



**Access of Developing Countries to H5N1
and other Potential Pandemic Vaccines**

**Vaccine Industry Perspective,
Considerations and Potential Contribution**

**WHO Meeting on Options for Increasing the Access of Developing Countries to
H5N1 and other Potential Pandemic Vaccines
Geneva, 25 April 2007**

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IFPMA Influenza Vaccine Supply International Task Force**

IFPMA Influenza Vaccine Supply International Task Force

- **Established in 2002 under IFPMA** (International Federation of Pharmaceutical Manufacturers & Associations)
- **To collectively addresses communication, policy, regulatory, scientific & technical aspects of pandemic preparedness**
- **To strengthen public health and industry approaches to seasonal and pandemic influenza issues by:**
 - **providing governments and inter-governmental bodies expertise from companies around the world that are developing vaccines;**
 - **assisting public bodies in their preparation against pandemic influenza, by providing expert opinions on key issues facing planner and policy makers.**

www.ifpma.org/influenza



IFPMA IVS Members

from Australia, Europe, Japan & North America

IVS Core Team

Chair : Luc Hessel (SP MSD)
Scientific Coordinator : Tony Colegate (Novartis)
Policy Coordinator : Bram Palache (Solvay)
Secretariat : Ryoko Krause (IFPMA)

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 **DENKA SEIKEN Co.,Ltd.**

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Biologicals

 **KAKETSUKEN**

 社団法人
北里研究所
The Kitasato Institute


MedImmune


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INTERNATIONAL

 **NOVARTIS**
VACCINES

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The vaccines business of sanofi-aventis Group


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vaccines for life


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Presentation Outline

- **IFPMA IVS contribution to increasing global access to pandemic vaccines**
- **The need for a holistic approach**
- **The way forward**
 - **Stockpiling of pre-pandemic vaccines for the developing world**
 - **Increasing global access to pandemic vaccines through special financing programs and pricing policies**
 - **Protecting against seasonal influenza**
 - **Continued sharing of influenza viruses**
 - **Creating new influenza vaccine capacity**
 - **Building healthcare infrastructure**
 - **Role of local production**
- **Conclusion**

IFPMA - IVS Contribution to increasing global access to potential pandemic vaccines

- **R&D investment into safe and effective vaccines, inc. antigen-sparing approaches to further stretch production capacity**
- **Investment in additional production capacity**
- **Measures to increase global access to vaccines for humans**

There is clearly significant role for Research-based industry to respond to key policy decisions on potential pandemic vaccine stockpiling and supply

The need for a holistic approach

- **Effectively countering the pandemic threat requires clear, robust and coordinated international, national and local strategies combining education, non-medical and medical interventions, vaccination, as well as other preventive mechanisms**
- **Several governments have established stockpiles of pre-pandemic bulk vaccines to immunize priority groups in anticipation of a pandemic**
- **A similar effort can be adopted by or for developing countries.**
- **WHO, in collaboration with other UN agencies and their Member States is the most appropriate and effective organization to handle this task**
- **Increasing global access to pandemic vaccines is a complex task with numerous scientific, technical, regulatory and policy challenges to overcome**

Stockpiling of pre-pandemic vaccines for the developing world

- **IFPMA IVS members**
 - Support the principle of stockpiling potential pandemic vaccine
 - Are involved in the scientific assessment of the relevance of this strategy
 - Are committed to exploring the technical and industrial implications of stockpiling for the developing world
- **The creation of such a stockpile requires strong political leadership and effective partnership**

Stockpiling of pre-pandemic vaccines for the developing world

- **The following technical aspects must be carefully considered:**
 - Forecasting the actual need for pre-pandemic vaccines
 - Defining the strain selection process for the production of pre-pandemic vaccines
 - Establishing a regulatory framework
 - Addressing aspects relating to storage
 - Establishing the governance of the stockpile
 - Ensuring maintenance/sustainability of stockpile
 - Defining procurement mechanisms
 - Establishing the deployment and distribution of final products
 - Designing a funding process

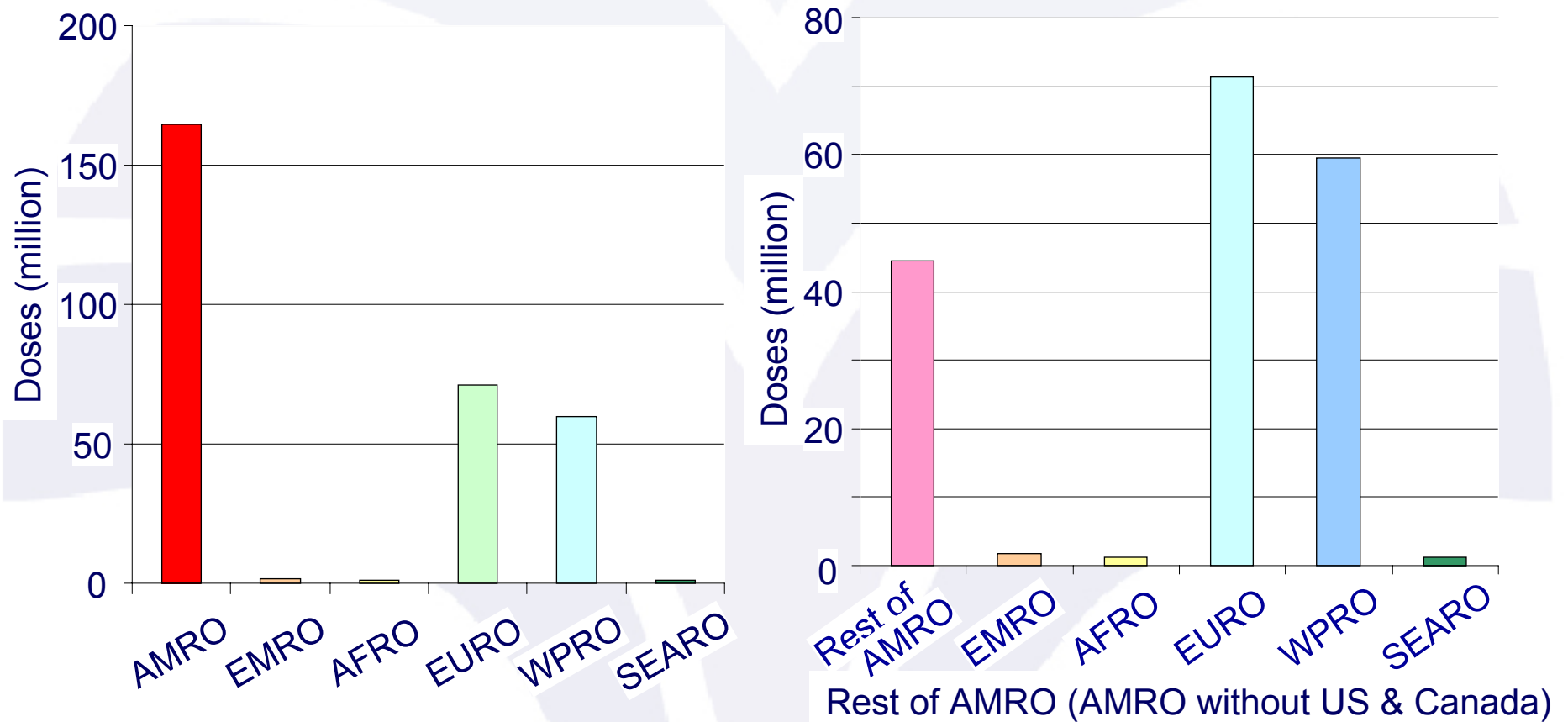
Increasing global access to pandemic vaccines through financing programs and pricing policies

- **Secure access to pandemic or pre-pandemic vaccines for developing countries which lack the resources to purchase pandemic vaccines or stockpile pre-pandemic vaccines**
- **Establish pricing policies for the procurement of vaccines for developing countries.**
- **Establish funding processes from supranational organizations and donors.**

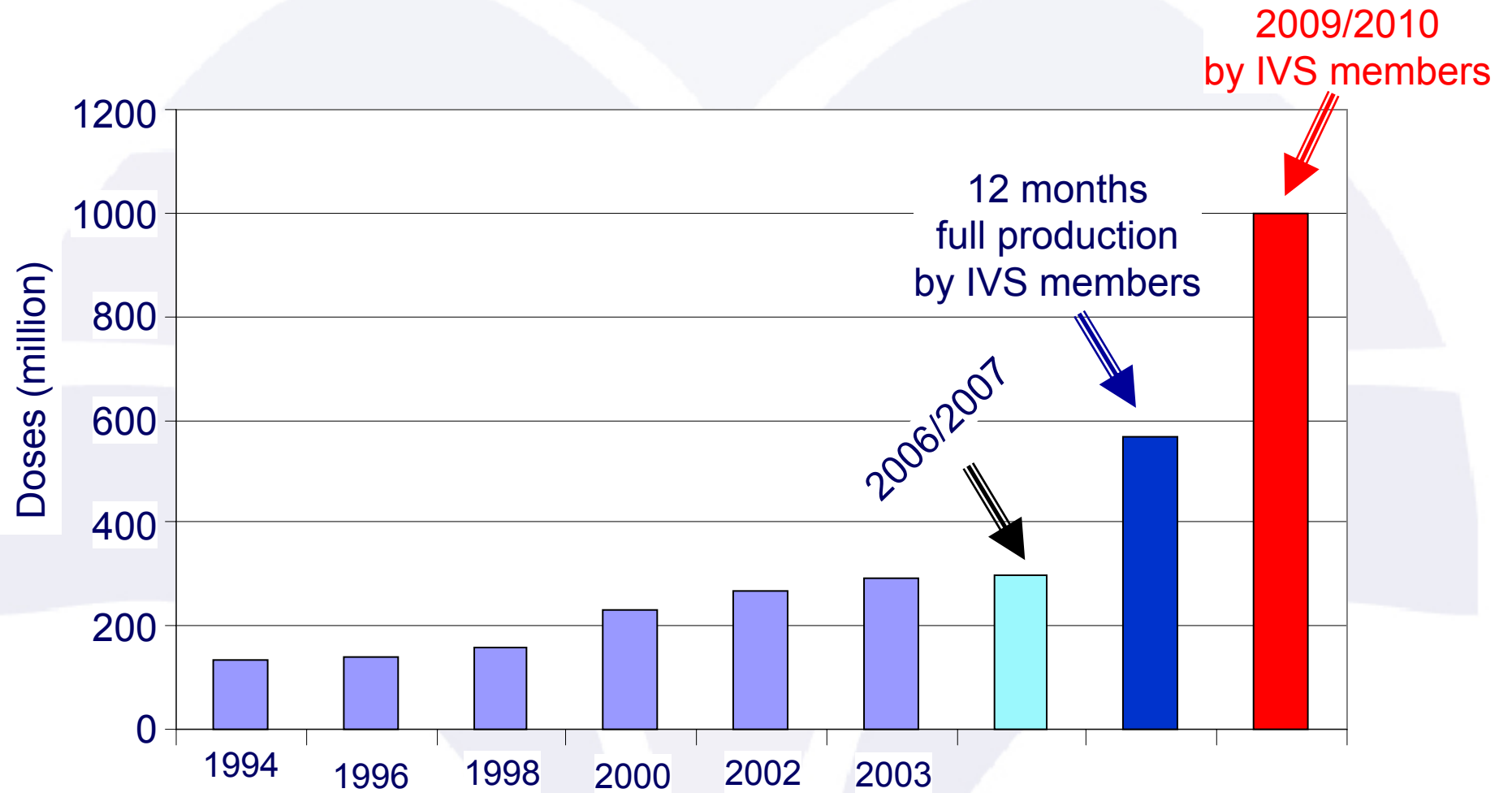
Protecting against seasonal influenza

- **There is an inextricable link between the vaccines against seasonal influenza and those that protect against a pandemic strain:**
 - **Manufacturing process inherently similar, and take place in the same production facilities;**
 - **Capability to produce pandemic vaccines tied to the capacity to manufacture seasonal vaccine**
 - **Production of seasonal vaccines is driven by current usage around the world**
- **The world must increase the usage of seasonal vaccines as recommended in the WHA Resolution in May 2003 and WHO Global Action Plan (Oct. 2006)**
 - **To benefit from annual protection**
 - **To increase its capacity to protect against a potential pandemic**

Seasonal Influenza Vaccines distributed in WHO regions 2006/2007



Seasonal Influenza Vaccine Usage



MIV Study Group: Vaccine 23: 5133-5144, 2005

Continued sharing of influenza viruses

- **The success of the WHO's Global Influenza Surveillance Network, and its benefits for public healthcare has been based on all parties sharing viruses for research, vaccine development and production**
- **The development and supply of both seasonal and pandemic influenza vaccines would be impacted if governments desist from sharing information on viruses circulating in their countries**
- **This would be the case even if countries agreed to share the virus with the WHO for risk assessment, but not for vaccine development and production**
- **Any intended enhancements to the current system, therefore, must be carefully evaluated and should involve appropriate stakeholder consultation**
- **IFPMA IVS members underscore their full support of the WHO's Global Influenza Surveillance Network and their wish to continue receiving viruses and related material provided through WHO Reference centers**

Creating new influenza vaccine capacity

- In the event of a pandemic, entire populations would require vaccination
- Industry is investing heavily to develop solutions to efficiently increase pandemic vaccine supply:
 - Antigen-sparing strategies;
 - Cell culture technology to increase the robustness of production;
 - Development of different types of influenza vaccine (whole virion)
- IFPMA IVS members are heavily investing to expand production facilities, to meet potentially growing demand

Building healthcare infrastructure

- **To prepare for a pandemic, several countries have taken the following step-by-step approach:**
 - **Develop and/or strengthen infrastructure for vaccine delivery;**
 - **Ensure implementation of seasonal influenza vaccination policies;**
 - **Develop a demand forecast system for seasonal vaccines;**
 - **Consider a policy on use of pre-pandemic vaccines;**
 - **Develop strategies to stockpile pre-pandemic vaccines and/or implement pre-emptive vaccination.**
- **IFPMA IVS recommends that other countries adopt this approach.**
- **Different types of partnership activities may be required, designed and agreed upon by all parties**

Role of local production (1)

- **Establishing local production in the developing world is often suggested as a solution to increasing access to vaccines**
- **While it may seem an attractive option, many challenges must be overcome to be successful**
 - **Vaccine manufacture is highly complex and consumes large amounts of time, as well as financial and human capital**
 - **Production is highly regulated and requires in-depth know-how, experienced and skilled personnel**
 - **Any production facility must be GMP-compliant (a formal validation of the process can take many years)**
- **Local production requires significant initial and ongoing investment to reach sustainability**

Role of local production (2)

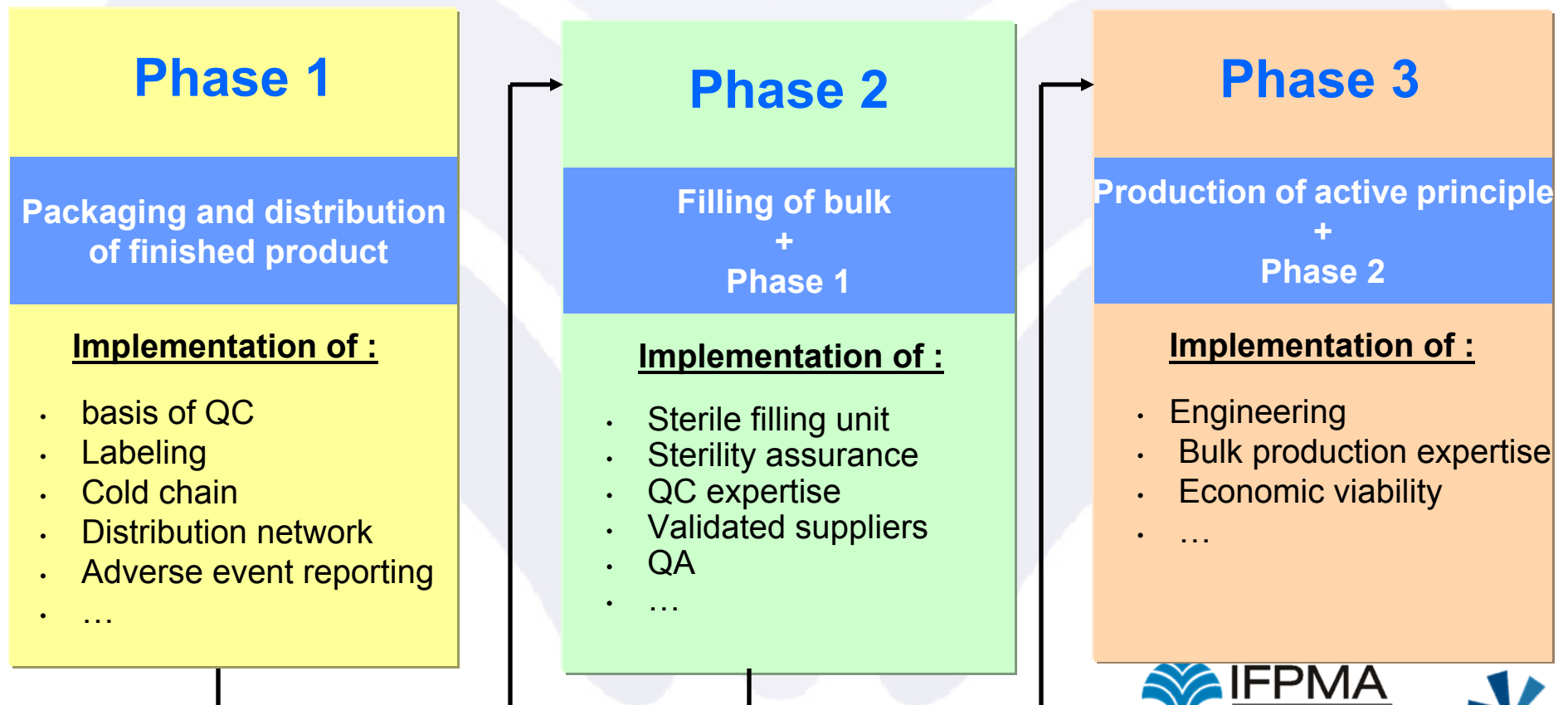
- **Successful partnership results from:**
 - A strong economic / strategic value for both parties
 - An appropriate level of expertise at the local level;
 - A set of realistic and achievable objectives
 - The ability to achieve consistent GMP conditions to meet quality standards for the vaccine
 - Having a competent national control authority to provide rigorous regulatory and quality oversight
- **Local production of influenza vaccines must be coupled with an implementation of a seasonal influenza vaccination program**

Role of local production (3)

- **Developing local influenza vaccine production must be considered:**
 - **On a case by case approach**
 - **In the framework of a long-term co-operation and partnership**
 - **Through a stepwise process**

Local production: a stepwise approach

Tech transfer must be considered in a step-by-step approach, in the framework of long-term co-operation, with the mutual interests of the different partners clearly identified, recognized, and respected.



Conclusion

- **IFPMA IVS members are committed to proactively supporting leadership initiatives by the WHO to collaborate with governments:**
 - **To effectively address pandemic preparedness;**
 - **To define public health strategies to identify high risk groups for vaccination, and**
 - **To develop approaches for the funding, allocation and distribution of potential pandemic vaccines**
- **Industry is prepared to contribute proactively to a global stockpile once its scope and magnitude has been defined by global public health authorities and private sector participation has been confirmed**