by whom.

Comments on Executive Summary and Introduction:

None

Goal 1 Comments: Develop new and improved vaccines

European CDC (Dr. Lsuzsanna Jakab, Director)

One area of interest not mentioned in this draft is studies of the long-term immunologic memory in relationship to optimizing immunization schedules. Many of the vaccines in use today have not been in use long enough to evaluate development of life-long immunity. Cohorts to be followed long-term need to be established, please see the excellent results from the Finnish MMR-cohort that now has been followed for 25 years.

United Kingdom (Dr. David Salisbury, Director, Immunization)

These are surely already high level vaccine development targets that have been identified in many fora.

Having the capability to test potential vaccine candidates in clinical trials within six months of identification of the need for a vaccine is seriously unrealistic!

Goal 2 Comments: Enhance the safety of vaccines and vaccination practices

European CDC (Dr. Lsuzsanna Jakab, Director)

2) Comments on the indicators for the National Vaccine Plan for a *ten-year period*
ECDC supports the existing indicators by each goal in the draft Plan and find especially the activities under the goal 2 concerning enhancing the safety of vaccines and vaccination practices very helpful, particularly the indicators for developing plans for further investigation of AEFI signals, that X% of individuals will be under active surveillance and conduct research to explore host factors and biological mechanisms associated with serious AEFls. Another indicator under safety could be that X% of all vaccinees should be monitored in Immunization Information systems.

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I think that the indicator that x% of infants, children, adolescents, adults and pregnant women will be under active surveillance for AEFIs is inappropriate. This either will lead to 'fishing/dredging' exercises or will not necessarily be adequate to the challenge. There needs to be a capacity to put in place adequately powered studies in various populations in response to signals that have been generated elsewhere.

I think the prospect that there will be answers on "host factors and biological mechanisms that are associated with serious AEFIs" worthy of annual reporting to the Assistant Secretary for Health, vaccine advisory committees, vaccine policy makers and other stakeholders is extremely slim.

Identification of host factors or genetic susceptibilities (p32 and p36) is unrealistic, certainly within the time-frame of this plan. The implication is that there could be screening for genetic factors for all children before immunisation and this is just not going to happen.

Page 39 – if HHS is going to do all that it commits to do in the Introduction paragraph, where are the resources to do this?

Goal 3 Comments: Support informed vaccine decision-making by the public, providers, and policy-makers

European CDC (Dr. Lsuzsanna Jakab, Director)

Another area not mentioned clearly is the identification of hard-to-reach groups and how the information about vaccines could aim to also reach these groups. In particular there are also a significant number of individuals and families around the hard-to-reach groups influenced by the hard-to-reach groups and that possibly could be reached with more in-depth information.

United Kingdom (Dr. David Salisbury, Director, Immunization)

Whilst setting process or outcome indicators for communications about immunisation are laudable, there are no criteria for what these should be and the levels are arbitrary. What will be bad and what will be good?

I am surprised that there needs to be a goal for a percentage of key decision and policy makers to report that they have had access to vaccine benefits, risks and costs to make informed decisions about vaccine policy. Do they not already have such information?

Whilst the last two targets of Goal 3 are ideals, I think it is highly unlikely that they could be implemented or their progress tracked.

Reducing barriers to immunisation is important but completely lacking is any form of programme management of performance. Why does it take the US so long to reach adequate coverage levels for new vaccines? What could be done to improve performance once a vaccine is in routine use? How can there be better conformity with recommended ages for immunisation? For example, is 25% coverage for HPV vaccine adequate and is the programme cost-effective? If not, what could be done to improve coverage?

3.1 p 42 – The UK does all these, and has done so for many years: these activities are invaluable.

A very wide range of stakeholders are identified for the activities under ‘3’. Who has the responsibility to lead and coordinate? Where are the resources or will these remain fragmented?

Goal 4 Comments: Ensure a stable supply of recommended vaccines, and achieve better use of existing vaccines to prevent disease, disability, and death in the United States

United Kingdom (Dr. David Salisbury, Director, Immunization)

It is clearly desirable that there should be reductions in financial and non-financial barriers to access to immunisation, but setting such a percentage reduction to X% is subjective without linkage to an outcome criterion.

Although there will be vaccine coverage target levels established in the Healthy People 2020 programme, there are no indications within the document about how coverage rates will be increased or poor performance identified and addressed. There is an implicit assumption that coverage improvements will follow these targets but that may not be the case.

I note the intention to have surveillance implemented in X% of states within Y years after an ACIP recommendation. But in the case of a new vaccine or vaccination programme adaptation, surveillance should be in place before implementation not after.

Page 48: Reducing financial barriers to immunisation is going to require either cheaper vaccines or more support to subsidise manufacturers' prices. Are additional funds going to be available and by what means will these be requirements be assessed and taken forward?

Page 4.3.1 What criteria could be used to assess cost-effectiveness in methods for assessing vaccination coverage? What would be value for money in different methodologies?

Goal 5 Comments: Increase global prevention of death and disease through safe and effective vaccination

Dr. Isao Arita, Japan

1. I would like to discuss a special establishment, Vaccine Research Institute for sub-Saharan Africa

The vaccine supply to many countries of limited resources has been an important issue. So far there have been several bilateral as well as multilateral programs or agencies responsible for this task. The available vaccine for the supply, through, has to procure from the manufacturers subject to market force. So far it has been operating smoothly. However, over the last decades, some changes have been occurring. Namely major manufacturers have been active expanding their production and RD. The small manufacturers have been loosing the competition and disappearing….

Here, I would like to propose, we must do something for eliminating HIV and malaria which are the cause of the disasters in people of sub-Saharan Africa. There,in many countries, the life span went down to 30 to 40 of age and 90% of world death caused by the two diseases occurring exclusively there. I believe, the vaccine would be the most powerful weapon to solve the problem. As the leader of vaccinology, your NVCP may wish to plan how to cope with this crisis in collaboration with nations who would share the concern. What about to plan and set up special international intuition (for instance, Sub-Saharan Vaccine Research Institute) in Accra or Johannesburg. It will focus on RD and if possible the production, for the purpose of introduction of vaccines for elimination of HIV and malaria in 800 million population there. They are most unfotunate population of ours. I am sure, if you initiate, there will be a great deal of support from the other continents That is also the symbolic action for MDGs... .

2. I would like to propose some measures to promote global polio eradication

Today I saw this week WHO polio update having shown the worrisome high incipience of polio in 2008. I share with many colleagues the frustration and concern fully about the slow progress in the global program We(Nakane, Fenner and myself) have published in our opinion " Is polio eradication realistic"(2006) in Science,312,852-864,and "Road map for polio eradication- establishing the link with millennium development goal No 4 for child survival ",.2008 when the G 8 meeting was held in Japan so that they might have it for the agenda. All what we said was to combine primary polio vaccination in new borne with EPI vaccination. Regrettably this idea was not implemented to day, but I would like to insist that this would make change.

From my experience in the smallpox eradication, namely the past" evidence oriented program." The critical evidence in polio has been that 75 to 85 % of polio cases were all in the age group of under 35 months, in other words, if you develop the herd immunity in children age group under three years, we can expect 80% reduction of the global

incidence. In smallpox, following the field experience we did find that the cases were circumscribed only around the patients in the densely populated area. The surveillance containment method was developed. For example, at that time, in India, UP and Bihar, they abandoned 100 % mass campaign and vaccinated only 50 households surrounding the infected house. In 17 months, smallpox disappeared in such a densely populated region of Ganges, 150 million pop as well as all India with population of 600 million..

Now for polio eradication,. why not we concentrate the OPV campaign in the age group, O to 34 months, specifically, the first three immunizations, up 14 months, instead of saying too broadly,"children under five years". To do this , I would like to refer to the recommendation done by USAID in 1988 when the global PE started.as shown below:

1 OPV vaccination ; Birth as early as possible. usually BCG vaccination coverage has been the highest among EPI vaccines in Africa and Asia
2 OPV vaccination ; 6 weeks with DPT
3 OPV vaccination ; 10 weeks with DPT
4 OPV vaccination ; 14 weeks with DPT

As of today, those nations having followed the schedule have been already free of polio transmission, in addition to their usual polio vaccination campaign for under five year children. They include those in South America, sub-Saharan Africa and Asia. But those without such schedule have been suffering the endemic polio. Nigeria and India showed coverage of DPT3, < 55% and I suspect that OPV3 coverage would be similar < 55%.. These were the figures of national average. In the South of India as well as that in Nigeria where polio has been endemic over the 20 years since the inception of the global PE;. I would not be surprised if they were <20% both in DPT3 as well as OPV3. In fact with JICA course participants in Japan from Nigeria, OPV coverage was very low in Kino. These observations are in agreement with the fact that the majority of polio occurred in children under 35 months.

European CDC (Dr. Lsuzsanna Jakab, Director)

2) Comments on the indicators for the National Vaccine Plan for a *ten-year period*
Also the indicators under goal 5 are of great interest to us; polio eradication, measles elimination, increased coverage of DTP, establishing Advisory Committees in more countries and enhance injection safety. ECDC will specifically focus the VPD-work certainly for 2009 but probably also for the coming years on supporting the work by WHO EURO on measles and rubella immunization in the European region and increase coverage to all childhood vaccines.

3) Comments on stakeholders' roles in the National Vaccine Plan:
As mentioned above safety issue are of highest priority at the ECDC and we hope to establish Immunization Information Systems enabling us to in collaboration with Member States develop Database Linked Safety systems at least in a few of the MS, preferably with a good geographical distribution. Europe has a long tradition in using

combination vaccines and with the now increasing number of vaccines being used together with the established combination vaccines active surveillance of safety is necessary. A global collaboration on vaccination safety would be most welcome. ECDC, together with the European Commission is also discussing the possibility to support the GAVI in order to improve his international commitment in the field of immunisation.

United Kingdom (Dr. David Salisbury, Director, Immunization)

I am uncomfortable with much of the language used within this table and within the body of the text. In many of the targets, there are insensitivities about the role of the US as opposed to that of national governments or other international agencies, and there are numerous instances where the achievement of the goal is outside of the US' ability to deliver the outcome. Certainly, the US can contribute greatly, and already does so, but it is not appropriate for the US to define what indicators or outcomes should be in place in other countries. The outcomes that are being sought are appropriate – I would suggest the use of alternative language.

Comments on Appendices:

None

Complete Comments by Stakeholder Sector – International Sources

Dr. Isao Arita, Japan

Thanks for your inviting me some comments on the draft National Vaccine Plan.

I have two points which may be relevant to the above plan for the next ten years. Since your national plan is also related to a promotion of global program for VPD control and eradication, I would like to comment briefly on two points below:.

Goal 3 I would like to discuss a special establishment, Vaccine Research Institute for sub-Saharan Africa

The vaccine supply to many countries of limited resources has been an important issue. So far there have been several bilateral as well as multilateral programs or agencies responsible for this task. The available vaccine for the supply, through, has to procure from the manufacturers subject to market force. So far it has been operating smoothly. However, over the last decades, some changes have been occurring. Namely major manufacturers have been active expanding their production and RD. The small manufacturers have been loosing the competition and disappearing. In Japan ,for instance, say there had been some 5 to 6 vaccine manufacturers 30 years ago but nowadays the active ones are only two. Believe, similar tendency in those in Europe and North America. As far as the market force improves RD and supply, it should be alright, but I believe, we should be alert to be ready in case the negative force in term of supply condition including price or shortage of needed vaccine. comes up. It was pity, a good research elements have disappeared along with disappearance of a number of small vaccine manufactures..

In an editorial of the recent Nature Weekly, Samuel Bowles wrote, the survival of mankind has been resulted from the conflict that parochialism and altruism act synergistically: these two elements are incorporated in human genes. In vaccine field, I would like to say; since the time of Edward Jenner, Paul Ehrlich and Salk/Sabin human has done very well, having eliminated smallpox and in the way, polio, measles and possibly other VPDs..

Here, I would like to propose, we must do something for eliminating HIV and malaria which are the cause of the disasters in people of sub-Saharan Africa. There,in many countries, the life span went down to 30 to 40 of age and 90% of world death caused by the two diseases occurring exclusively there. I believe, the vaccine would be the most powerful weapon to solve the problem. As the leader of vaccinology, your NVCP may wish to plan how to cope with this crisis in collaboration with nations who would share the concern. What about to plan and set up special international intuition (for instance, Sub-Saharan Vaccine Research Institute) in Accra or Johannesburg. It will focus on RD and if possible the production, for the purpose of introduction of vaccines for elimination of HIV and malaria in 800 million population there. They are most unfotunate population

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What is going in Bihar or Kano? Babies are borne, They are guarded by mothers breast feeding and thus being much less exposed to the fecal oral rout of polio wild virus infection. As soon as they leave the mothers breasts they will be infected, thus making the highest age group in 12 to 23 months, next comes the age group of 25 to 35 months. This means, the early vaccination of babies up to 14 weeks after the birth, can produce long time immunity, thus making herd immunity against polio virus. Unless doing this, susceptible babies will get increased as they reach the higher months of age, accumulated and then outbreaks with endemic polio. The primary vaccination in early weeks after the birth is a simple and principal method of vaccination schedule, but regrettably poor performance of this in India and Nigeria. What is then the efficacy of OPV supplemental campaigns, say every two months in a year. The sorry evidence has been that such action has not been effective to stop the transmission as well as to reduce the susceptible babies to WPV when they grow into the second year. Also. WPV infections cause a large number of subclinical infection among community, creating continuous transmission, we call it "endemic"

Sorry to talking, say"basic" but I would hope, WHO ACPE who met in last November 2008 would support the findings and then, the proposal. My proposal here is that Nigeria, India and any countries of continuing polio transmission, they have to improve urgently the coverage of OPV3 in the primary vaccination up to 14 weeks as recommended by USAID and followed by the nations with successful eradication. To me, except India north and Nigeria north, they have been all capable to have done DPT3 with OPV3 to the extent WPV can not survive. Pakistan and Afghanistan have done better coverage of new borne,but the war made them difficult. Monovalent OPV may be useful for this primary vaccination campaign, but I am not sure. Still trivalent OPV would do the job.Theoretically a good primary vaccination would be the key to complete the global game.

For India, as the smallpox eradication was done by India, all health canters in infected district will have to get one week polio week; stop the office work., go to the village and do primary polio vaccinations of every babies three times up to 14th week. In Nigeria, perhaps WHO should arrange to recruit local staff from southern Nigeria to form special team for joint work. The teams visit a village every month for the primary vaccinations. Also recruit the staff from border areas of Niger. I talked this with a few health officers from MOHs, Niger.Benin, Mali etc. They seemed to be pleased ; They all said they would do it.

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Meanwhile,.I am preparing a paper on this for publication. When it is ready, I shall submit it to you..

Best wishes Isao Arita

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European CDC (Dr. Lsuzsanna Jakab, Director)

The European Centre of Disease Prevention and Control (ECDC) was established in 2005. It is an EU agency with the aim to strengthen Europe's defences against infectious diseases. The programme on Vaccine-Preventable Diseases (VPD) was set up in 2006 and covers vaccination issues in general and the following fourteen diseases in particular: diphtheria, human papilloma virus (HPV) infections, measles, mumps, pertussis, poliomyelitis, rabies, rotavirus infection, rubella, tetanus, varicella, and invasive bacterial infections with *Haemophilus influenzae* type b (Hib), *Neisseria meningitides*, and *Streptococcus pneumoniae.* Issues regarding vaccines against influenza, tick-borne encephalitis, tuberculosis and viral hepatitides A and B are covered in collaboration with other programmes at the ECDC.

We appreciate the possibility to provide comments on the Draft of a new US National Vaccine Plan (dated November 26, 2008) and wish to comment on the following issues:

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ECDC supports the five broad goals that the Plan is built around. The goals in the Plan fit well with the aims of the programme on Vaccine-Preventable Diseases at ECDC concentrating on 1) *safety* of *vaccines and vaccination practices* having developed self-assessment tools for Member States to evaluate their systems for reporting AEFIs and causality assessment tools, 2) *informed vaccine decision-making by the public, providers and policy-makers* by establishing a new permanent Scientific Panel of Experts on Vaccinology (EVAG, 15 members) and developing educational tools to be used for training of nursing and medical students, and information to the public, and produce evidence-based guidance on introduction of new vaccines, 3) *achieving better use* of *existing vaccines to prevent disease, disability and death,* specifically measles and rubella vaccines through preparing a selfassessment tool for Ministries of Health in Member States to evaluate their measles and rubella programs with the aim of eliminating measles and rubella from the European region, but also pneumococcal, Hib, HPV, varicella and rotavirus vaccines, and 4) *increase global prevention* of *death and disease through* safe *and effective vaccination,* by looking into the possibilities for the ECDC and the European Member States to participate in to the proposed Global Safety DataNet

One area of interest not mentioned in this draft is studies of the long-term immunologic memory in relationship to optimizing immunization schedules. Many of the vaccines in use today have not been in use long enough to evaluate development of life-long immunity. Cohorts to be followed long-term need to be established, please see the excellent results from the Finnish MMR-cohort that now has been followed for 25 years. Another area not mentioned clearly is the identification of hard-to-reach groups and how the information about vaccines could aim to also reach these groups. In particular there

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Yours sincerely,

Lsuzsanna Jakab
Director

*(Mainly responsible for these comments has been Dr. Kari Johansen, Expert in Vaccine-Preventable Diseases)
DIR-09-184-ZJ 2/2

United Kingdom (Dr. David Salisbury, Director, Immunization)

Comments on Goals within Executive Summary:

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(2) *Comments on the goals, objectives, and strategies for the National Vaccine Plan for a ten-year period:* Please comment on the existing goals, objectives, and strategies in the draft Plan, and suggest specific goals, objectives, or strategies to be added to it, if the existing ones do not address your concerns. Are there any goals, objectives or strategies in the draft strategic Plan that should be discarded or revised? Which ones, and why?

Please see my comments above. Overall, I think there are too many targets for too many people – some are measurable and some are aspirational. Where numerical targets are set, there will need to be explicit criteria that justify the figures that are chosen.

(3) *Comments on the indicators for the National Vaccine Plan for a ten-year period:* Please comment on the existing indicators in the draft Plan, and suggest target estimates for them. Please suggest new indicators to be added to it, if the existing ones do not address your concerns. Are there any indicators in the draft strategic Plan that should be discarded or revised? Which ones, and why?

Please see my specific comments.

(4) *Comments on stakeholders' roles in the National Vaccine Plan:* Please identify which stakeholders you believe should have responsibility for enacting the objectives

and strategies listed in the draft Plan, as well as for any new objectives and strategies you suggest. Specifically identify roles your organization can play in the Plan.

My concern is not the roles and responsibilities of individual agencies or stakeholders but the identification of how this project will be managed and by whom.