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Vaccines Production in Pakistan

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Author [1]Dr. Fazli Hakim Khattak

[1] AUTHOR IS THE HEAD, DEPARTMENT OF HEALTH ECONOMICS AT PIDE ISLAMABAD

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Regards

Dr. Fazli Hakim Khattak

HOD, DOHE, PIDE

LIST OF ACRONYMS

Acquired Immunodeficiency Syndrome	AIDS
Biological Production Division	BPD
China Pakistan Economic Corridor	CPEC
Deoxyribonucleic Acid	DNA
Drug Regularity Authority	DRA
Eastern Mediterranean Regional Office	EMRO
Exocrine Pancreatic Insufficiency	EPI
Federal Board of Revenue	FBR
Glaxo Smith Kline	GSK
Government of Pakistan	GOP
Human Immunodeficiency Virus	HIV
Human Resource Development	HRD
Information Management System	IMS
National Health	NHSCR&C
National Institute of Health	NIH
Plant, Machinery, and Equipment	PME
Principal Component	PC
Research and Development	R & D
Sustainable Development Goals	SDGs
United Nations	UN
United Nations International Children's Emergency Fund	UNICEF
World Health Organization	WHO

Vaccines Production in Pakistan (VPIP)

ABSTRACT

The safe and efficacious vaccine is the most effective way to combat a disease specially a deadly disease like rabies, tetanus, measles, meningitis, and hepatitis etc. No health interventions are as simple, powerful and cost effective as vaccines and these prevent millions of deaths globally. Vaccines have transformed public health throughout the world particularly for children and global immunization program a powerful tools to control the burden of vaccine preventable diseases. Access to quality vaccines at affordable cost represents a challenge to health systems due to the few manufacturers, the limited capabilities of national regulatory authorities and under-funded health systems, particularly in low and middle- income countries. A limited proportion of vaccines used in routine and non-routine immunization programs is produced locally by four main institutions in EMRO i.e. VACSERA (Egypt), Razi Institute (Iran), NIH (Pakistan) and Tunis. There are 18 countries, produce 51 types of vaccines for their own consumption, however a few of the country's export and supply vaccines to other countries. It includes China, India, Brazil, Cuba and Indonesia. There is a vast scope of vaccine due to growing population of Pakistan. There are possibilities for Joint Venture in the area of vaccine production with China, Iran, Egypt and Tunis, a preferently with China using the CPEC window for investment in the country.

It is estimated that nearly 85% population of world is living in developing countries and only 15% population is living in developed countries. While developed countries contribute towards 82% of global vaccine sales and developing countries contribute only 18%. The growth of global vaccine market from 2000 to 2013 is US$ 5 billion to US$ 24. It is estimated that this vaccine market will rise to US$ 100 billion in 2025. In 2012 UNICEF purchased 50% of global volume of vaccine does mainly EPI vaccines. The global vaccine leaders are GSK having 23% market share, Sanofil Pasteur 17%, Pfizer 13%, Merck 12% and Novartis 10% market share while remaining 25% is contributed by other vaccine manufacturers.

Key words: Vaccine, Immunization

INTRODUCTION

Global scenario

Currently 120 new vaccine products are in development phase and out of it 60 products are of importance for developing countries. Recently, a vaccine for dengue fever is under registration process while vaccine for zika virus is under clinical trials. Vaccine products against cancer, hepatitis C and HIV/AIDS are under active research and development processes.

In Muslim region a limited proportion of vaccines used in routine and non- routine immunization programs is produced by the VACSERA-Egypt, Razi institute-Iran, Biofarma -Indonesia, and pasteure institutes-Tunis. China and India are also major vaccine producers and India is supplying vaccine products like Measles and Polio to UNICEF. Biofarma- Indonesia is a WHO pre-qualified manufacturer and supplying Measles vaccine to WHO.

Pakistan scenario

Vaccines can be produced in Pakistan either by shared manufacture, ready to fill material, Concentrate or from raw material using seed bacteria and seed viruses (Basic Manufacture). It was noted that US $ 600 million were to be spent on EPI and Polio during next 3-5 years. Therefore, it is a crucial need to produce this paper as first step toward this sacred task.

Vaccines are important tools in disease prevention and their availability in good quality and of at affordable cost represents a challenge for health systems. The two public health interventions, have had the greatest impact on global health, are clean water and vaccines. However, it is profoundly tragic that despite the availability of simple vaccines, almost 1.5 million children still die each year from vaccine preventable diseases. New global changes and challenges, including increased competition, difficulties in accessing cutting edge technology, reduction in the number of vaccine suppliers, limited market and profit margins and decreased interest in vaccine production by the industrialized countries, are putting additional strains on self- sufficiency initiatives.

Multinational manufacturers have traditionally supplied a large proportion of the vaccines to EPI, which targets the killer diseases of childhood, are now diverting their business to more profitable products. This move has created a void for EPI vaccines, which is being filled by manufacturers from developing countries. Over 60% of all the BCG vaccine and over 80% of all measles vaccine produced globally are manufactured in India and Indonesia. These factors have direct and great implication for

the policy makers in Pakistan. The 2005 earthquake disaster and 2010 floods in Pakistan had exposed our vulnerability to the critical availability of life saving Vaccines and Biological like anti tetanus serum.

METHODOLOGY

There is a little literature available on manufacturing of vaccines in Pakistan. Therefore, comprehensive review of literature was undertaken the record of the National Health Services Regulation and Coordination Division (NHSCR), considered NIH and the data available with GAVI Headquarter. International and multilateral companies involved in the vaccines business were studied. Work done by UNICEF, WHO, and Project history of EPI since 1978has been reviewed and provided a firm base for this policy paper. This is a desk research correlated with the past 03 National Health Policies i.e. 1990, 1997 and 2001being formally approved/ tabled before the cabinet in different regimes. Work done by Prof. Atta ur Rehman (Ex. Chairman, HEC) and chairman of the vaccines committee (2007) was value addition to accomplish this paper.

DISCUSSION

Vaccine Manufacturers (DCVM) in Developing Countries

The DCVM is an affinity group of vaccine producers comprised of vaccine manufacturing companies from developing and middle-income countries globally, interested in networking and collaboration amongst themselves. The group is made up of state-owned and private large- and small-scale producers. Some member companies are capable to produce high quality vaccines suitable for both local markets for sale and to UN agencies including UNICEF, WHO and GAVI Global Vaccine Fund. Other companies are at earlier stages of development. In order to be a member, the company must be actively manufacturing vaccines for human use.

Vaccines Market Potentials

In Pakistan about 80% of the vaccines market is the public sector. Based on IMS data the total size of the private vaccine market in Pakistan is estimated at Rs. 2 billion annually. This is a small fraction of the annual market size of Rs. 140 billion (US 1.4 billion) for pharmaceuticals. There is an estimated requirement of EPI vaccines of Rs. 28 billion for (2015-20), and Polio Vaccine requirements are Rs. 30 billion for 03 years. The annual requirements of vaccines for EPI is Rs 5.6 billion, and Rs 10 billion for polio in the public sector. Total annual intakes vaccines in public and private sector is Rs 17.6 billion per annum. It is clear that concerted efforts are required to start vaccines production locally as the market is quite sizeable.

In the private sector, there are several multinationals such as Glaxo Smith Kline (GSK), Aventis, Wyeth, Crucill and Novartis, supplying vaccines in the country. Only one national company Amson Vaccines is doing some valued steps in vaccine manufacturing for TT and Hep B vaccines. Following are a few vaccines and industries status in the country: -

Table 1: Vaccines and Industries Status

Vaccine	**Industry**
Hepatitis B	GSK, Aventis, Amson, Macter, Highnoon
Rabies	Aventis, Chiron, Berna and Indian Immunological
Tetanus	Amson, Berna and Aventis
Hib	Aventis, GSK
Influenza	Chiron, Aventis, Crucill and GSKB
Typhoid:	Aventis, Berna & GSKB
Combination vaccines:	GSK, Aventis

The most significant role in public health being carried out by NIH is prevention of vaccine preventable diseases by production of quality vaccines and anti-sera as per WHO guidelines and provides it to national immunization program, government hospitals dispensaries and to armed forces. Production of vaccines is the only corporate function of NIH while rests of NIH functions are non-corporate public health functions.

Manufacturing of quality vaccine and anti-sera is carried out by Biological Production Division (BPD) of NIH. BPD has 06 production units namely;

1. Measles Vaccine Production Laboratory
2. Tetanus Toxoid Production Laboratory
3. Cell Culture Rabies Vaccine Production Laboratory
4. Allergy Vaccine Production Laboratory
5. Typhoid & Cholera Vaccine Production Laboratory

These units manufacture following 09 products by the way basic and shared manufacturing technology.

1. Measles vaccine
2. Tetanus Toxoid
3. Cell Culture rabies vaccine
4. Allergy vaccine
5. Typhoid vaccine
6. Typhoid & Cholera vaccine
7. Anti-snake venom serum (polyvalent)
8. Anti- snake venom serum (trivalent)
9. Anti- rabies serum (ARS)

Vaccine Market in Pakistan

EPI is the largest user of vaccines in the public sector since 1978. It aims at protecting children by immunizing them against 09 vaccines preventable diseases, childhood, tuberculosis, poliomyelitis, diphtheria, pertussis, measles, tetanus and childbearing, and pregnant women against tetanus.

Government of Pakistan through NHSR&C Division provides support to the program through development program i.e. PC-I. The PC-I for the period 2010-2015 at a total cost of Rs. 27.00 billion. This ensures the commitment of the Federal Government for the provision of vaccines, syringes, cold chain equipment, transport, printed material and launching of health education and motivation campaigns. Another PC-I at a cost of Rs.38.00 billion was approved for a period of 05 years 2015-2020. This huge investment is based on the policy direction provided in vision 2025 to meet the SDGs targets related to infant, children, and mothers' mortalities

Routine EPI Vaccine & Requirements

The EPI performance chart for (2015-2020) is given in the following table: -

Table 2: EPI Performance

Sr.No.	Item of Activity/Output	Unit	Scope of vaccines	Financial expenditure (PKR) million
	1. Vaccines	Dose		
1	i) Polio Vaccines	Dose	236733230	157,318,761
2	ii)BCG Vaccines	Dose	60,564,224	65,672,359
3	iii) Pentavalent	Dose	12,721,850	345,301,7624
4	iv) Pneumococcal Vaccine	Dose	2630,600	107,2599288
5	v) Rotavirus Vaccines	Dose	-	-
6	vi) Measles Vaccines	Dose	71,157,893	2,049,469,157
7	vii) TT Vaccines	Dose	63,107,812	439,283,368
	2. Syringes	No.		
8	i) AD Syringes (0.05ml)	No.	26,072,339	179,662,387
9	ii) AD Syringes (0.5ml)	No.	62,696,415	454,431,795
10	iii) Disposable Syringes (2ml)	No.	2, 544,920	14,524,252
11	iv) Disposable Syringes (5ml)	No.	13,238,793	80,858,578
12	**3. Safety Boxes**	No.	1,176,811	119,082,087
	4. Health Education & Communication Material	No.	1,017,859	151,037,055
14	i) Production of TV Spots	No.	7	4,037,210
15	ii) Airing/telecasting	Dose	214	3,203,168
16	iii) Production Radio Spots	Dose	-	-
17	iv) Advertising on Print Media	Dose	4,782	112,689,298
18	v) Advocacy meetings/Seminars	Dose	1,012,856	31,107,379
21	**5. ORS**	Pkt	4,070,000	26,990,000
22	**6. Establishment Charges**	No.	56	145,570,996
23	**7. Contingencies**	No.	Lumpsum	333,071,155
	Total (Local)			**12,746,242,697**
24				
25	**GAVI**			**1,611,666,755**
	World Bank/JICA – PEI			**12,583,762,539**
				26,941,671,991

Source: - EPI, PCI, Federal EPI Programme, 2015 (NHSR&C Division), Islamabad.

Total local cost of vaccines met through the PSDP is Rs, 3.12 billion (11.6 %) of the total cost, whereas donors and development partners are providing vaccines of Rs. 14.2 billion therefore total cost of vaccines is Rs,17.32 billion which is 64% of the total PC-1 cost. The vaccines imported and consumed by the private sector is not corrected. Population of Pakistan is growing at 2.4 % per annum and resources decreased for children & mother vaccines. The financial cost will further enhance that will consume our foreign exchange resources in future.

Non- EPI Vaccines

The following vaccines are used in Pakistan in the private sector. These are not included in any government program: -

a. Tissue culture Rabies vaccine (major vaccine)
b. Anti-Snake Vaccine Serum (available but in limited supply)
c. Meningitis (meningococcal vaccine, special purpose for Hajj)
d. Influenza vaccine (seasonal vaccines, every year a short is required)
e. Varicella vaccine (Chickenpox, underutilized vaccine)
f. Vi-polysaccharide Typhoid Vaccine
g. Combo vaccines
h. Cholera-Typhoid vaccine (classic TAB, century old used in armed forces0
i. Gas Gangrene
j. Yellow fever (available from special outlets)

Wastage of Vaccines

Vaccines wastage factor is important to consider for avoiding the wastage of resources. Following is the wastage chart by WHO for different vaccines: -

Table 3: Wastage of Resources

Vaccine	Allowed Wastage Rate as per WHO and EPI policy guideline	Wastage Factor	Wastage Percentage reported
BCG	50%	2	50%
OPV	20%	1.25	20%
Penta	5%	1.05	5%
PCV	10%	1.11	10%
Measles	40%	1.67	40%
TT	20%	1.25	20%

Source:- Federal EPI Programme, NHSR&C Division, Islamabad

Public Sector Production Facilities

The National Institute of Health (NIH) is a premier research organization in the field of public health. The institute acts as the research arm of the National Health Services Division and a WHO collaborating center for research in viral diagnostics. Its Biological Production Division (BPD) manufactures bacterial, viral vaccines and therapeutic anti sera. Vaccines are produced both from raw material i.e. “Basic Manufacture” and through “Production Sharing” i.e. buying of bulk concentrates and processing for filling and packaging into final containers.

FINDINGS AND WAY FORWARD

1. Low Investment and Limited Production

In order to make real progress both the public and private sectors must play their roles in Pakistan. During the last 40 years, research and development leading to the improvement of the existing vaccines and the development of the new vaccines has gradually shifted to the private sector in the developed world. Many of the public vaccine producers in industrialized countries being the source of know-how and technology transfers to developing world are being privatized or function as viable public-private partnerships. Unlike the situation 40 years ago, most of new vaccine research and development is undertaken by private sector companies and is funded either by private venture capital and/or from profits on sales. Also, public university research becoming increasingly linked to pre-existing intellectual property agreements with private companies.

2. Donor dependence

The GoP working with the donors have developed some Immunization Programmes where there is guarantee of co-financing like the pentavalent with GAVI, is a good proposition in the short run. The donor program is also fraught with the potential risk of interruption, due to the rapidly changing geopolitical and security situation in the world.

3. Human Capacity in Basic Sciences, Biotechnology, Vaccines & Biological

Pakistan has one of the lowest rates of enrollment in basic sciences and molecular biology in its centers of higher education. Despite all investments at the biotechnology end, unless there is trained manpower, and a research culture in our education and research institutions, the dividends will be very limited and short lived. Policies should evolve that focus on bridging the gaps in skilled manpower with critical thinking and laboratory skills that will enable us to achieve these goals.

4. Absence of Vaccine Policy

There is no clear policy for Biotech products and vaccines to encourage investments in this sector. The neighboring country India and Iran have taken it seriously by offering many incentives and technology grant supports which translated into the growth of this segment.

5. Inefficiencies in Drug Regulatory Authority (DRA) and Drug Testing Labs

To monitor the quality of locally produced vaccines, a fully functional Regulatory Authority is an urgent need of the day. There is a slow performance DRA in Pakistan. This is a

serious bottle neck and need immediate attention of the policy makers.

6. Incentives in Vaccines Manufacturing Sector

Consistent government support, for the success of projects of national interest, cannot be undermined by any means. A few avenues, where government's support would be required are:-

a) Tax Holiday

Reduce the operating cost and keeping the final price of local vaccines in check, duties & taxes need to be lowered. e.g. Tax holding for 10-15 years may be granted. In consultation of Finance (FBR), Commerce, and Industry Divisions, the following incentives may be considered:-

- Corporate Tax on Income of the company may be exempted. Income, profits, gains made out of the project should not be taxed during tax-holiday period.
- Turnover Tax on Sales Revenue of the company to be exempted.
- Zero rating of .W.H. Tax, Sales Tax, and Excise Duty on Import of PME (Plant, Machinery, and Equipment), tools, and consumables.

7. Buy Back Agreement

Government of Pakistan should offer a "Buy-Back Agreement" with the vaccine producers to ensure production at an economically viable level on consistent basis. Among other things, the buy-back agreement should:-

- Define methodology for the sale and purchase of vaccines and commercial terms including billing and payments.
- Assure a minimum amount (revenue) every month to the company for meeting operations and maintenance expenses, debt servicing, insurance changes, and expenses of fix nature.
- Fix payment obligations for the purchaser (public sector entity) and guaranteed by GOP.

8. Research & Development Cost Sharing

Research & Development is an investment in future; and biotech, of all fields, perhaps needs it more today than ever before (Pakistan's scenario). Local production of vaccines should be complemented by an equally effective and intense effort in R&D. It will play a pivotal role in future success and attaining self-sufficiency-level for the new product.

9. Strategies for Local Purchase of Vaccines

Considering the industry requirements and plea for incentives to produce quality vaccine with technology transfer components, the following strategies can facilitate the process which are grouped in different categories.

a) Biological Production Division (NIH)

There are 03 projects costing Rs.62 million funded through PSDP are und implementation in N.I.H. Funds allocation for the project is Rs. 24 million during 2019-20. Following is the detailed statement of projects with cost and funds allocation: -

Table 4: Projects with Cost and Funds Allocation

Sl. No.	Name of Scheme	Estimated Cost	Allocation 2019-20
1.	Establishment of NIH Allergy & Vaccine Centre at CHE Hospital-NHSRC, Shahbaz Town, Quetta	55.586	17.586
2.	Feasibility study for Project "Up-gradation of Drugs Testing facilities in Drugs Control and Traditional Medicines Division NIH, Islamabad	3.000	3.000
3.	Feasibility study for Strengthening and capacity enhancement of ORS Production unit according to the current GMP standards at NIH, Islamabad	3.500	3.500

Source, PSDP, PDR, June 2019.

The strong role of the national public sector vaccine production facility i.e. the NIH Vaccine Laboratories is recognized. This institution needs to be strengthened and allocated the required resources and manpower to meet the challenge of local production of vaccines.

b) Private Sector

- National Industry must be encouraged to increase investments in vaccine R&D especially in sectors where the public sector is not currently developing vaccines or unable to meet the national demands. These include TT, Measles, BCG and combination vaccines like pentavalent liquid vaccines or future Therapeutic vaccines etc.
- The local industry should be given a decisive and preferential treatment in Public Sector National level program like EPI and Prevention of Hepatitis for vaccines and Biological which include biotech products and therapeutic purposes.

c) Human Resource Development.

The HEC, MOST and NHSR&C should allocate sufficient funds to initiate research projects on related topics under the supervision of identified investigators in Universities of Pakistan. Post-graduate students should be trained, and encouraged to work in the following research areas;

- Study the immunobiology of particular pathogens to identify the candidate immunogens for better vaccines to prevent such infections.
- Investigate the short comings in vaccines produced by old technologies to justify the use of new methods for developing more effective and cheaper vaccines.
- To develop and study novel approach to address the immunopathological questions related to vaccines.
- Studies to identify advantages over technologies and uniqueness for particular immunological problems. Such investigations are necessary to understand the technicalities involved in developing a successful vaccine production program.
- Studies on Edible, DNA and other research vaccine.
- Studies on Biotech products like Biopharmaceuticals and Therapeutic vaccines.
- Studies on Interferon interleukin action and its role on resistance to antiviral therapy.
- Joint Collaboration with China to get vaccine technology through CPEC

can be sought out. Similarly, the collaboration for vaccine production may be taken with the regional muslim countries including Iran, Egypt, Tunis and Indonesia.

10. Training of Scientists and Researchers

- Ensure active participation of trained and qualified Immunologists, Pediatricians, Microbiologists, Biochemists, Epidemiologist, Clinicians, Quality Assurance Experts, Veterinarians and other Basic Scientists at all steps involved in vaccine/ Biological Product Preparation as per WHO Criteria.
- These experts should be involved in activities like GMP inspections, clinical evaluation, proper testing of local and imported Biologicals.

11. Veterinary Vaccines

This is one of the most important segments in Vaccines. Its economic impact is comparable to human vaccines. This can revolutionize the social sector in Pakistan. It is a strong supporting agent for livestock ultimately help the poor people in the rural areas.

The six institutes in Pakistan producing these vaccines include:

- Veterinary Research Institute Lahore
- Veterinary Research Institute Peshawar
- Veterinary Research Institute Quetta
- Sindh Poultry Vaccine Center Karachi
- Nuclear Institute of Agricultural Biology Faisalabad
- Poultry Research Institute Rawalpindi

Almost 95% of vaccines against large animals are produced locally in public sector institutes. But Foot and Mouth diseases vaccines are imported. A few private entrepreneurs have started to produce vaccines in limited quantity. About 2- Domestic Poultry is not fully vaccinated; however, all commercial poultry farms are hundred percent vaccinated against the viral disease. The Breeders of flocks do not use local vaccine to avoid vertical transmission of virus. It is estimated that poultry vaccines worth Rs. 1.2 billion are imported every year. There is urgent need to have Specific Pathogen Free Eggs production facilities in the country for the production of better-quality vaccines. Biotechnological Interventions can be very effectively used for production of better-quality vaccines for poultry diseases to capture ever-increasing demands for all types of poultry vaccines.

Vaccines for the infectious disease of dogs and cats are imported. The Veterinary Research Institute (VRI) Lahore is producing Anti-Rabies vaccine for dogs in limited quantity but these are not well accepted by the dog's owners. They prefer to use imported vaccines for their pets/dogs etc. It is estimated that every year 02 million doses of Rabies vaccine for dogs and cats are imported.

CONCLUSION

The needs for public health and new vaccines in Pakistan are enormous and increasing. Despite, the mandate of the NIH to supply the vaccine needs of the country, the majority of public sector vaccine requirements have been met through import of vaccines produced by multi-national suppliers. The NIH has been providing a fraction of national requirements. Pakistan has fully advanced in the field of technology, know how, and having well qualified and trained human resources. Indigenous vaccine production can be started with the support of the available HRD and Technology, and gradually these inputs can be refined for enhanced Production and export of vaccines to other countries of the regions.

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