

The timeline: Civil society participation and the bureaucracy

ABI Health Cluster-Social Watch Philippines

9 March 2018

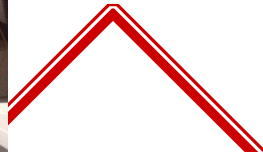
1-5PM

UP CIDS



- Social Watch embarked on a mission to push for increased social spending in the national budget; a mission that continues to this day.
- The work of ABI-Social Watch and WomanHealth is to push for healthcare based on equity and social justice.
- People's real priorities, needs, and demands should meaningfully inform policy, plans, and budget. This is done through people's alternative budget proposals
- Proposals are outcomes and outputs of collective work of the 9 ABI Health Subclusters:

Health promotion and integrative health; Health human resource; Reproductive health; Indigenous peoples; Access to medicines; Children and youth; Persons with disability; Older person; HIV and AIDS



“

Why is this about people's right to health?

- ◆ **Participatory governance plays a major role in achieving Universal Health Care**
- ◆ **There is a need to put public back into governance**



Declaration of Alma-Ata

International Conference on Primary Health Care, Alma-Ata, USSR, 6-12 September 1978

The International Conference on Primary Health Care, meeting in Alma-Ata this twelfth day of September in the year Nineteen hundred and seventy-eight, expressing the need for urgent action by all governments, all health and development workers, and the world community to protect and promote the health of all the people of the world, hereby makes the following

Declaration:

I

The Conference strongly reaffirms that health, which is a state of complete physical, mental and social wellbeing, and not merely the absence of disease or infirmity, is a fundamental human right and that the attainment of the highest possible level of health is a most important world-wide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector.



- ◆ **Public health services also enforce the dynamic forms of public participation and accountability**
- ◆ **People’s right to participation is considered as the “the right of rights,” the basic right of people to have a say in how decisions that affect their lives are made.**

The United Nations Committee on Economic, Social and Cultural Rights (UNCESCR), General Comment No. 14: The Right to the Highest Attainable Standard of Health (Article 12) adopted in 2000: participation in all health-related decision-making at the community, national, and international levels is an important aspect of the right to health. It particularly directs states to use participatory methods to adopt and implement a national public health strategy and implement a plan of action to achieve it.



- ◆ **On cutting corners: Ethical short cuts and health risks should not be made in the name of “public health.”**
- ◆ **Participation in policy, planning, and budgeting has been technicalized**
- ◆ **The public finance process is, despite efforts, still an “open yet closed” space for people’s participation**



Basic social services, equity, and the market

- It is our priority that social services have substantive investment – not leaving them to the private sector and the market.
- Support for basic social services, such as education and health, has very powerful redistributive impact
- There is a dominant market forces in the health sector, hence the dire need to scrutinize and engage public investments in social services, including health care.
- Health policies should be oriented towards the people and not the market. This means rethinking the development and regulation of vaccines and drugs, to ensure not just accessibility and affordability but safety and security. For the longest time, our push has been, for regulatory bodies such as the Food and Drug Administration (FDA) and the National Center for Pharmaceutical Access and Management (NCPAM) to be independent from drug-procuring agencies to ensure check and balance.

**The timeline:
Civil society
participation
and the
bureaucracy**





Public Health Finance and People's Right to Health and Participation

- The Dengvaxia issue shows us how the health sector policy, planning, budgeting, and monitoring principles and processes are closely interlinked.
- Government-civil society advocacy on generating funds for health, of which is the Sin Tax revenues, has helped increase the DOH budget to up to three fold from 2013-2018.
- Apart from pushing for and our advocacy on generating resources, our main responsibility is the tracking and efficient monitoring of the funds. We push for substantive investment in health and remain questioning, *are we spending on the right things?*

The timeline



May 2015

Civil Society
consultation
on the FY 2016
DOH budget



Sept to Dec 2015

CSOs attended House of
Representatives and
Senate Budget briefings,
hearings, and plenary
discussions on the FY
2016 DOH budget

The PhP 3.5 Billion-worth Dengvaxia program was never discussed in any of these discussions in 2015, during budget preparation and legislation phases for FY 2016 budget

Nor in these documents that CSOs use: budget briefer, technical budget notes, people's proposed budget, National Expenditures Program

Table 8. Major Programs and Activities for FY 2016

Program	Major Activities
National Health Insurance Program	<ul style="list-style-type: none"> Subsidize enrolment of 15.44 million DSWD identified NHTS-PR families Subsidize enrolment of 2.8 million Senior Citizens
National Immunization Program	<ul style="list-style-type: none"> Infants: <ul style="list-style-type: none"> Fully immunize 2.2 out of 2.3 million infants (95%) Provide 400,000 infants with Pneumococcal vaccine
	<ul style="list-style-type: none"> Adolescents: <ul style="list-style-type: none"> Provide 4.7 million Grade 1 and Grade 7 students with Tetanus-Diphtheria and Measles-Rubella vaccine
	<ul style="list-style-type: none"> Senior Citizens: <ul style="list-style-type: none"> Provide 1.2 million senior citizens with influenza vaccine Provide 500,000 senior citizens with Pneumococcal vaccine

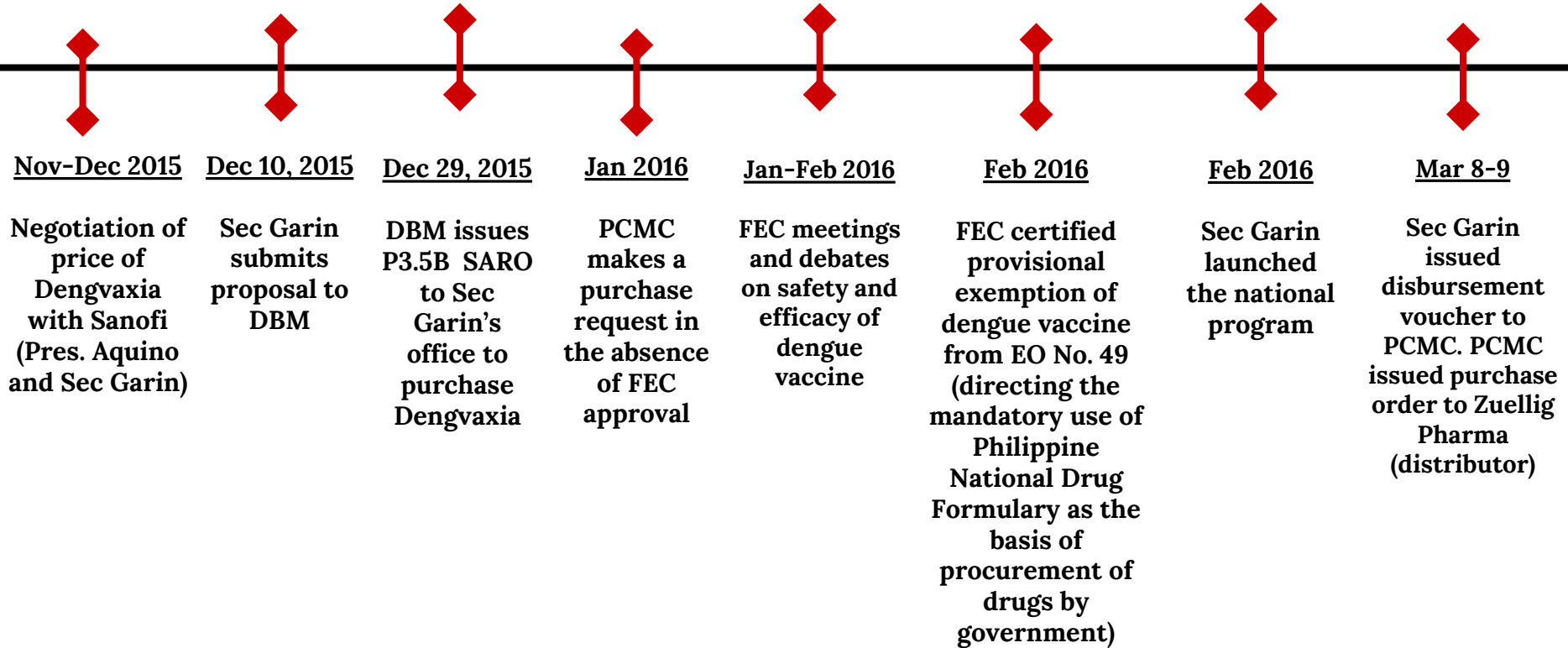
DEPARTMENT OF HEALTH

BUDGET BRIEFER FY 2016

DOH Budget briefer for the FY 2016 budget

Program	Major Activities
Family Health	<ul style="list-style-type: none"> Provide 4.4 million children < 5 years old with vitamin A supplementation
	<ul style="list-style-type: none"> Provide 2.7 million poor women with FP commodities and services
	<ul style="list-style-type: none"> Routine and School-based immunization
	<ul style="list-style-type: none"> High Impact Strategies for 5 Critical Health Programs (Hi5) for Regions and Hospitals (Infant, Under-5 and Maternal Health, HIV/AIDS, and Service Delivery Network)
Control and Elimination of Infectious Diseases (TB, HIV/AIDS, Rabies,	<ul style="list-style-type: none"> Diagnosis and treatment of: <ul style="list-style-type: none"> 280,607 TB cases; 3,885 Malaria cases; 35,000 HIV/AIDS cases
	<ul style="list-style-type: none"> Increase from: <ul style="list-style-type: none"> 29 to 36 Malaria-free provinces

The timeline



The timeline does not cite other major events. Source: CNN, presentor's own notes, HOR DOH budget hearing minutes

The timeline



March 27, 2016

CSOs wrote to Sec Garin and later met at DOH, asking questions on Dengvaxia safety and efficacy



Apr 4, 2016

CSOs came out with a Press Release and held Press Conference on Dengvaxia:
“why the rush to roll out the Dengue Vaccine?”



Apr 4, 2016

Department of Health rolled out the mass vaccination program



July 2016

The WHO releases 2nd paper – the vaccine may be ineffective or may theoretically even increase the future risk of hospitalized or severe dengue illness in those who are seronegative at the time of first vaccination regardless of age.



Jul 21, 2016

Sec Ubial convened the Dengue Expert Panel to review whether the dengue introduction is in conformity with the SAGE recomm. Recommendation was to stop the 1st dose immediately. Only those pupils who have been given 1st & 2nd dose will be given 3rd dose and enhance parallel studies to ensure vaccine safety and efficacy



Sept 6, 2016

2017 DOH Budget Briefing. Inclusion of children from Region VII in the recipients of the dengue program was raised by Hon. Garcia:

“I will not demand that you will now say yes but certainly we will be very active again in the pre-plenary and even in the Plenary to fight for this Region VII poor children that need this vaccine.”

The timeline does not cite other major events. Source: CNN, presentor's own notes, HOR DOH budget hearing minutes

The timeline



Sept 27, 2016

DOH Budget Hearing, a legislator threatened to defer the passage of the DOH budget in plenary

“if I cannot get a clear answer from you that you will include Region VII and continue with the program that is properly budgeted for...I am sorry I will have to move for the deferment of your budget.”



Oct 3, 2016

CSOs held press conference in response to legislators holding the DOH budget hostage:

“Health advocates raised alarm on House members’ attempt to hold 2017 DOH budget due to dengue vaccine with unproven safety”



Oct 3, 2016

Sec. Ubial convened Dengue Vaccine Advisory Group to consult on the expansion of the dengue vaccination program. Advisory Group recommended expansion of the immunization program to Region 7 and other areas based on epidemiologic data (signed by 7 specialists)



Oct 4, 2016

DOH Budget Plenary - As per new expert panel recommendation,



Oct 2016

Dengue vaccination program continues



Oct 27, 2016

DOH “Dengue Meeting” with FEC, Dengue Vaccine Advisory Group, NITAG, Dengue Expert Panel, FDA



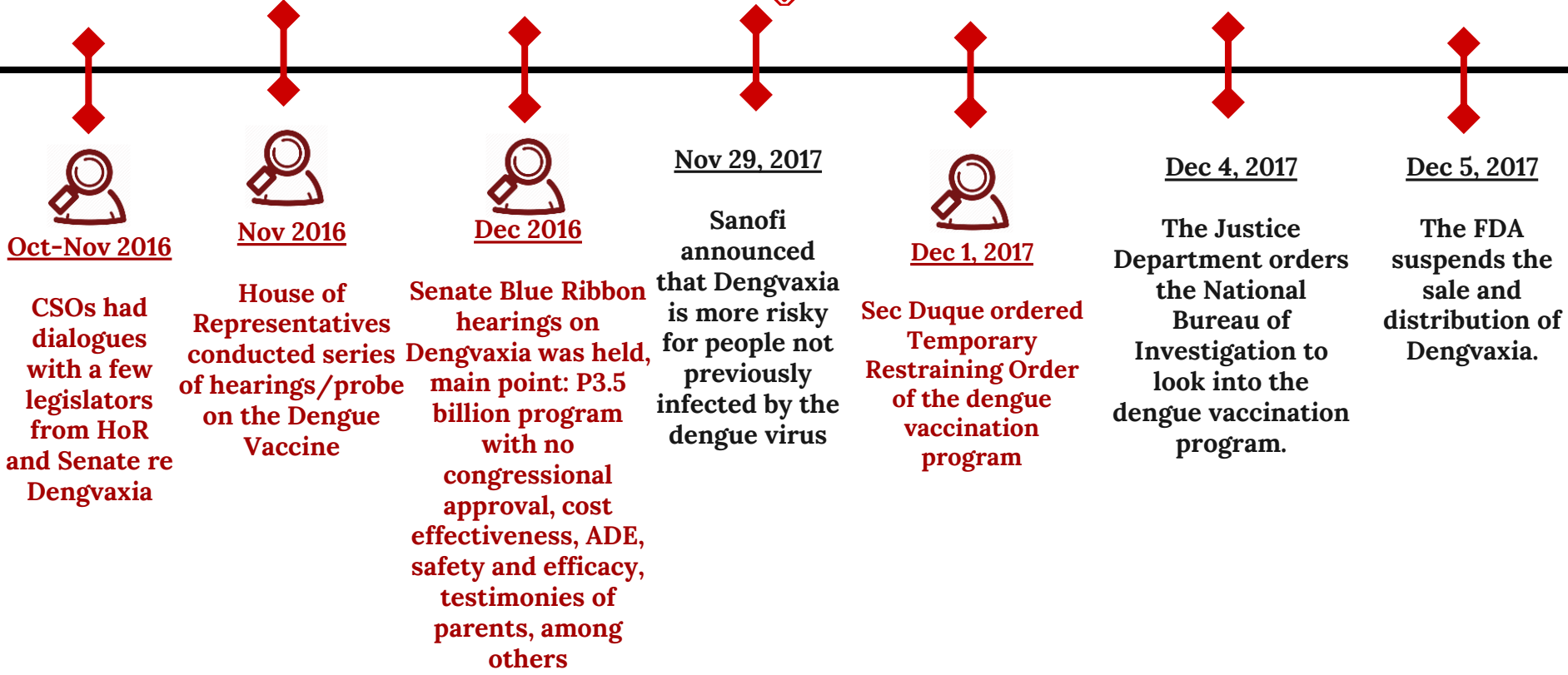
Oct 2016

CSOs sent letter to Philippine Health Research Ethics Committee to look into the trial

The timeline does not cite other major events. Source: CNN, presenter’s own notes, HOR DOH budget hearing minutes

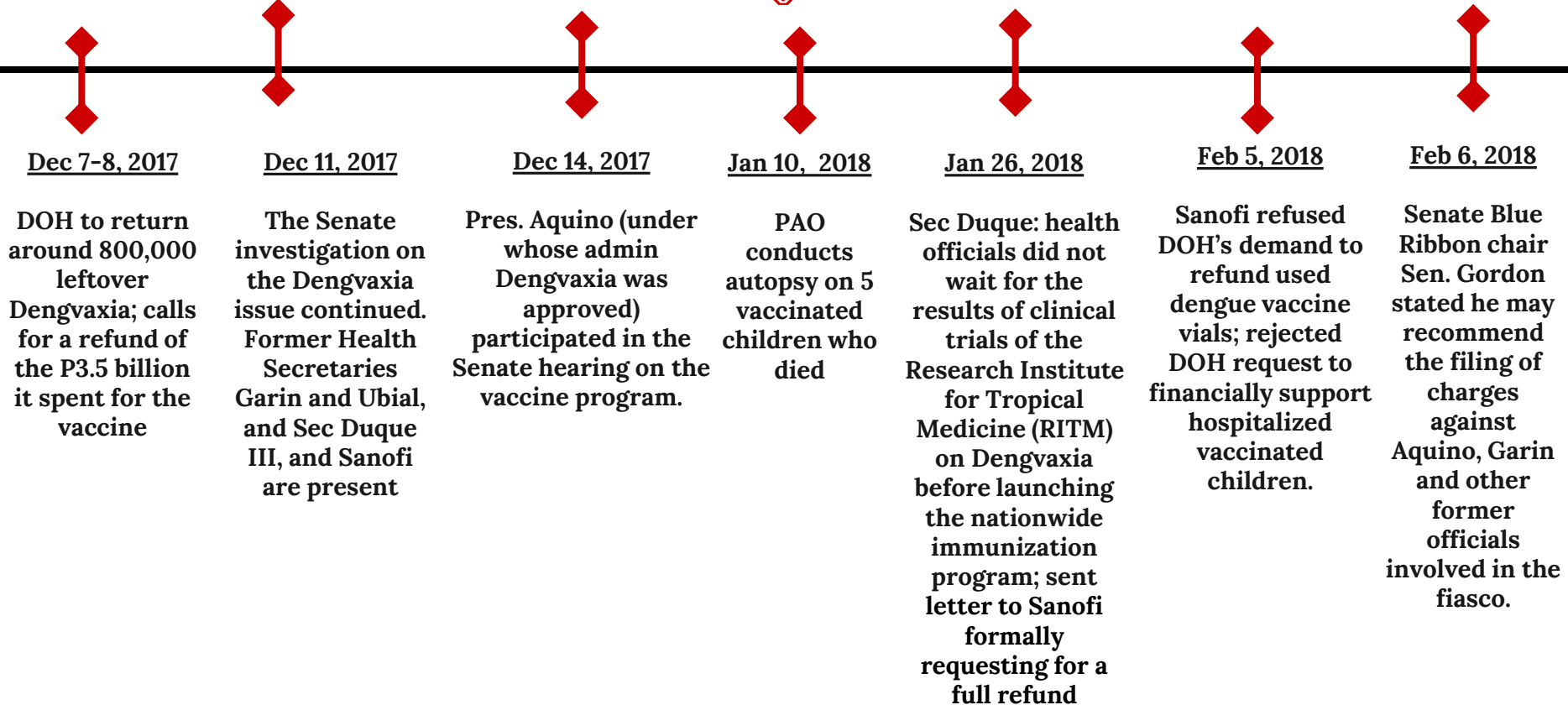


The timeline



The timeline does not cite other major events. Source: CNN, presentor's own notes, HOR DOH budget hearing minutes

The timeline



The timeline does not cite other major events. Source: CNN, presentor's own notes, HOR DOH budget hearing minutes

“Why the rush to roll out the dengue vaccine?”

Health advocates urged DOH to delay vaccination until it is proven safe for children

Public health advocates, healthcare workers, academics and civic organizations decried the Department of Health's haste in the roll out of the vaccine to fight dengue infection among children aged nine to ten years of age.

Dr. Antonio Dans, Professor of the University of the Philippines College of Medicine, pointed out that from the start, Sanofi Pasteur was concerned about a potential problem with dengue vaccines – while the vaccine could lower the number of cases of dengue initially, it could later increase the severity of disease for those who get it. Dans said this phenomenon, called “antibody dependent enhancement (ADE)” is being monitored closely by the pharmaceutical company.

Dans explained that it takes time to study ADE. Citing the company's own studies, Dans explained that this may be happening by the 3rd year after vaccination. While the Sanofi and the DOH claimed ADE was only seen in children lower than 9 years old, the data showed that it could be happening in both younger and older children, and in adults as well.

“The real dengue we are afraid of is severe dengue, not the mild ones”, said Dans. “If a vaccine prevents mild disease but causes severe dengue, we shouldn't be using it at all.” Dans pointed out that Sanofi and DOH are aware of the possibility they there may be a rise in cases of severe dengue two years after this program is implemented.

The DOH is planning intensified surveillance, and is securing parental consent for vaccination. Dans said these procedures are not usually done for vaccines proven safe. He claimed the greatest proof that DOH and Sanofi are aware of the possibility of ADE is the fact that their clinical trial is going on. “If they are sure that ADE is no longer possible, they should stop the trial,” Dans added.

Dr. Anthony Leachon, President of the Philippine College of Physicians Foundation, raised the apparent haste in the vaccination.



Health advocates raised alarm on House members' attempt to hold 2017 DOH budget due to dengue vaccine with unproven safety

ARTICLE

By Press Release
Published: October 3, 2016 | No Comments

Doctors and other public health advocates urged the House of Representatives members to stop the threat of some legislators to defer the passage of the 2017 budget of the Department of Health because of exclusion of vaccine with unproven safety.

The groups also appealed to the legislators to continue investigating the safety and efficacy of the dengue vaccine that is being administered to children starting this year.

"There is significant doubt in the scientific community about the safety of the dengue vaccine in question," said Dr. Antonio Dans, an epidemiologist from the UP College of Medicine who has been analyzing the studies on the dengue vaccine. "A trial that included Filipinos showed that the incidence of severe dengue increased up to five times more, three years after children were vaccinated."

Mercy Fabros, Coordinator of Alternative Budget Initiative (ABI) Health Cluster, a consortium of civil society organizations engaging the annual health budget, feared that the legislators' insistence to continue the dengue vaccination program was grounded on incomplete information.

Don't block the DOH budget, but do delay new anti-dengue vaccination

October 4, 2016 3:57 pm · 0 comments

Views: 169



Anti-dengue vaccine group speaking before reporters Photo © Ibarra Matzo

PLEASE don't block the passage of the proposed 2017 Department of Health (DOH) budget, but do delay the introduction of new doses of a controversial anti-dengue vaccine until independent studies were done by credible experts to clear clouds of doubts on its safety and efficacy.

JO-ANN DIOSANA

WomanHealth Philippines, Young Women Collective



WE APPEAL TO THE LEGISLATORS
NOT TO DEFER
THE 2017 BUDGET OF THE DOH
BECAUSE OF [THE CANCELLATION
OF THE DENGUE VACCINE
PROGRAM].

**THEY SHOULD ALSO
INVESTIGATE FURTHER
HOW THE PROGRAM WAS
APPROVED IN HASTE.**





18 October 2016

Dr. Leonardo D. de Castro

Chairman

Philippine Health Research Ethics Board (PHREB)

Dear Dr. de Castro,

It has come to our attention that a placebo-controlled trial on the vaccine Dengvaxia, developed by Sanofi-Pasteur, which started 4 years ago, is currently continuing in selected areas of the country despite the manufacturer's public pronouncement that the vaccine has been proven "safe and effective." In fact, as you may very well know, the Department of Health launched it as a public health program earlier this year, targeting a million 9 year-old children from three (3) regions in the country: NCR, IV-A, and III.

We are alarmed that the children who started the trial are still receiving the placebo. Guided by the Declaration of Helsinki, as summarized in the International Conference on Harmonization, it is unethical to continue giving them placebo if it is indeed true that the vaccine has been proven safe and effective. To quote from Section 2.1.3 (Ethical Issues under Choice of Control Group and related Issues in Clinical Trials):

"When a new treatment is tested for a condition for which no effective treatment is known, there is usually no ethical problem with a study comparing the new treatment to placebo. Use of a placebo control may raise problems of ethics, acceptability, and feasibility, however, when an effective treatment is available for the condition under study in a proposed trial. In cases where an available treatment is known to prevent serious harm, such as death or irreversible morbidity in the study population, it is generally inappropriate to use a placebo control."

In addition, if the claims of the manufacturer about the safety and effectiveness of the vaccine is true, and that there are no longer doubts about the drug, we believe that the health of children in the placebo group is under threat, and that that the trial should be stopped immediately. In the interest of public safety, ethics in research, and as mandated by ICH, **we, from civil society, therefore request for a review of this trial by PHREB.**

We hope for your prompt action on this urgent matter.

Sincerely

**CSO letter to the
Philippine Health
Research Ethics Board,
request for a review of
the Dengvaxia trial
October 2016**

POSITION PAPER ON THE DENGUE VACCINATION PROGRAM
OF THE DEPARTMENT OF HEALTH
18 November, 2016

Alarmed by a DOH program to vaccinate 1 million children against the dengue virus, amidst questions about cost-effectiveness, safety and ethics, we the undersigned individuals hereby declare:

1. That there is lingering uncertainty about the long-term safety of this new vaccine against dengue fever. Evidence from the manufacturer's trial shows that there may be a paradoxical increase in the incidence of severe dengue beginning a few years after children are vaccinated, and possibly continuing for the rest of their lives. This danger especially applies to children who have never had dengue fever before.

The clinical trials on dengue vaccine were specifically designed to assess this danger. Sadly, this danger has been confirmed. In one study involving Asian children aged 2-14 years, vaccination increased the incidence of severe dengue by 400% on the 3rd year after vaccination [1]. The authors concluded that the reasons for the rise in dengue need further investigation. We agree. Until these trials are completed, we recommend, as many other groups have, that children should be tested for past dengue infection before vaccination.

2. A cost-effectiveness study assessing potential use in the country was done but funded by the manufacturer rather than by an independent body [2]. The study was biased in that there were clear measures to minimize expenses (it did not account for the potential cost of increased disease severity arising from the vaccine), and maximize savings (effectivity was assumed to last 10 years when it is clear that protection wanes by the 3rd year). These strategies make the vaccine seem highly cost-effective.
3. The current program is not a feasible strategy for easing the dengue burden in the entire country. The program cost the Philippine government 3.5B PhP, for just 1 million children in only three regions, representing a mere 1% of the population [3]. Scale-up of this program, even for the lowest quintile of wealth, is simply not a viable option for the country.
4. There was inadequate community preparation for the implementation of the program. From the time the Formulary Executive Committee (FEC)

issues guidance, it usually takes 12-18 months to prepare health workers and communities to introduce a new vaccine. Administrative orders and guidelines need to be issued to local government units. Field manuals need to be produced and translated into dialects. Health workers need to be trained to give the vaccine and answer questions from parents and children. Referral systems for adverse events need to be activated and tested, a research protocol for monitoring on adverse events should be in place. These could not have been done in 26 days. Many parents, teachers and healthcare workers claim they were never fully informed about the benefits and potential side effects of the vaccine.

In view of all these problems, and in the interest of public safety, we strongly recommend that the DOH dengue vaccination program be suspended, pending completion of results of ongoing studies.

Signed:

**CSO position paper
on the dengue vaccination
program
November 2016**



Who decides for people's health?

- ◆ **Who decides what for public health?**
- ◆ **When and where are decisions regarding public health are made?**
- ◆ **How are these decisions made?**

How does the government decide on how much to spend for what? Is this process democratic, transparent, and participatory? Are decisions made by legitimate actors reflected in the real spending of the resources? The answer to these questions will lead us to conclude that what we have is not actually a scarcity of resources, but of democracy and people's participation in the budget.

“

- ◆ **There is scarcity of democracy, not of resources - scarcity is a matter of perspective - it is determined by the ideology and preferences of the state.**
- ◆ **Health is too important to merely subject to medical experts.**
- ◆ **Corporations and pharmaceutical companies are strong but the solidarity of people will make us not surrender.**
- ◆ **Hard-learned lessons should inform reforms such as the Budget Reform Bill (on procurement lapses issues) and the Universal Health Care Bill (HTAC/HTAG representation and independence)**

"A sophisticated and penetrating analysis of 150 years of quiet warfare between American women and 'expert' professionals"
—Mother Jones

For Her Own Good

150 YEARS OF THE
EXPERTS' ADVICE TO WOMEN



BARBARA EHRENREICH
DEIRDRE ENGLISH

Immaculate Deception

A New Look at Women and
Childbirth in America
SUZANNE ARMS



© Book Rescue LLC