



*Avian Influenza
And Pandemic Preparedness
The Vaccine Industry Perspective*

*IFPMA Influenza Vaccine Supply international task force
(IFPMA IVS ITF)*

PAHO meeting, Washington DC, 21st November 2005



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- General Structure of IFAPMA IVS ITF - Krause
 - Production Capacity – Delannoy
 - Regulatory and other Challenges – Palkonyay

IFPMA Influenza Vaccine Supply (IVS) international task force

Influenza Vaccine Supply
International Task Force



- A specialized group of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)
- Established in 2002 with the aim of ensuring adequate capacity to produce and distribute influenza vaccine in inter-pandemic and pandemic years
- Representing influenza manufacturers from all over the world actively involved in influenza vaccine research and/or manufacturing and distribution



- Baxter (EU)
- Berna Biotech (EU)
- Biken (JPN)
- Chiron Vaccines (EU)
- CSL (AUS)
- Crucell (EU)
- Denka Seiken (JPN)
- GlaxoSmithKline Biologicals (EU)
- ID Biomedical (CND)
- Kaketsuken (JPN)
- Kitasato (JPN)
- MedImmune (USA)
- Nobilon (EU)
- Sanofi Pasteur (EU / USA)
- Sanofi Pasteur MSD (EU)
- Solvay (EU)



IVS's Objectives

1. To assist business leaders in vaccine manufacturers in making the decisions necessary to ensure adequate capacity and resources to develop, produce and distribute influenza vaccine in inter-pandemic and pandemic years
2. To assist Health Authorities and policy makers in making decisions on Influenza vaccination recommendations, the level of vaccine use and vaccine delivery strategies




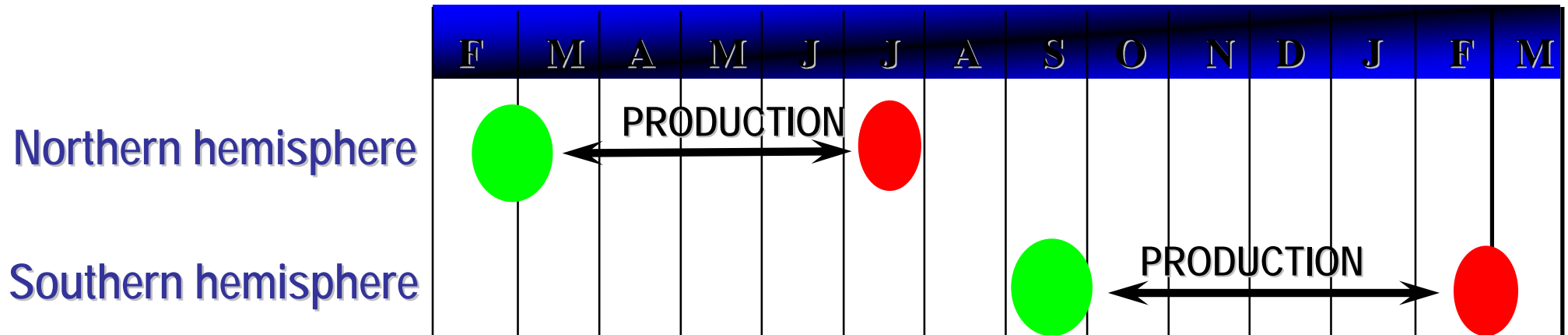
- Influenza vaccine production needs dedicated facilities: additional capacity means huge long-term investments: 3 to 5 years to develop and validate a new production line
- Influenza vaccine production capacity is linked to the market needs during the Interpandemic periods
- Influenza vaccine usage during the Interpandemic periods relies on existing recommendations and their level of implementation (vaccination coverage)

Industrial production timelines for influenza vaccines

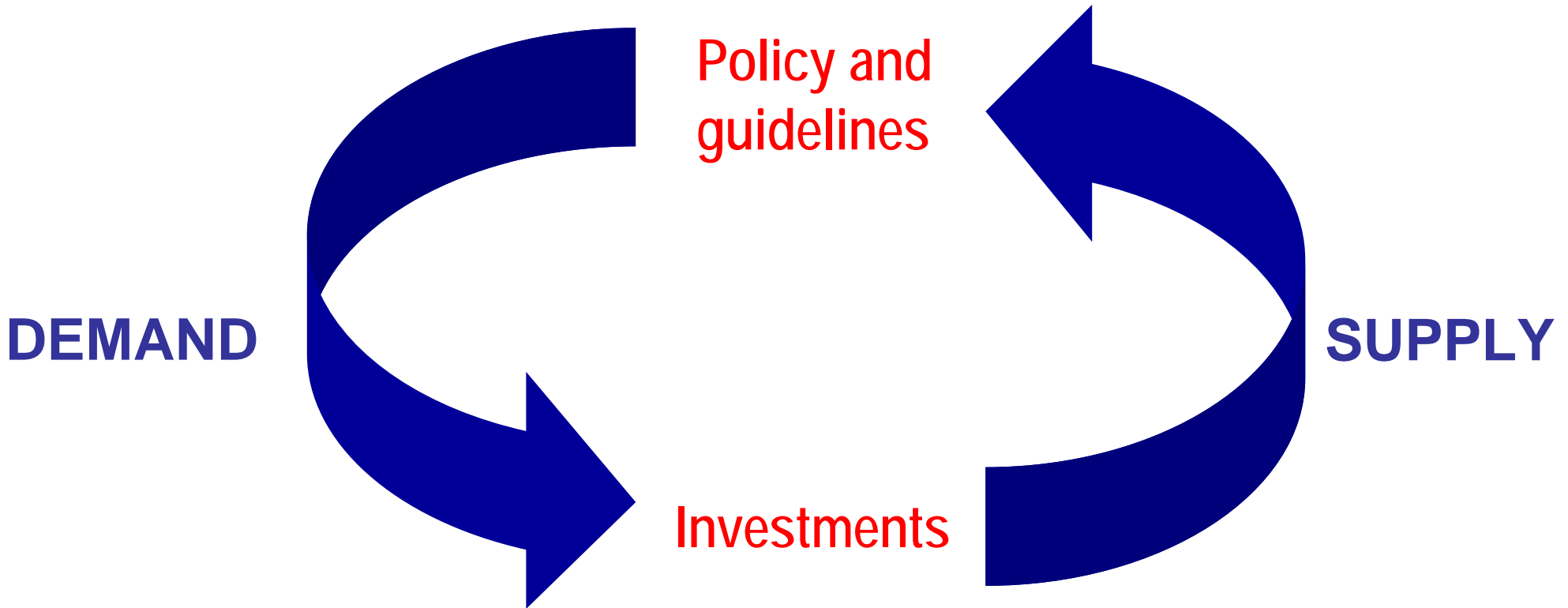
Each year: 2 new vaccines within a 6-month timeframe

 Choice of strains

 Vaccine on the market



What influences influenza vaccine production capacity and usage?



Industry produces according to market “demand”, not “needs”:

- Shortfalls in vaccines lead to public health crisis
- Over-capacity of vaccine is an economic loss



Influenza vaccine worldwide production



North America

Japan

Australia

(25 %)

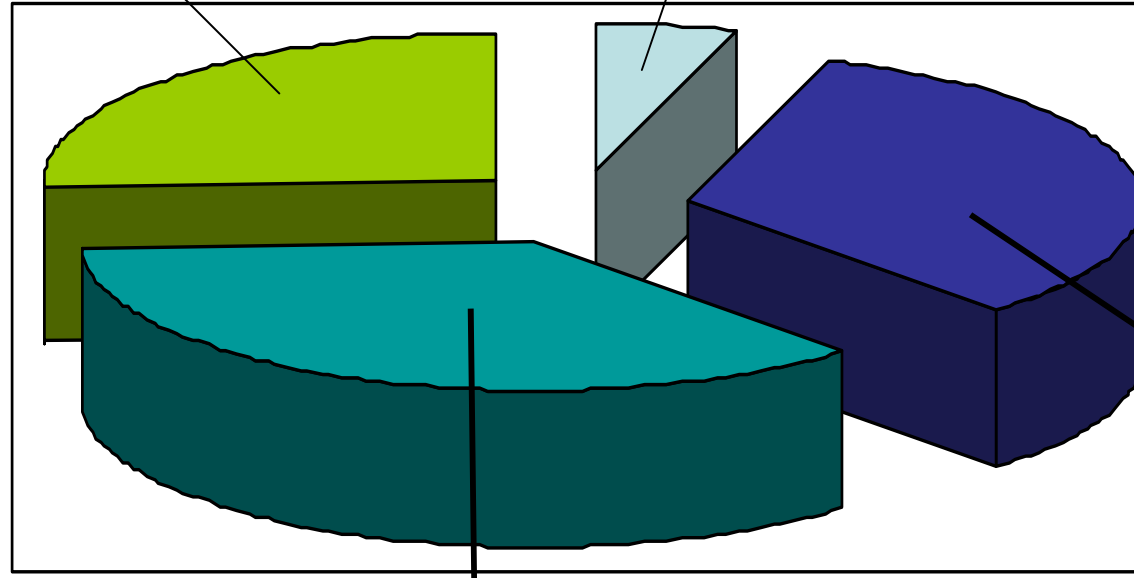
ROW

(5 %)

Worldwide production 2003

292 million doses

(9 countries, excluding purely local production)



EU production

190 Million doses

(65%)

***90 million doses
distributed in Europe***

100 million doses

Distributed outside Europe

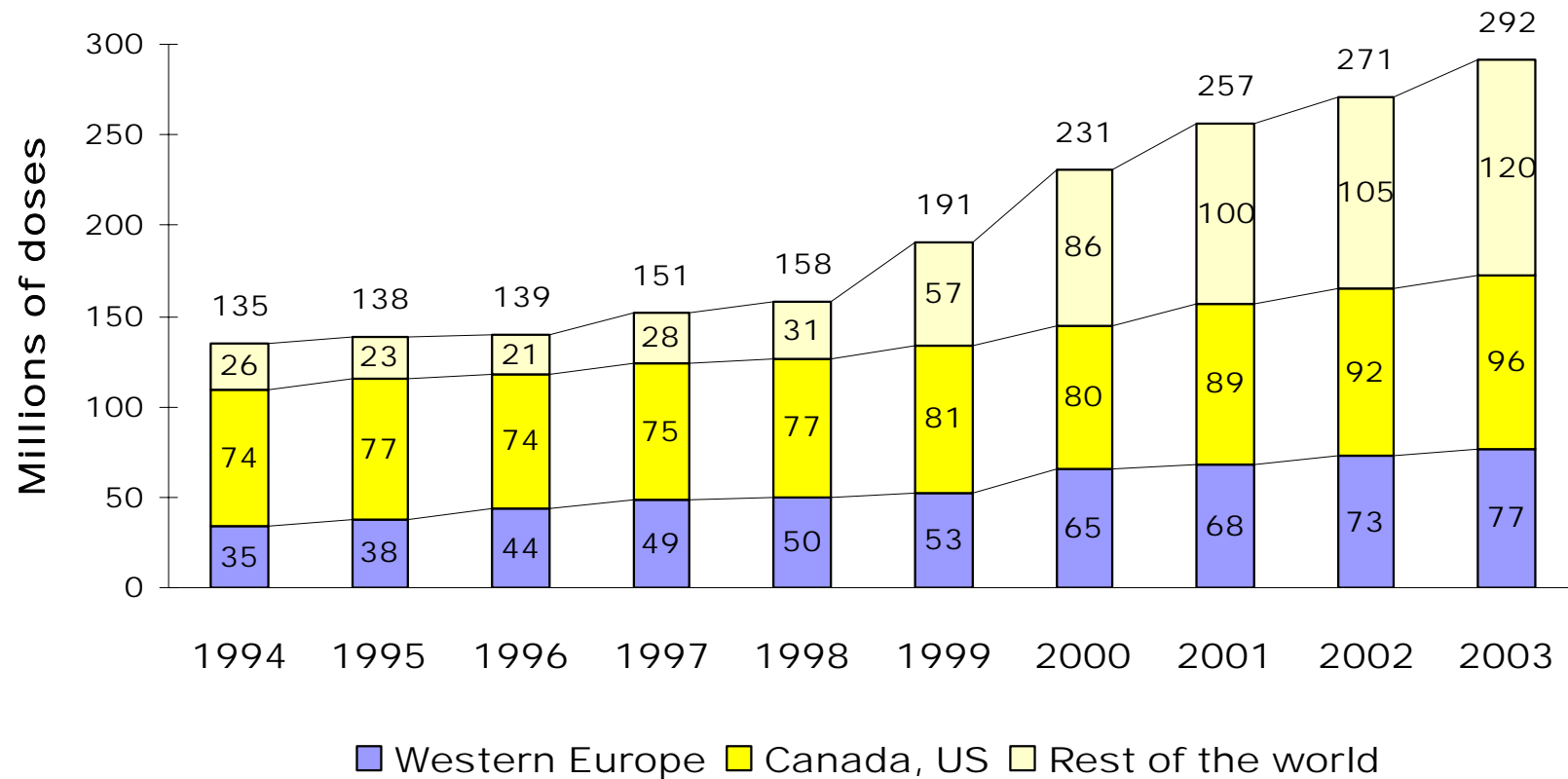
***(97 % of doses for South America, Eastern Europe,
Middle East, Africa, Asia)***



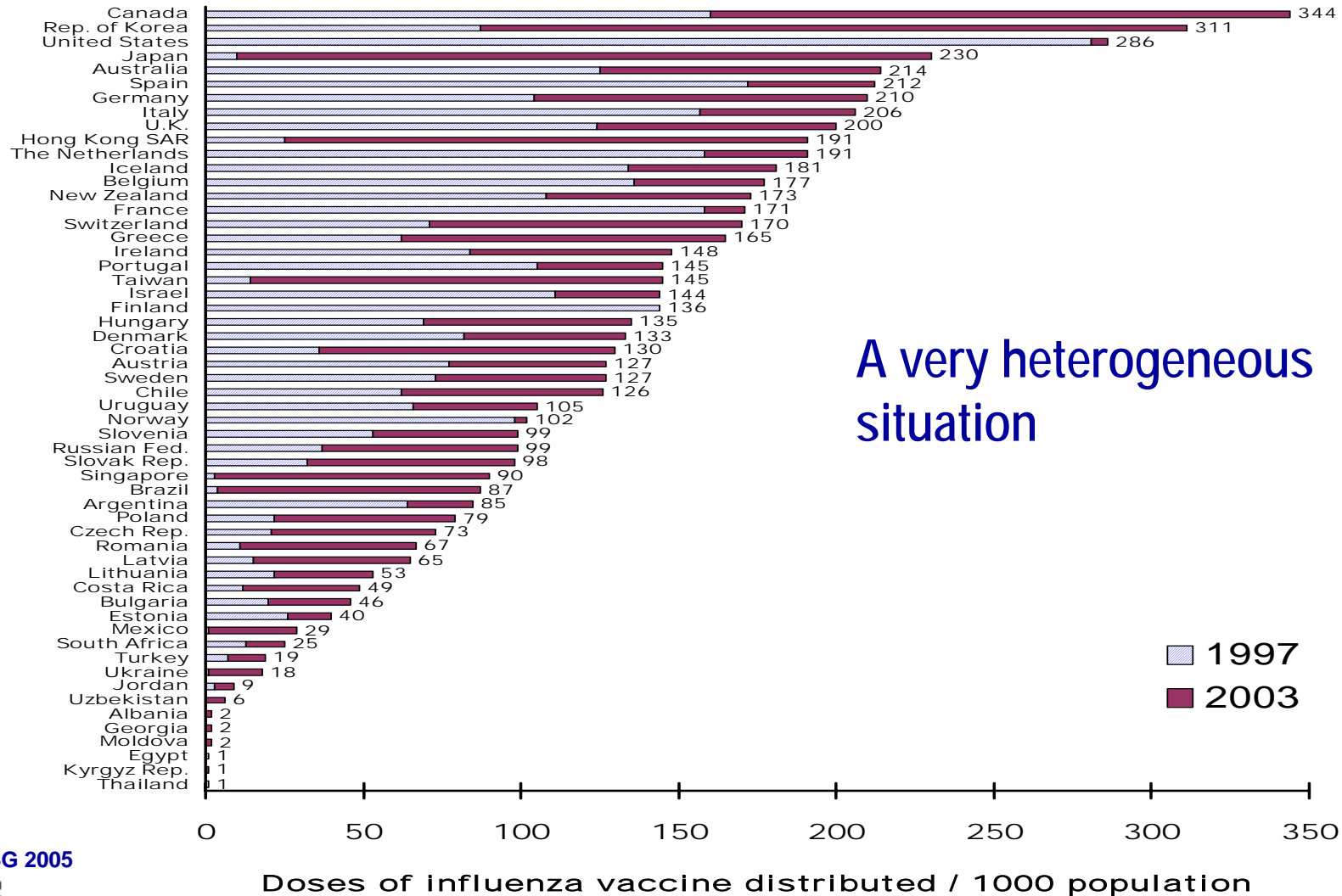
Increasing vaccine production capacity an ongoing effort

216% increase in the past 10 years

Expected further significant increase within 5 years



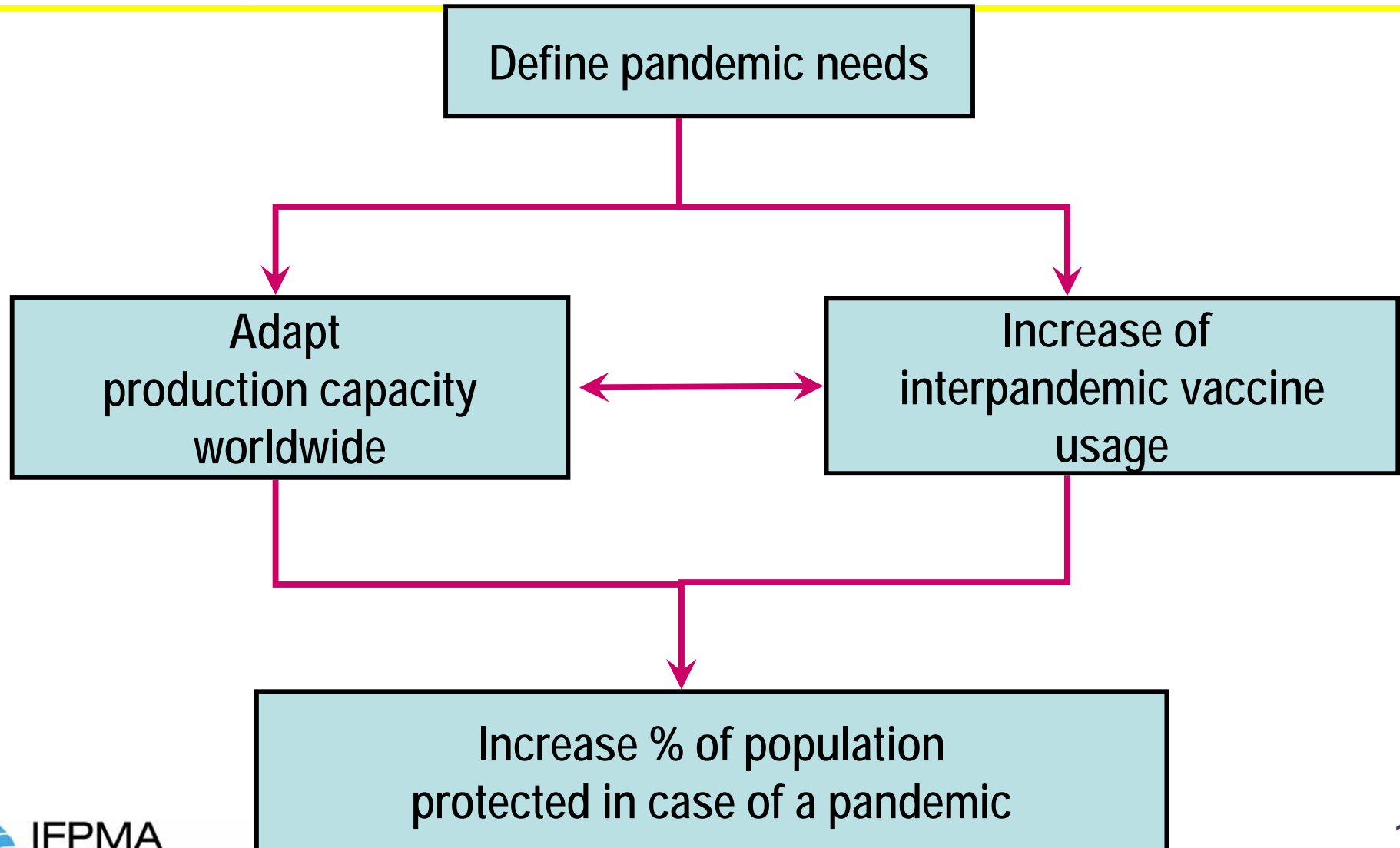
Influenza Vaccine Usage (1997-2003)



Factors influencing the production capacity of pandemic vaccines

- Pandemic vaccines will be different from Interpandemic vaccines but... will be produced in the same facilities as those used for Interpandemic vaccines
- No (limited?) stockpiling is possible
- The antigen content in pandemic vaccines represents a key factor influencing global production capacity

Link between pandemic and inter-pandemic needs



Increasing Production capacities



- **Decrease antigen content (Ag sparing strategies)**
 - **R&D programmes**
- **Increase production capacities**
 - **Anticipating pandemic needs by adapting the inter-pandemic use of influenza vaccines**
- **Relies on influenza vaccination policies during inter-pandemic periods**
 - **Extending vaccination policies in more countries (industrialised and emerging)**
 - **Implementing vaccine recommendations (meeting the WHO recommendations on vaccination of high risk groups) (75% by 2010)**
 - **Considering wider influenza vaccine recommendations in children**
 - **Extending national recommendations to younger adults**



What has been done / initiated?

- **Regulatory approaches**

- **Regulatory guidelines and processes for the development and registration of pandemic vaccines**
- **Incentives to industry (e.g. waiving fees for scientific advice, prototype and pandemic vaccines registration by EMEA)**

- **R&D approaches**

- **Short term(< 3 years) outcome: to develop as quickly as possible pandemic vaccines based on existing technology**
- **Medium / long term outcome: to improve the performance of influenza vaccines and encourage R&D into new vaccine concepts**

Short-term approach: to develop a « mock-up vaccine

- A prototype vaccine prepared with potential pandemic strains (e.g.) adapted to vaccine production, developed to define in clinical trials the optimal formulation to be used for actual pandemic vaccine (and not intended for commercial use)
- Relies on existing technology and know-how for Interpandemic vaccine production
- Should use all existing approaches (10 to 12 possible candidates in EU) to optimise availability and potential supply
- Should be compatible with existing regulatory guidelines and processes, e.g. fast track variation to an existing license

Challenges in the Development and Registration of Influenza Pandemic vaccines



- **Clinical development and regulatory process**
 - Need for a consolidated approach (USA, EU, ROW)
 - Technical support (scientific and regulatory)
 - Financial support (R&D)
- **GMO classification of the pandemic vaccine strain (EU), and Biosafety constraints in production facilities**

**Need for collaboration and commitments
between authorities and industry**



What remains to be done

- Further harmonise regulatory pathways (EU and USA)
- Continue to develop appropriate financing mechanisms to support the development of prototypes vaccines short term & long term
- Continue to implement existing recommendations and review influenza vaccine strategies for seasonal influenza vaccination
- Establish contractual agreements with Industry to ensure production, supply and distribution of vaccines in accordance with global public health needs
- Reinforce mechanisms to ensure equitable distribution, including policy regarding export to other countries without vaccine facilities

WHO/PAHO has a critical role to play in increasing influenza vaccine supply



- Support the establishment, adaptation and implementation of influenza vaccination strategies both during the Interpandemic and pandemic periods (developed and developing countries)
- Generate data that would support increase in vaccination use in Interpandemic periods and monitor vaccination usage
- Coordinate with Member States the way to ensure appropriate supply and distribution of vaccine
- Mobilise financial support to production capacity building
- Clarify what other approaches can be explored
- Include industry as a equal partner in these activities



- Vaccine production and access is currently limited but can be improved
- Understanding and properly addressing risks and constraints is essential to reduce potential public health threat
- Vaccine manufacturers are already increasing production capacities and are committed to develop and register pandemic vaccines
- Short, medium and long term solutions exist and have to be further defined through collaborative efforts and partnership in which industry has to be fully involved



- Successfully addressing influenza pandemic threat justifies an active partnership and coordination between vaccine manufacturers, governments, international agencies and NGOs
- National authorities should be prepared by:
 - Anticipating pandemic vaccine demand and supply agreements
 - Ensuring adequate Interpandemic influenza vaccination coverage rates (existing and extended recommendations)
- National and international financial is needed to support R&D activities (technical support towards rapid registration process, support monovalent bulk production and stockpile if justified)