

# Update of WHO activities: Global Action Plan to Increase Supply of Pandemic Influenza Vaccines

Meeting of the 4<sup>th</sup> Joint EC/ECDC/WHO Workshop on  
pandemic influenza preparedness

Luxembourg – 25-27 September



**World Health  
Organization**

# **Informal Consultation on Technical Specifications for an International H5N1 Vaccine Stockpile 17-18 October, Geneva 2007**

**Overall desired outcome: Identify appropriate regulatory strategies for an international H5N1 human influenza vaccine stockpile regarding:**

- the minimum non-clinical and clinical pre-licensure considerations for an H5N1 vaccine international stockpile.
- provisions for strains change due to drift variance to ensure donations in the stockpile remain adequately potent and acceptable to NRAs.
- the minimum requirements to maintain, distribute, receive and deploy vaccine from an international H5N1 influenza vaccine stockpile.
- further studies, on target quality, safety and efficacy

# WHO scientific consultation on options for the use of human H5N1 influenza vaccines and the WHO H5N1 vaccine stockpile, October 1-3, 2007, Geneva

## Scope and objectives of the meeting to:

- review and summarize the current scientific evidence on vaccine safety, immunogenicity, and effectiveness of human H5N1 vaccines
  - \* How many doses to provide protection – HI titers
  - \* Duration of immunity
- identify potential options for the use of an H5N1 vaccine stockpile (s) and the data that support each option
- draft policy recommendations for consideration by the WHO's SAGE committee on how H5N1 vaccines and the WHO stockpile should be used

# WHO Global action plan to increase pandemic influenza vaccine supply

- **Increase use of seasonal vaccine**
- **Increase production capacity for pandemic vaccine**
- **Research and development technologies**

# Government of Japan & UNICEF

- WHO prequalification of influenza vaccines
- Support developing pandemic vaccine production capacity in developing countries
  - Eligible technologies: inactivated (whole virus or split) and live attenuated vaccines, produced in eggs or on cell culture
- NRA strengthening
- Mathematical modelling
- Assessment on the deployment capacity of a country to deliver a pandemic vaccine

# US Government: Establishment production capacity for influenza vaccines in developing countries

- Request for Letters of Intent, November 2006
- Selection of projects to be further developed in full proposals, December 2006
- Full proposals received and evaluated, February 2007
- Six proposals approved

# ADB support

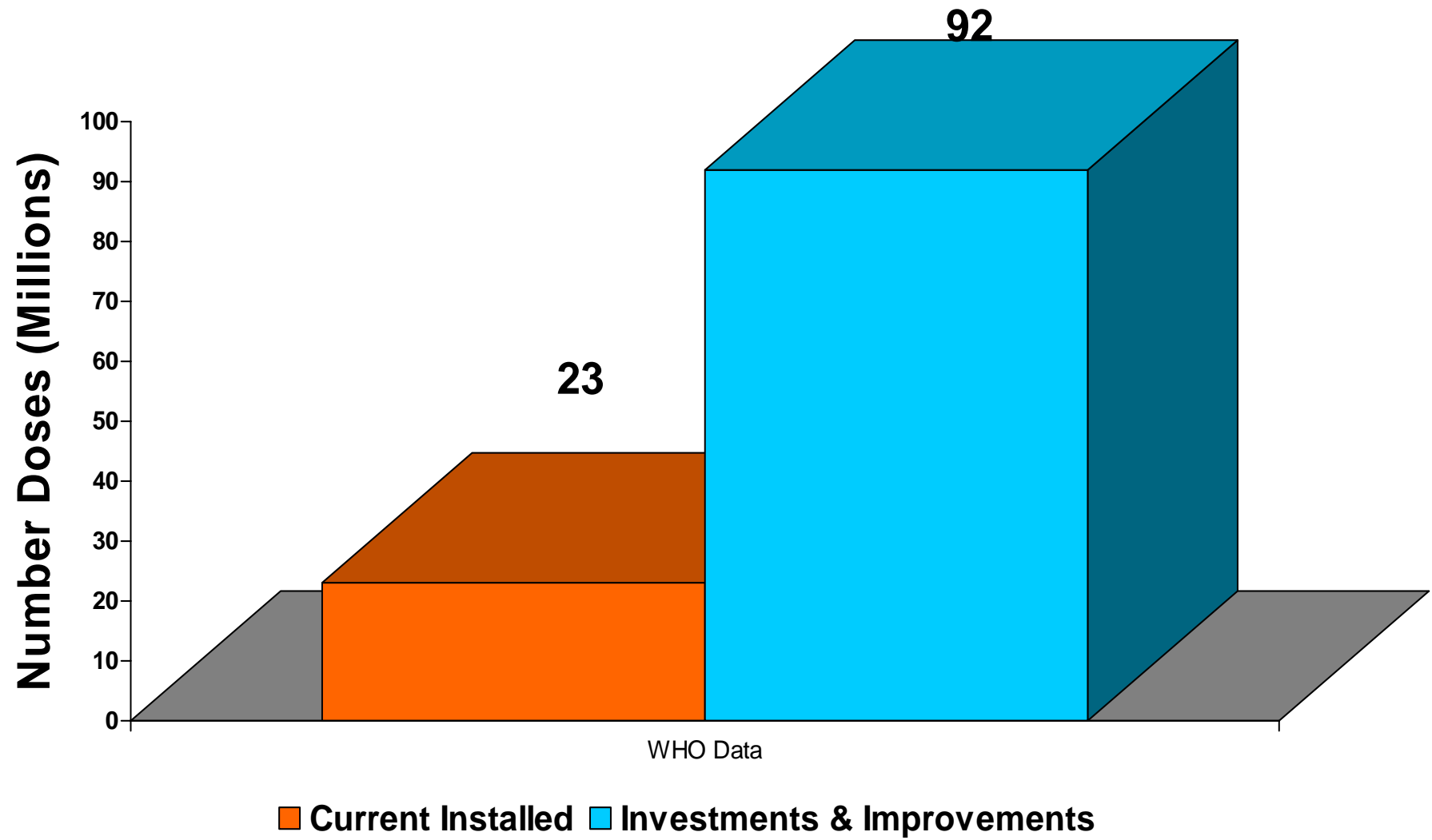
- Assess capacity in Asia of production of influenza vaccines with the aim of building capacity in middle income countries
- Prepare inventory of range of cells lines and vaccine strains available
- Assist in transfer cell lines and reagents
- Harmonize regulatory procedures for the licensing of influenza vaccines
- Review feasibility of converting poultry vaccine facilities for production of human influenza vaccines
- Mapping the IP landscape

# Antigen Sparing Approaches

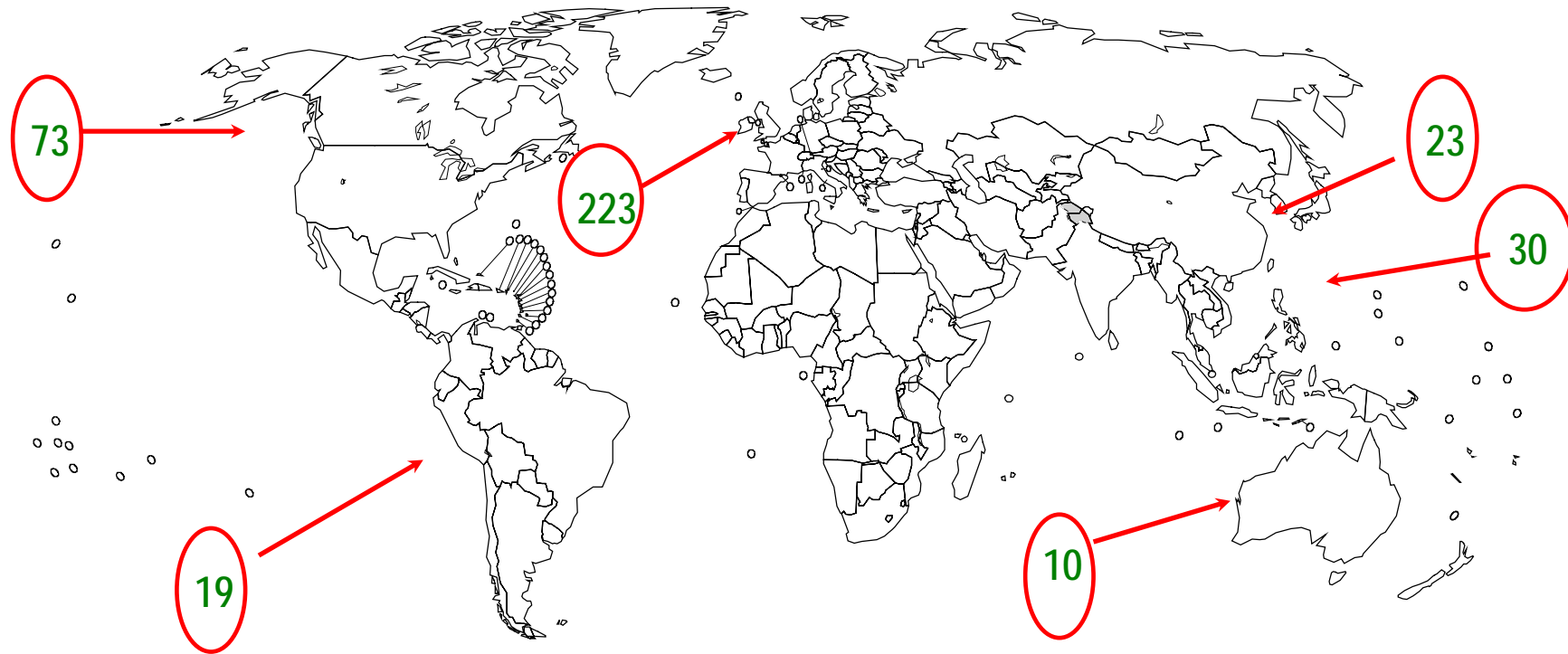
- **Intradermal Delivery with Needle-free injectors**
  - Intradermal delivery known to permit dose-sparing for seasonal vaccine (5-fold)
  - Clinical study in Dominican Republic (with CDC)
- **Adjuvant Development**
  - Proprietary adjuvants known to permit dose-reduction for pandemic vaccine (10-15 fold)
  - Access limited
  - IVR coordinating public sector adjuvant development program to ensure supply of appropriate adjuvants to all manufacturers



Results from WHO Assessment in one country, December 2006:  
Estimated Potential Increases in Total Seasonal Influenza  
Vaccine (in doses) as a result of tentative improvements and  
investments in six visited *Facilities*



# Estimated number of seasonal trivalent influenza vaccine doses (in millions) produced by manufacturers, by geographic region, based on available data., March - 2007



Sources: data collected by site visit, reports, or by manufacturer

The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.  
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# GLOBAL ACTION PLAN (GAP) ADVISORY GROUP (AG)

*October 19, 2007 - WHO Geneva*

- Mapping of supply/demand for influenza vaccines
- Prospects for increased production from IFPMA manufacturers
- Research for new technologies:
- GAP business plan
  - \* Discussion on GAP priorities



**Mapping the Landscape, WHO  
Global Influenza Survey –  
*Preliminary Results for EURO***

Source: Governments from 40  
Member States in the region

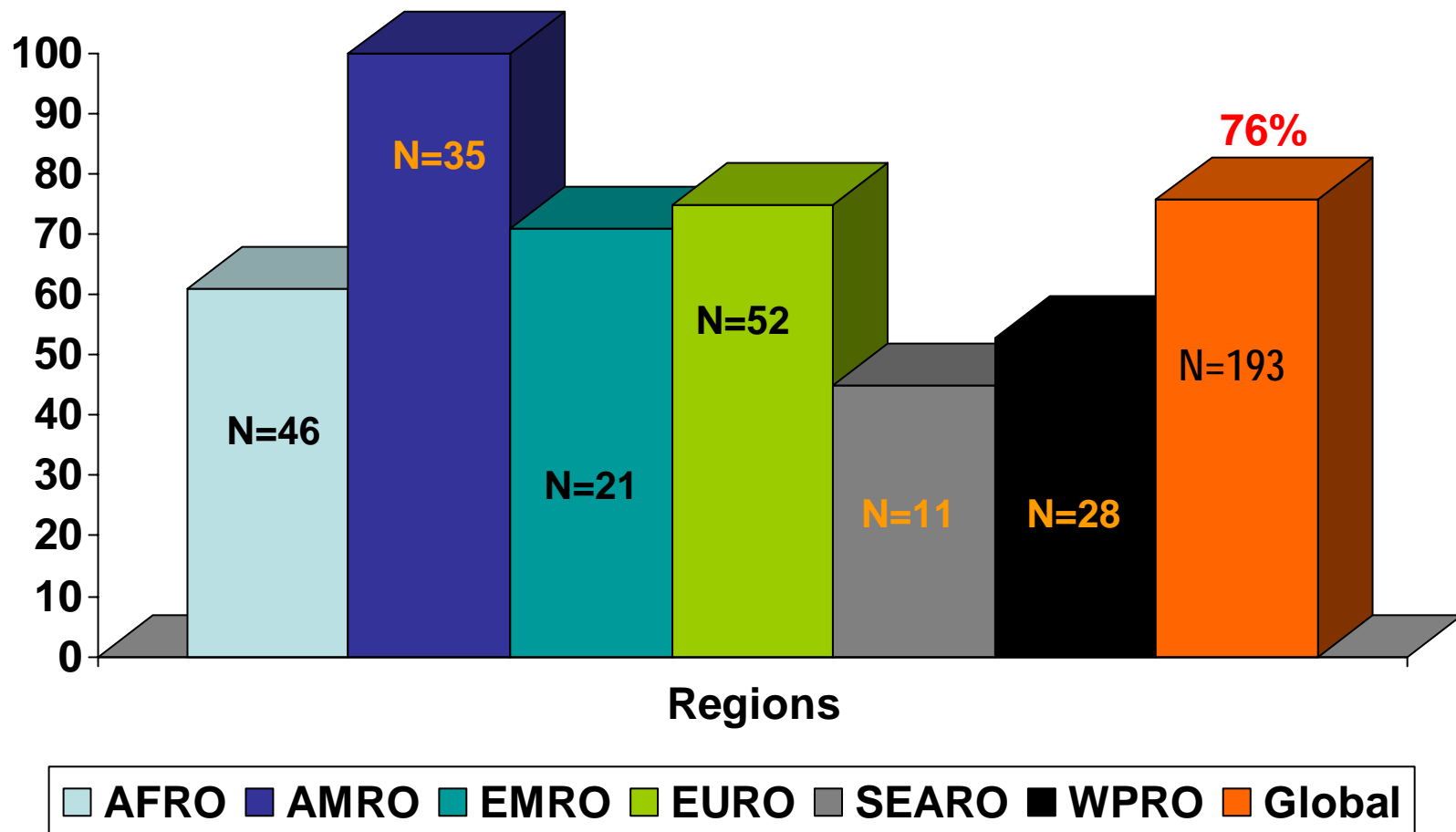
# 147 countries by WHO region that provide the denominator and therefore form the data base for the report.

**Table 1. Number of countries, by WHO region, that filled in the survey form.**

<b>WHO Regions</b>					
<b>AFRO</b>	<b>AMRO*</b>	<b>EMRO</b>	<b>EURO</b>	<b>SEARO</b>	<b>WPRO</b>
<b>28</b>	<b>43</b>	<b>15</b>	<b>40</b>	<b>6</b>	<b>15</b>

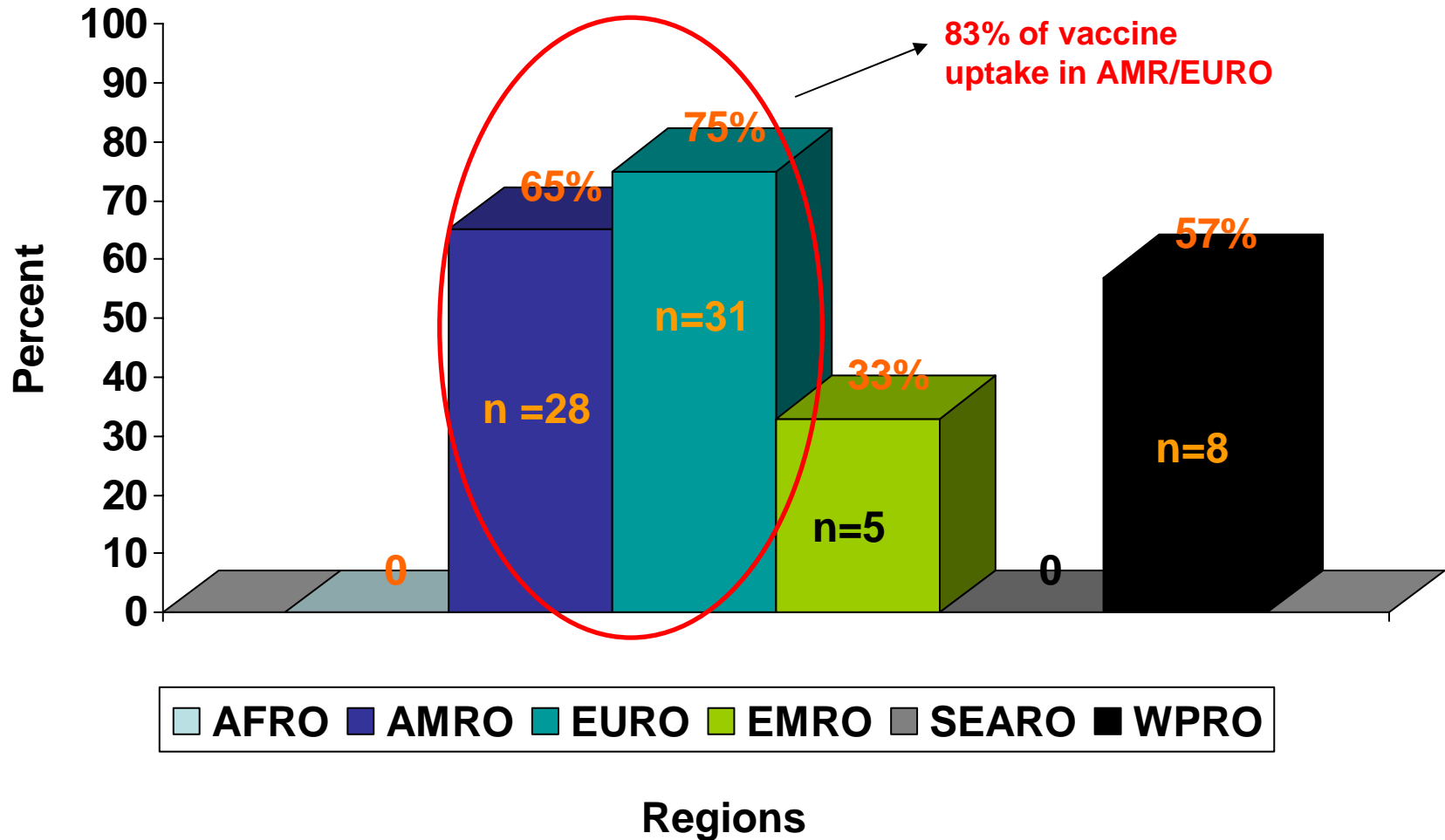
\*AMRO/PAHO has 35 Member States, however they also collected data from countries and territories from the region.

# Percent of countries responding to survey by region - *Preliminary* results as of June, 2007\*



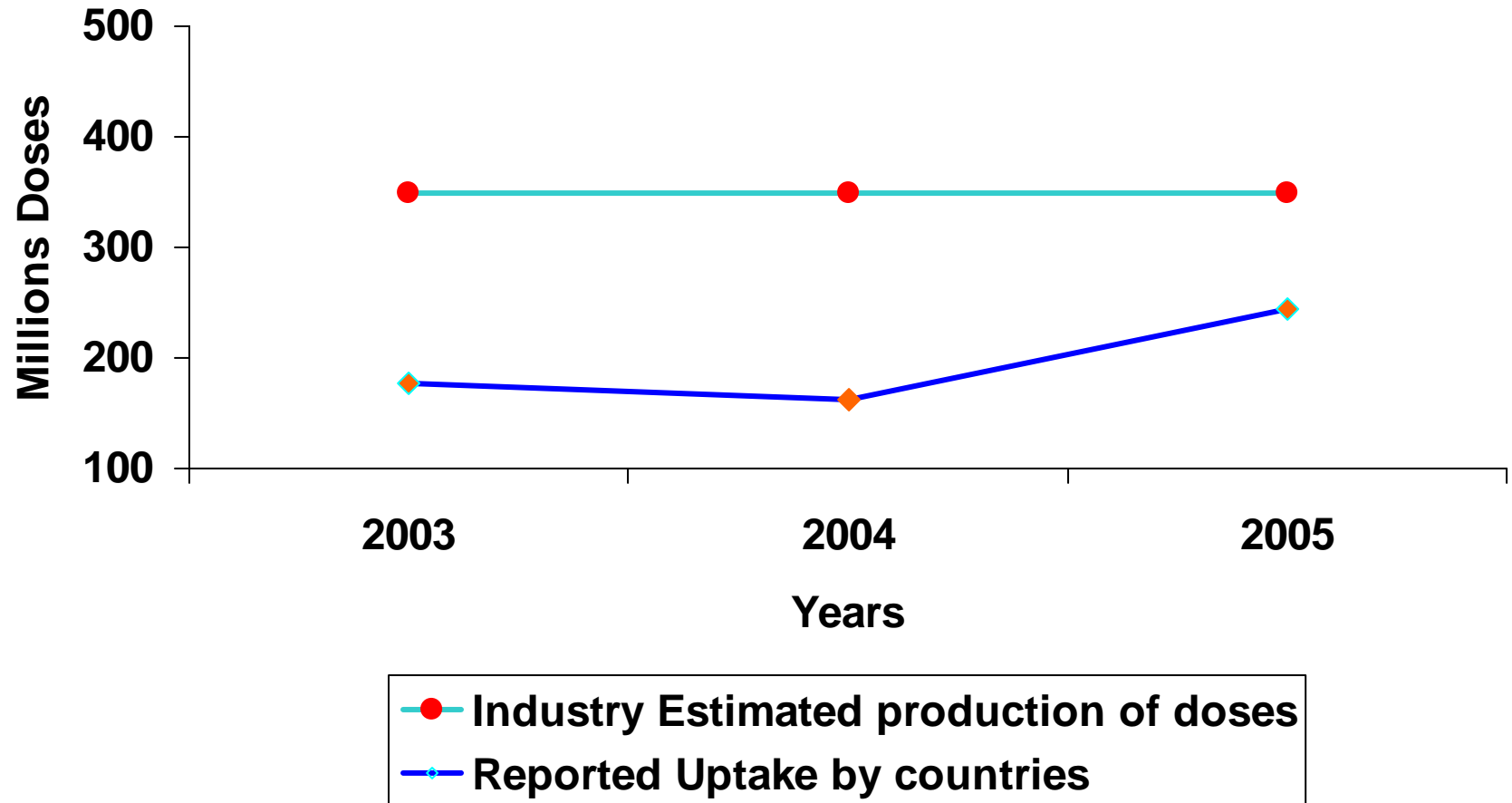
\*data from 2005

# Percent of countries by Region that answered 'Yes' , to using a seasonal influenza vaccine



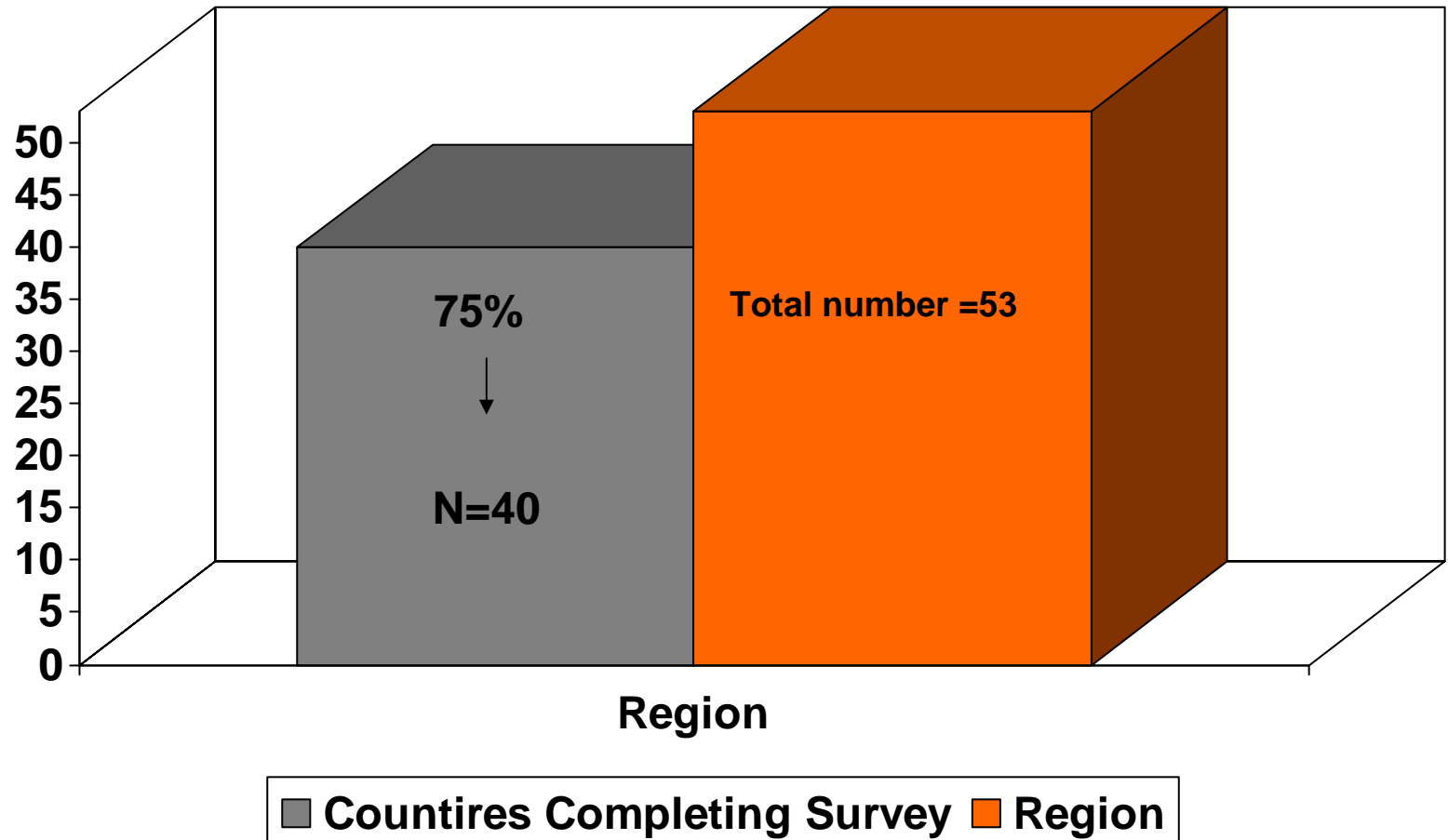


# Estimated global trends of seasonal influenza vaccine uptake for 2003-2004-2005 (doses in millions) – WHO Survey, 2007\*

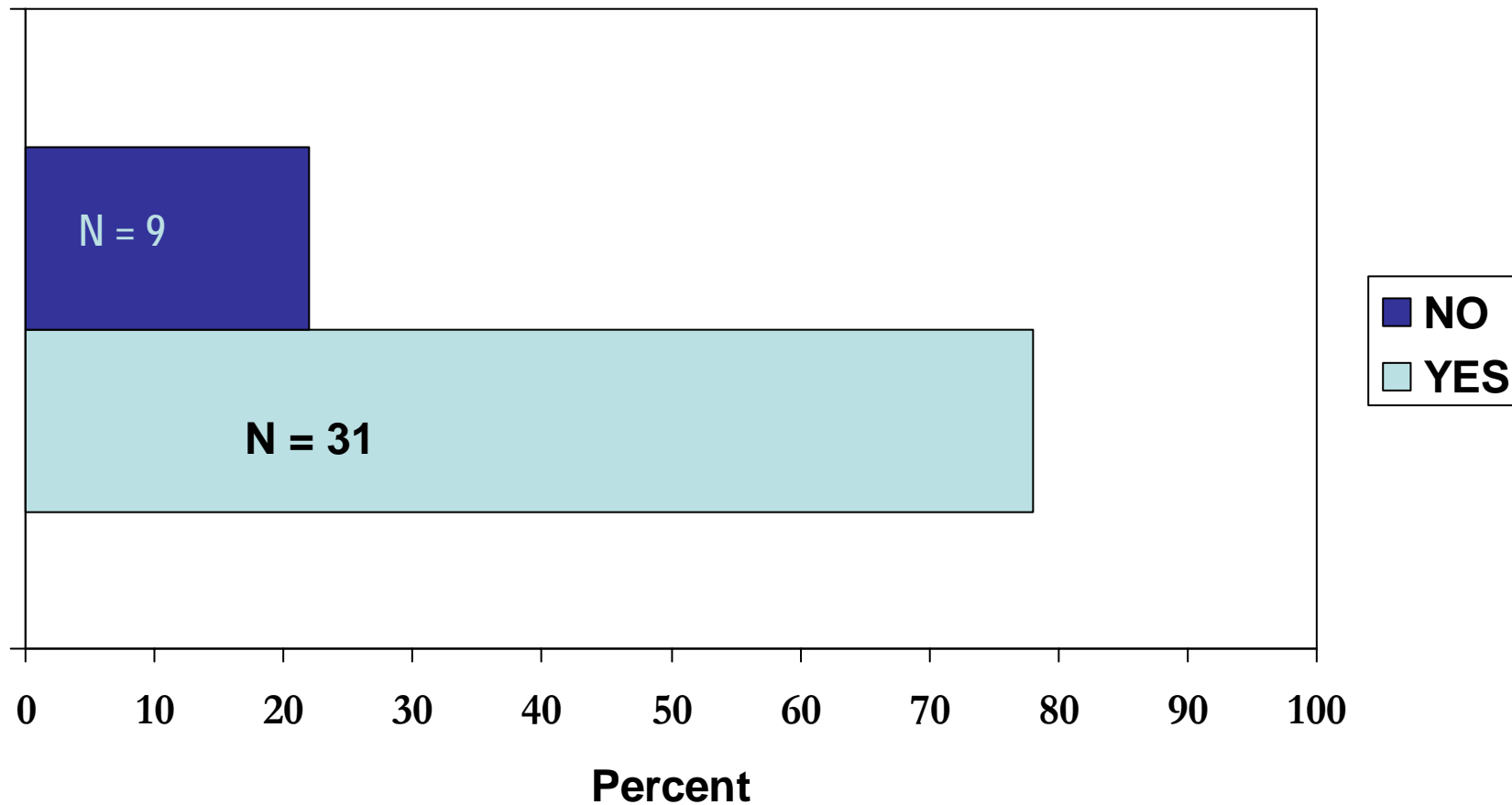


\* data from 2005

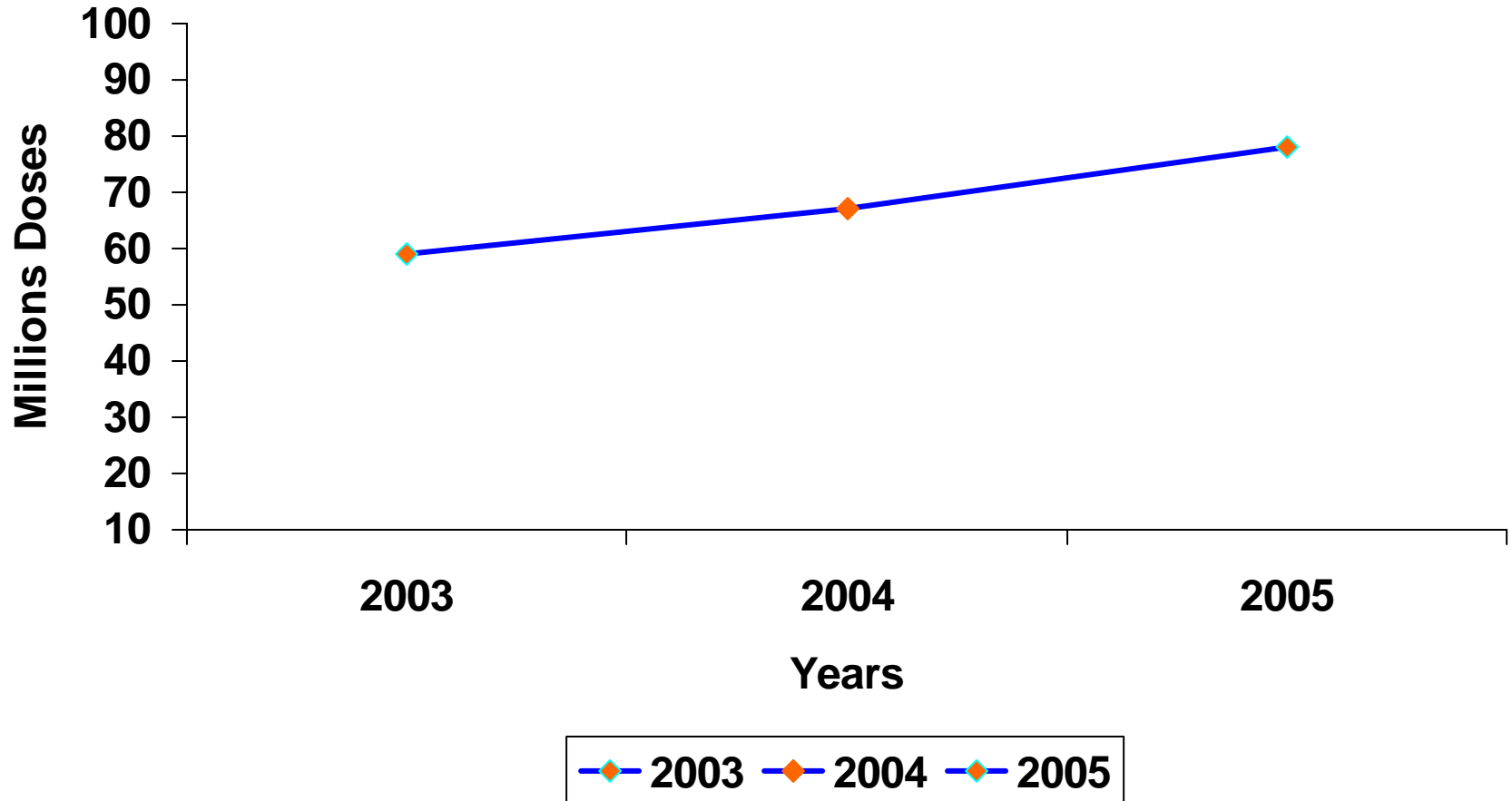
# Number countries in Euro responding to survey - *Preliminary* results as of June, 2007



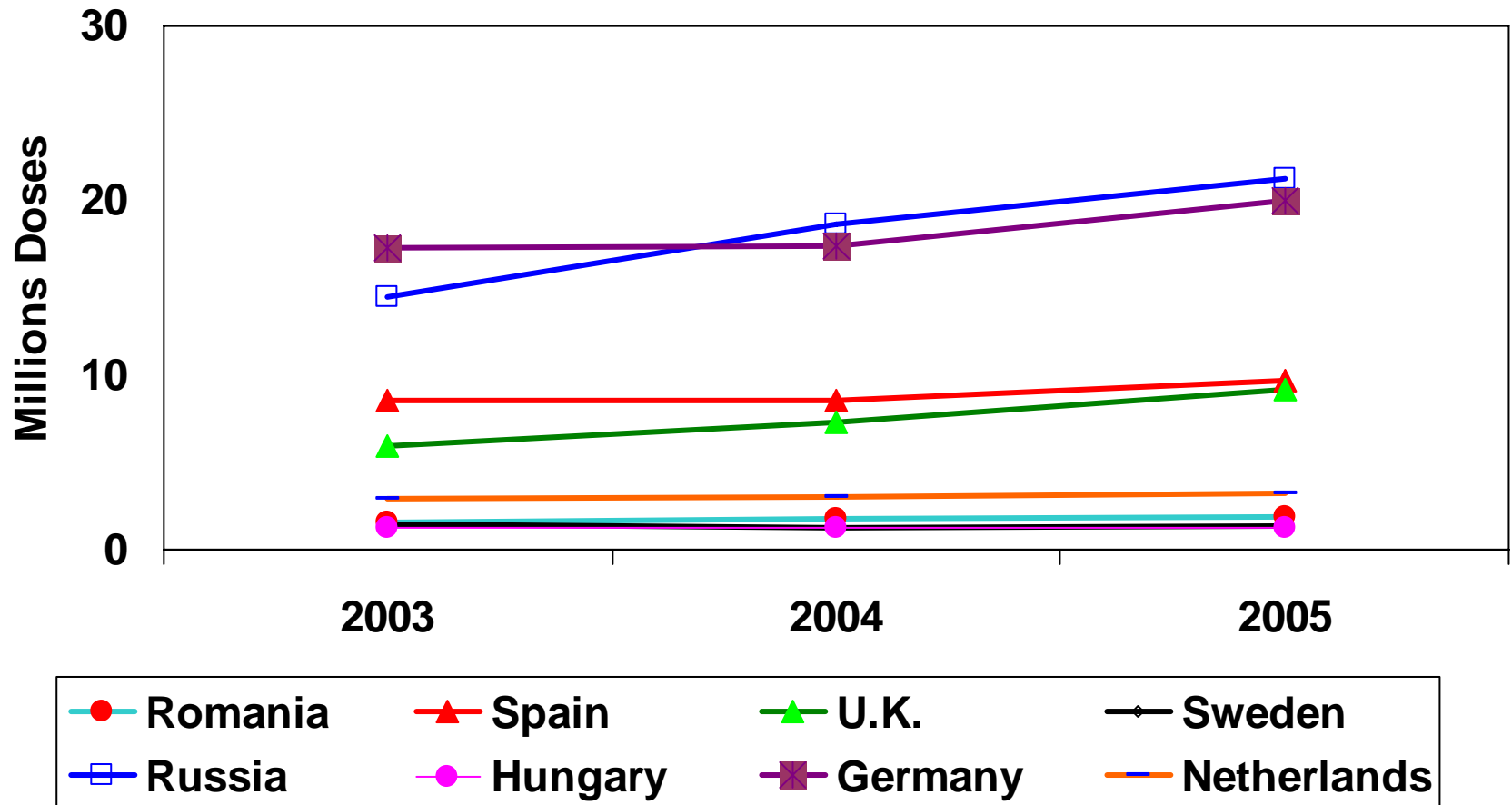
# Percent of countries in EURO using a seasonal influenza vaccine (n=40)



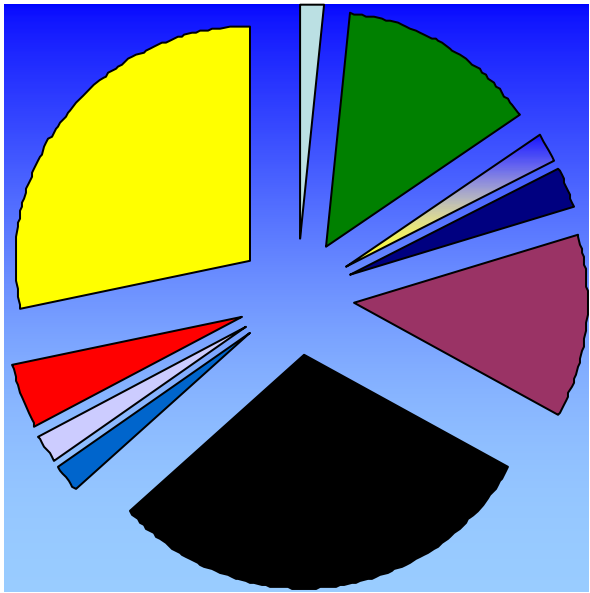
# Estimated trends of seasonal influenza vaccine uptake for 2003-2004-2005 (doses in millions) – EURO region, WHO Survey, 2007



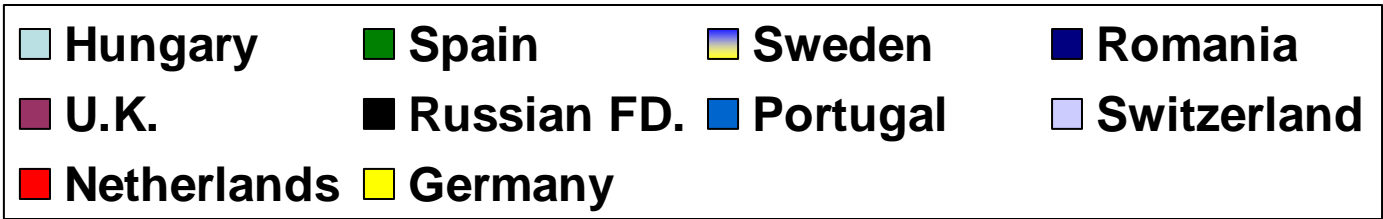
# Reported trends in influenza vaccination uptake 6 countries in EURO, 2003-2005, (doses in millions)



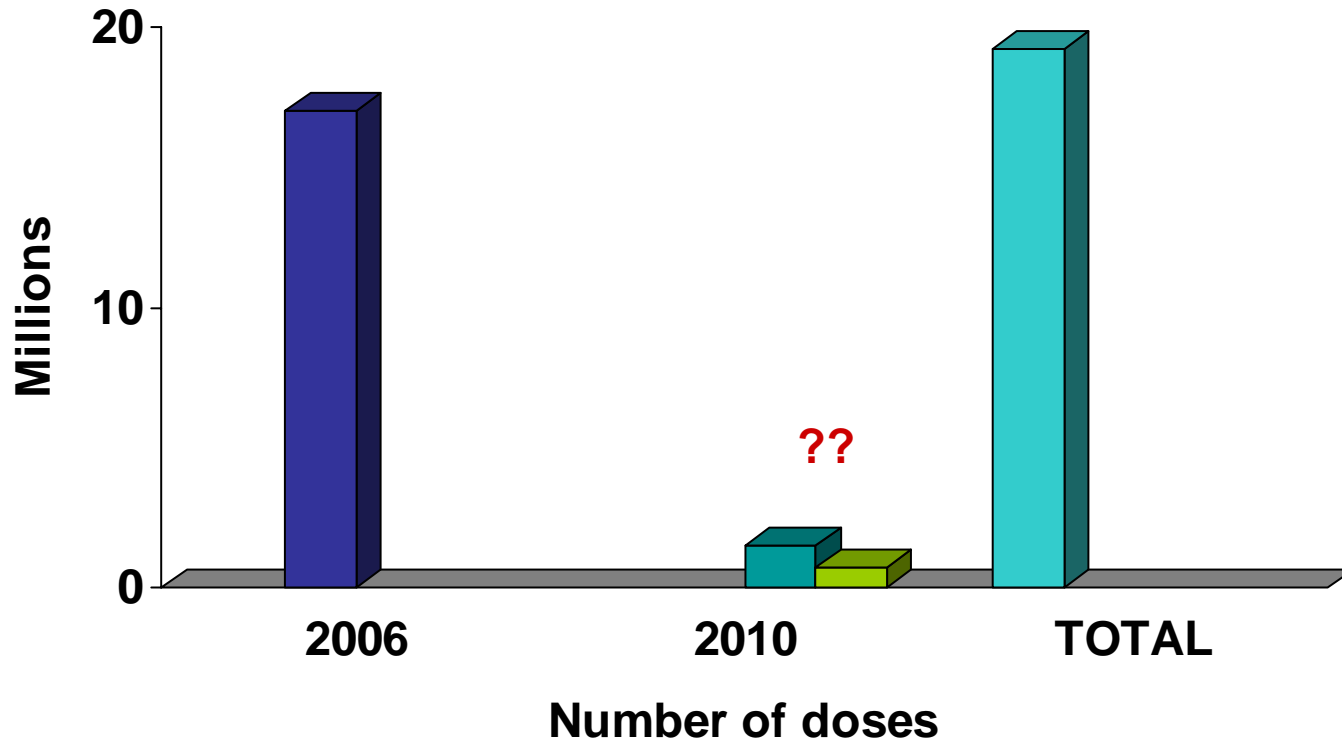
# Comparison of uptake of seasonal influenza vaccine doses 2005, by countries, EURO



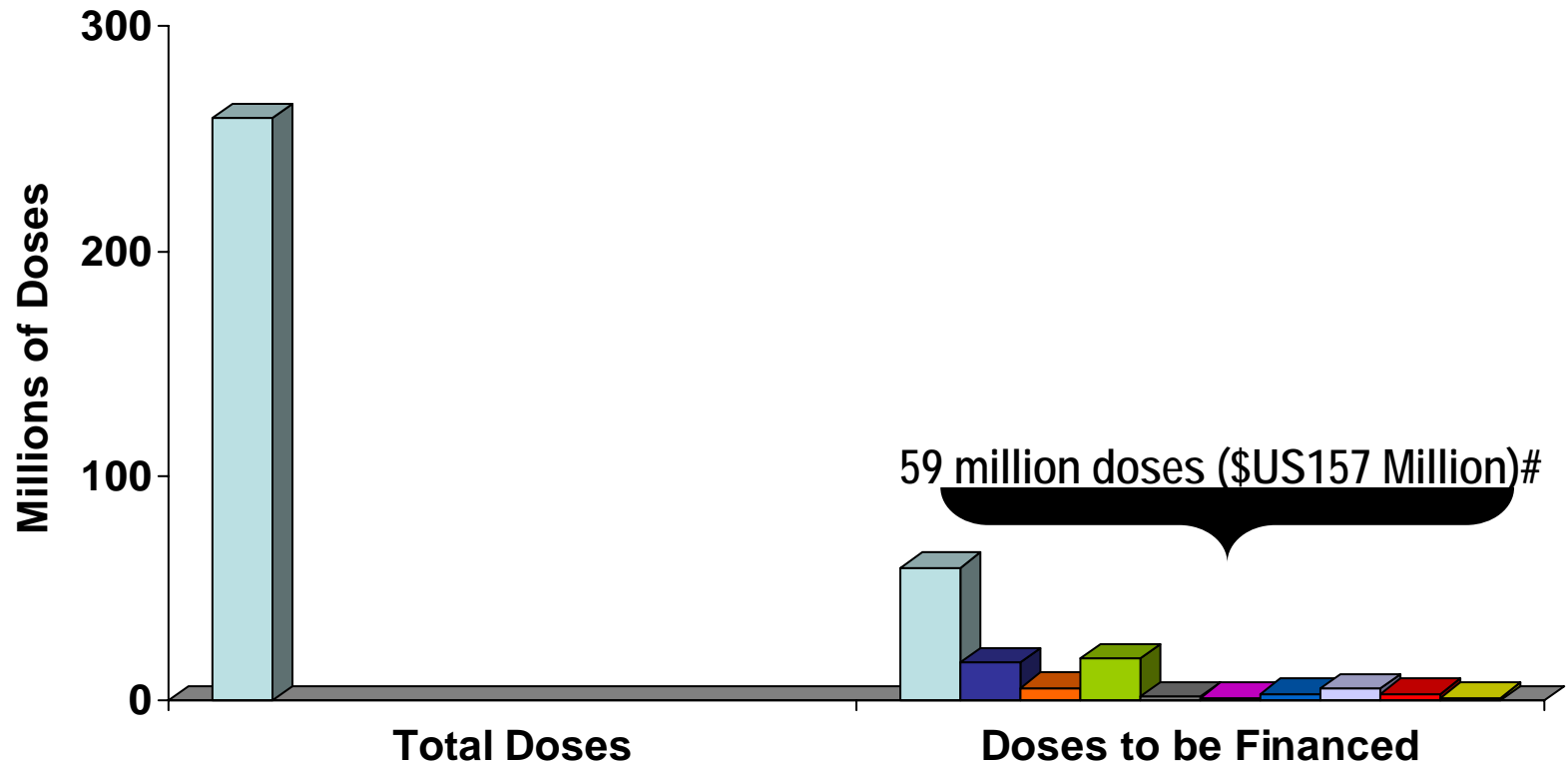
90% of total reported uptake d  
(77 million, for Region in 2005)



# Estimated seasonal influenza vaccine doses that countries are planning to introduce between 2006 -2010 - EURO



# Would your country purchase doses of a pandemic influenza vaccine and would your country require financing for their purchased, by country, EURO

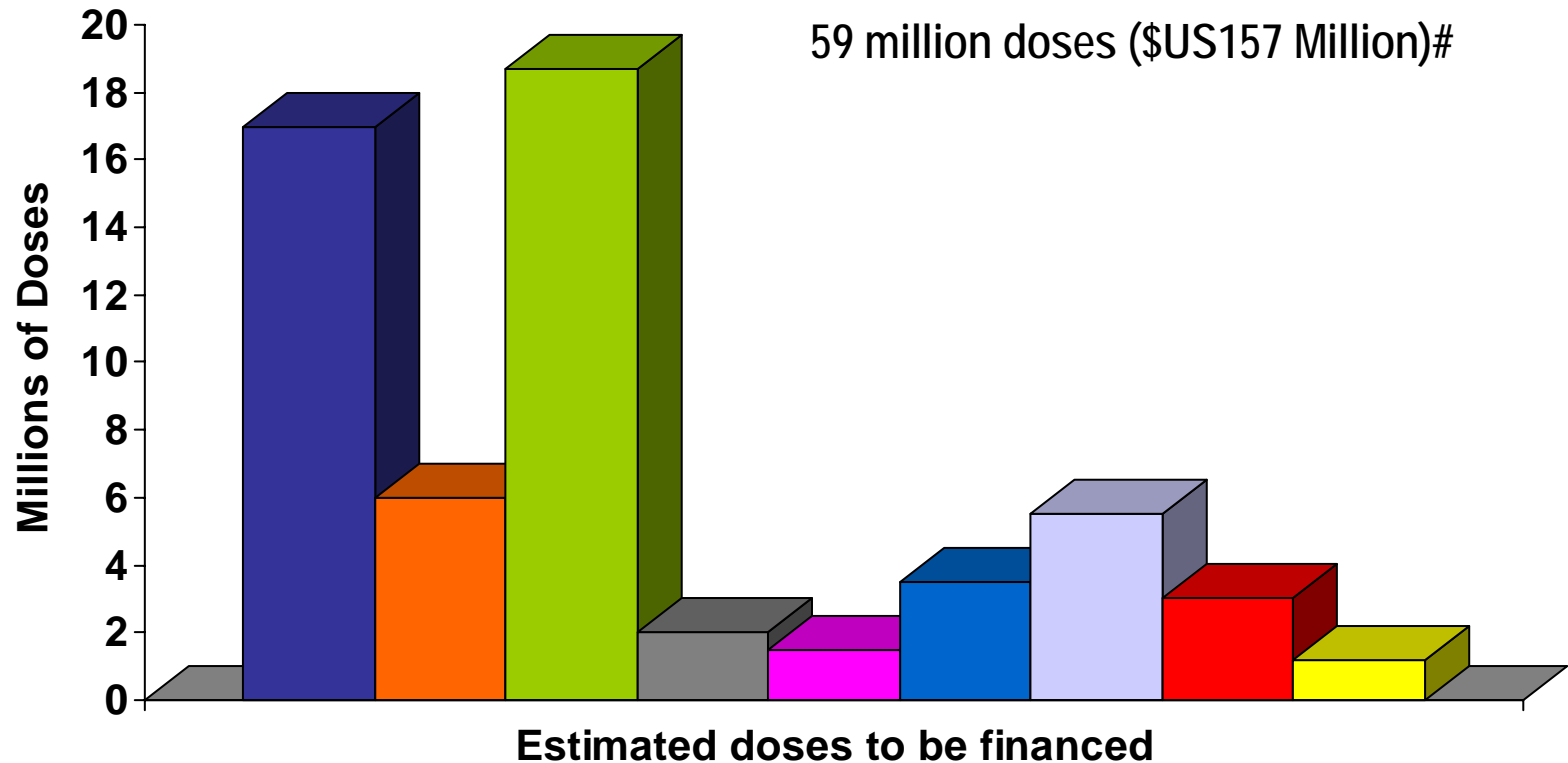


■ Total	■ Uzbekistan	■ Belarus	■ Ukraine	■ Georgia
■ Kazakhstan	■ Turkmenistan	■ Romania	■ Serbia	■ Others

# Cost estimate based on \$2.66 per dose seasonal influenza vaccine – PAHO- RF- 2007

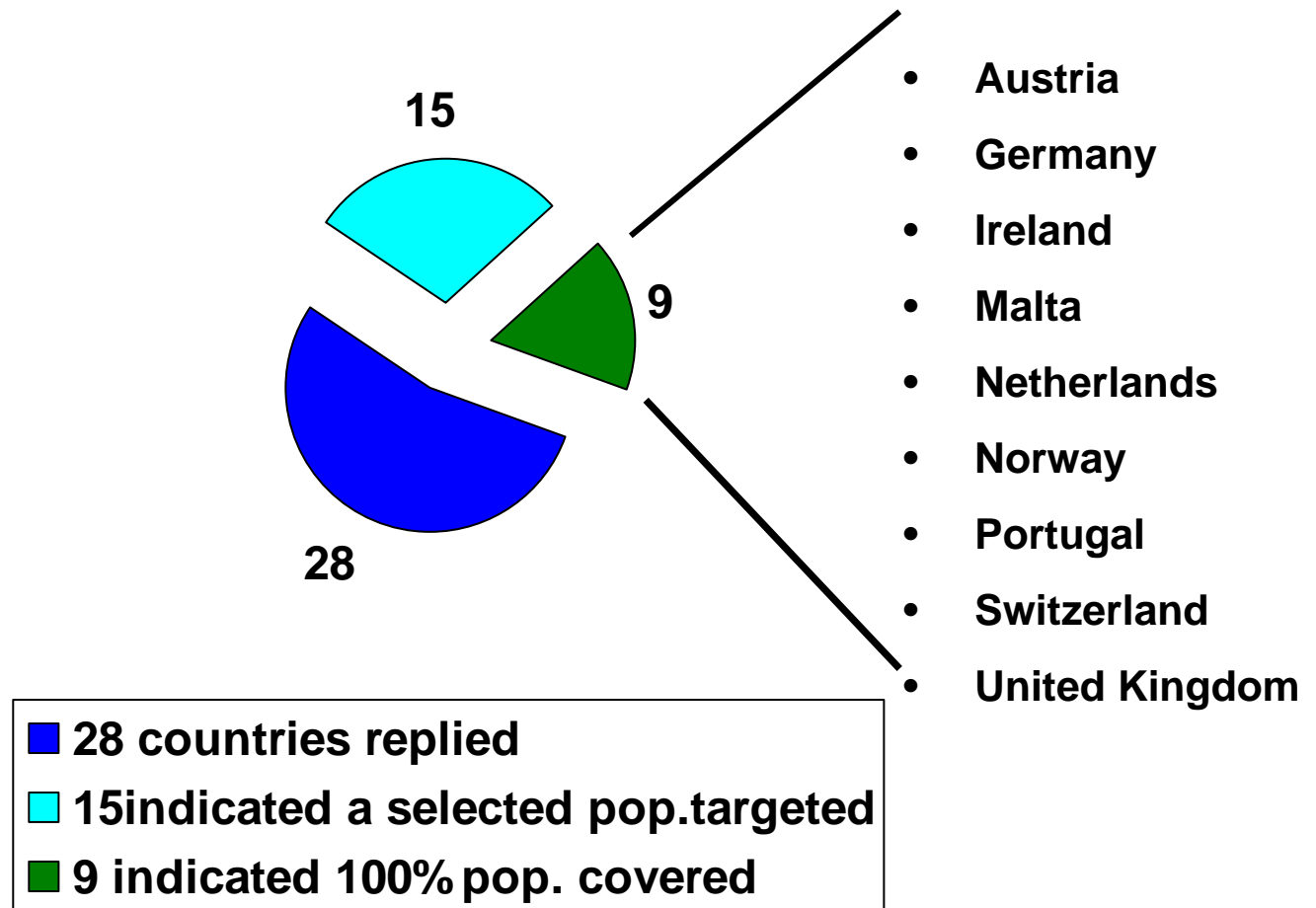


# Would your country purchase doses of a pandemic influenza vaccine and would your country require financing for their purchased, by country, EURO

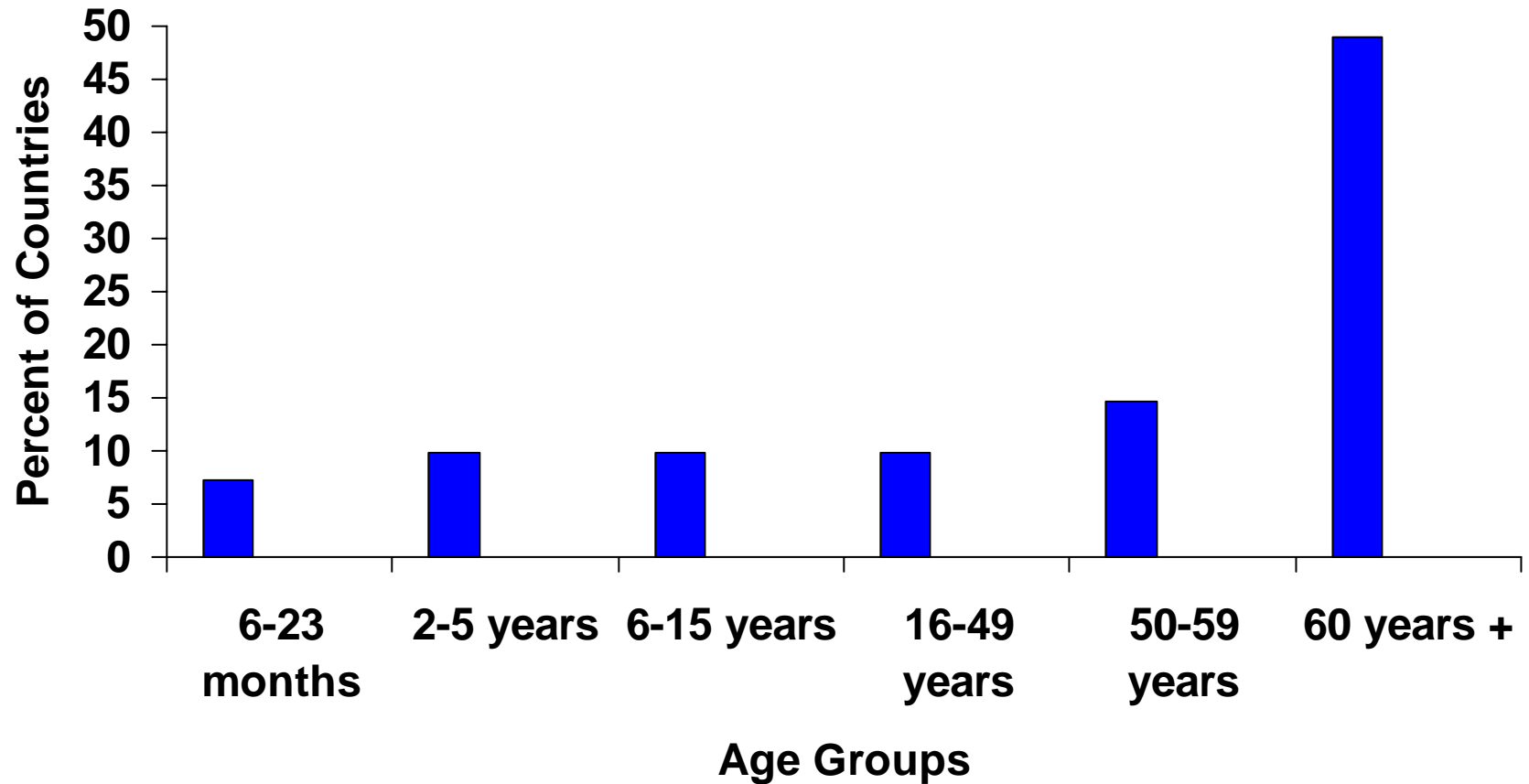


# Cost estimate based on \$2.66 per dose seasonal influenza vaccine – PAHO- RF- 2007

# Countries indicating pandemic vaccine policy, EURO – WHO survey, 2007

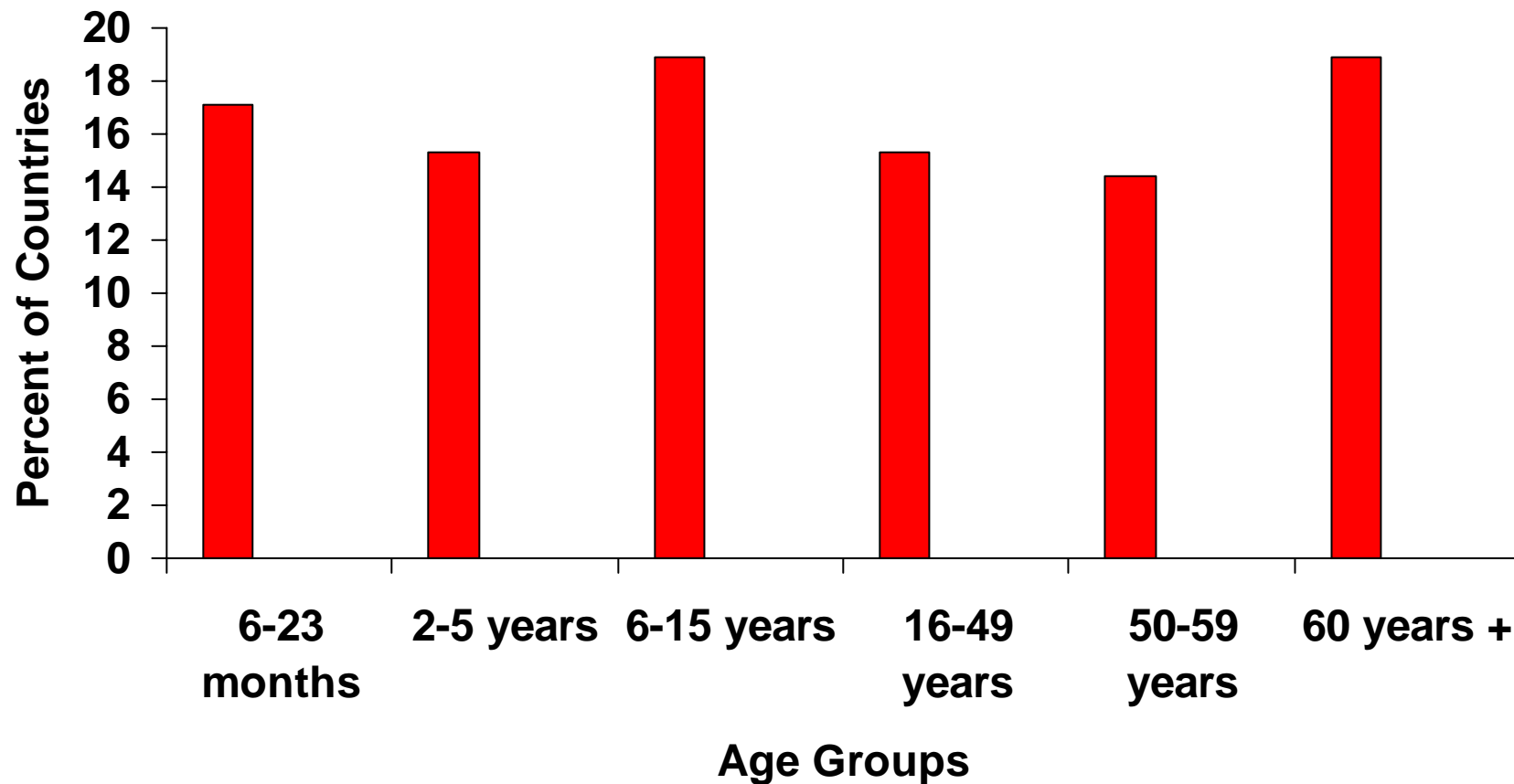


**Age groups targeted for with seasonal influenza vaccination in  
EURO countries\* with **routine** program.  
WHO Survey results, 2005**



\* 21 countries filled in the fields related to this question

**Age groups that will be targeted for pandemic influenza vaccination  
in EURO countries\* who indicated a positive response  
WHO Survey results, 2005**



\*21 countries filled in the fields related to this question

# Some preliminary observations: EURO (1)

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## Quality of data:

- Many inconsistencies in the filling the fields in the form.
- Many countries with large populations did not complete the survey form or failed to complete key fields that would have provided valuable information

## Conclusion:

- Many countries with mature influenza programs cannot provide basic information on seasonal vaccine coverage.
- Based on the quality of the data received, and missing responses from many Member States, WHO cannot provide a clear opinion on the state of global preparedness on the part of Member States to mitigate a influenza pandemic using a vaccine when it is made available..

# Some preliminary observations EURO (2)

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- There are regulatory issues that need to be addressed as earlier as possible because countries are targeting the very young to receive a pandemic vaccine, in addition for those countries that will include seasonal influenza vaccination into their childhood immunization schedule.
- Training programs need to be prepared to train staff in all aspects on the use of influenza vaccines, including the development of a robust post marketing surveillance capacity.

# Some preliminary recommendations

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- All countries need to review their influenza pandemic preparedness plans to assure:
  - that the role of vaccination is clearly spelt out.
  - that a logistical plan/map showing the distribution all points is included
  - that a command and control protocol is part of the distribution plan
  - that disease surveillance for influenza is adequately addressed
  - that plans are made to stockpile or assure access to the required syringes for the application of a parenteral immunization
- All countries need to review with their NRA the regulatory pathways that need to be strengthened or developed for lot release licensing and post marketing of these vaccines.
- All countries with plans for introducing seasonal influenza vaccines into their national immunization schedules need to consider all the issues and impact of this policy decision. Most importantly discuss with their suppliers and or other procurement agencies the availability of this product.

**This paper was produced for a meeting organized by Health & Consumer Protection DG and represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumer Protection DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.**