



Global production capacity of seasonal influenza vaccine in 2011

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ABSTRACT

The effectiveness of vaccines to mitigate the impact of annual seasonal influenza epidemics and influenza pandemics has been well documented. However, the steady increase in global capacity to produce annual seasonal influenza vaccine has not been matched with increased demand, and thus actual vaccine production. Currently, without a significant increase in demand for seasonal influenza vaccine, global capacity will be far from able to meet even the essential needs for a monovalent vaccine in the event of a severe influenza pandemic. Global commitment to the development of influenza vaccine production capacity was renewed at a consultation leading to the Second Global Action Plan on Influenza Vaccines (GAP) in July 2011. To monitor progress on the GAP, the World Health Organization has carried out periodic surveys of influenza vaccine manufacturers. This latest survey compares current maximum global capacity and actual production of seasonal influenza vaccine in 2011 with data from surveys carried out in 2009 and 2010; analyses global influenza production capacity in the context of sustainability; and discusses options to increase demand, based on strong evidence of public health benefit.

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1. Introduction

The effectiveness of vaccines to mitigate annual seasonal influenza epidemics and the potentially devastating impact of influenza pandemics has been well documented. What is sometimes less recognized is the intrinsic link between production capacity for seasonal influenza vaccine – which tends to be aligned with demand by immunization programmes – and potential vaccine availability for pandemic influenza vaccination. Indeed, rapid production of a pandemic influenza vaccine in the billions of doses needed to meet expected demand currently depends entirely on global capacity to produce seasonal trivalent influenza vaccines.

The Global Action Plan on Influenza Vaccines (GAP), published in 2006, is a comprehensive strategy to reduce the global shortage of influenza vaccines for seasonal epidemics and severe pandemics in all countries through three main approaches: (1) increasing seasonal vaccine use; (2) increasing vaccine production capacity; and (3) research and development [1]. Since 2006, significant progress has been made: new and expanded facilities have been announced in both developed and developing countries; the amount of antigen required per dose is now lower due to new adjuvants; production yields have improved; and advances have been made with new technologies. Global commitment to the development of influenza vaccine production capacity was renewed at a consultation leading

to the Second GAP in July 2011 [2]. To monitor progress on vaccine production capacity, the World Health Organization (WHO) has carried out periodic surveys of influenza vaccine manufacturers. The latest survey compares current maximum global capacity and actual production of seasonal influenza vaccine in 2011 with data from surveys carried out in 2009 and 2010 [3,4], analyses global influenza production capacity in the context of sustainability, and discusses options to increase demand, based on strong evidence of public health benefit.

2. Methodology

New information on global seasonal influenza vaccine production capacity was collected via a survey conducted by WHO from December 2011 to April 2012. The questionnaire, developed in Microsoft Excel[®], was sent electronically to all known (28) vaccine manufacturers with established seasonal influenza vaccine production capacity in 2011.¹ The questionnaire requested each manufacturer to report both its estimated total production capac-

¹ Abbott Biologicals; ADImmune Corporation; Baxter; Berna-Crucell; Biken; Bio Farma; Cantacuzino Institute; Changchun Changsheng Life Sciences Limited; Chemo-Sero-Therapeutic Research Institute; China National Biotec Group (Changchun Institute of Biological Products, Lanzhou Institute of Biological Products Co., Ltd., and Shanghai Institute of Biological Products); CSL; Dalian Aleph Biomedical Co., Ltd.; Denka Seiken; GlaxoSmithKline Biologicals; Green Cross Corporation; Hualan Biological Bacterin Co., Ltd.; Institute of Virology, Vaccines and Sera Torlak; Kitasato; MedImmune; Microgen; Novartis Vaccines and Diagnostics; Omniinvest; Panacea Biotec; NPO Petrovax Pharm, LLC; Sanofi Pasteur; Serum Institute of India; Sinovac Biotech; Zhejiang Tianyuan Bio-Pharmaceutical Co., Ltd.

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ity and its actual production (in millions of doses) of 2011 trivalent seasonal Southern Hemisphere (SH) vaccine and/or 2011–2012 trivalent seasonal Northern Hemisphere (NH) vaccine by type of formulation [inactivated or live attenuated, non-adjuvanted or adjuvanted (with adjuvant type), and antigen content per dose]. Manufacturers with multiple production facilities were requested to report capacity and production data aggregated across the countries if the facilities were in the same WHO Region. Manufacturers were requested to disaggregate these data by WHO Region if their facilities were located in more than one WHO Region. Information on future vaccine production facilities was obtained through the GAP programme at WHO.

3. Results

Twenty-seven vaccine manufacturers (96%) responded to the survey. For the one manufacturer who did not respond, data provided in 2010 was used in the analysis, as no major change in the company had taken place between 2010 and 2011. The estimated global annual capacity for seasonal trivalent influenza vaccine production was 1420 million doses, with 75% of this capacity dedicated to NH vaccine production (Table 1). This represents an increase of 544 million doses (62%) over the previous estimates based on data from the 24 manufacturers with production capacity in 2009 [3].

3.1. Seasonal influenza vaccine production

In 2011, 25 manufacturers representing 34 production facilities produced 620 million doses of seasonal trivalent influenza vaccine, which was an increase of 47 million doses (8%) from the 2009 estimated production of 573 million doses [4]. Twenty-three (68%) facilities produced only NH vaccines and 11 (32%) produced both NH and SH vaccines. No facilities produced only SH vaccines. Three manufacturers reported capacity to produce influenza vaccines, but did not produce trivalent seasonal influenza vaccine in 2011.

Table 1
Capacity and actual production of seasonal trivalent influenza vaccine in 2009 and 2011.

Vaccine	Doses (millions)	
	2009	2011
Seasonal trivalent vaccine capacity	876	1420
Northern Hemisphere seasonal vaccine capacity		1069
Northern Hemisphere seasonal vaccine production	470 ^a , 500 ^b	534 ^c
Inactivated Northern Hemisphere vaccine produced for 2011/2012 season		506
15 µg antigen for each component (non-adjuvanted)		447
15 µg antigen for each component (adjuvanted)		30
7.5 µg antigen for each component (non-adjuvanted)		14
5 µg antigen for each component (adjuvanted)		14
Live attenuated Northern Hemisphere vaccine produced for 2011/2012 season		29
Southern Hemisphere seasonal vaccine capacity		352
Southern Hemisphere seasonal vaccine production	112 ^d , 73 ^e	86 ^f
Inactivated Southern Hemisphere vaccine produced for 2011/2012 season		86
15 µg antigen for each component (non-adjuvanted)		79
15 µg antigen for each component (adjuvanted)		7
Live attenuated Southern Hemisphere vaccine produced for 2011/2012 season		0

^a 2008/2009 season.
^b 2009/2010 season.
^c 2011/2012 season.
^d 2009 season.
^e 2010 season.
^f 2011 season.

3.2. Northern Hemisphere seasonal influenza vaccine estimated capacity and actual production

The estimated global annual capacity for NH seasonal trivalent influenza vaccine production in 2011 was 1069 million doses, while the reported number of doses actually produced for the 2011–2012 season was 534 million doses, i.e. only 50% of global capacity. Of actual NH vaccine production, the vast majority of doses (86%) were the inactivated non-adjuvanted formulation. The estimated annual production capacity in 2011 was a 22% increase over the 876 million doses estimated in 2009 [3], while actual NH production increased 7% in 2011 compared with the 2009 estimate [4].

3.3. Southern Hemisphere seasonal influenza vaccine estimated capacity and actual production

The reported global annual capacity for SH seasonal trivalent influenza vaccine production in 2011 was 352 million doses, while the reported number of doses actually produced for the 2011 season was 86 million doses, i.e. only 24% of global capacity. Only doses of the inactivated formulation were produced, 92% of which were non-adjuvanted. Actual SH production decreased 23% in 2011 compared with the 2009 estimate [3].

3.4. Current and future seasonal influenza vaccine production by WHO Region

In 2011 there were 21 countries with seasonal trivalent influenza vaccine production capacity (Table 2). Production capacity was estimated as 691 million doses (48%) in the WHO European Region (EUR), 378 million doses (27%) in the Region of the Americas (AMR), 324 million doses (23%) in the Western Pacific Region (WPR), and 28 million doses (2%) in the South-East Asia Region (SEAR) (Fig. 1). In terms of actual production, EUR produced nearly

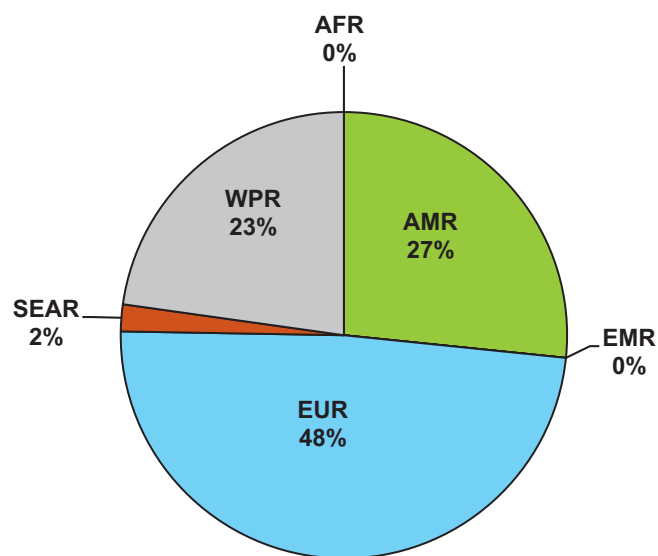


Fig. 1. Global production capacity of seasonal trivalent influenza vaccine in 2011 by WHO Region. AFR, WHO African Region: no trivalent seasonal vaccine production capacity in 2011. AMR, WHO Region of the Americas: trivalent seasonal vaccine production capacity in 2011 in Canada and the United States of America. EMR, WHO Eastern Mediterranean Region: no trivalent seasonal vaccine production capacity in 2011. EUR, WHO European Region: trivalent seasonal vaccine production capacity in 2011 in Austria, Belgium, Czech Republic, France, Germany, Hungary, Italy, Netherlands, Romania, Russian Federation, Serbia, Switzerland and United Kingdom. SEAR, WHO South-East Asia Region: trivalent seasonal vaccine production capacity in 2011 in India and Indonesia. WPR, WHO Western Pacific Region: trivalent seasonal vaccine production capacity in 2011 in Australia, China, Japan and Republic of Korea.

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