Original Article

Highlights of the final draft of the national policy document for science, technology and innovation in vaccine production in Iran

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ABSTRACT

Introduction: Vaccination has been the most effective human intervention in alleviating human sufferings and death. Vaccine production in Iran has a long history; however, in the face of a changing global landscape, it requires a new roadmap for research, development and production in the coming decades. **Methods:** This document was drafted based on Article A of the "Comprehensive National Scientific Roadmap", in compliance with priorities laid out in the primary directives as well as the key concerns of the stakeholders outlined in the 20-year vision for the country, the fifth development plan, the Comprehensive National Scientific Roadmap and the Scientific map of Health System. In addition, policies of various developed and developing countries, related WHO publications and published literature on policymaking were reviewed to obtain data pertaining to topics such as the current vaccine landscape, historical and current trends, the challenges and obstacles in vaccine research, development and production as aids to decision making. **Results:** In the course of several sessions, the selected panel outlined the vision, mission, expected outcome, main objectives and the founding principles of the national policy document for science, technology and innovation in vaccine production in Iran. In addition, guidelines in areas of policymaking, management and laws, financial resource allocation, knowledge production, publication and knowledge sharing, human resources, expansion in product manufacturing and services, entrepreneurship and communication were outlined. **Conclusion:** Vaccine production in Iran is facing many challenges and to become a successful player in the global vaccine market, it requires implementation of the guidelines that have been outlined in this draft. Remaining a supplier of traditional vaccine to the domestic market, in the face of increasing competition from the emerging manufacturers, is not a viable option for this industry.

KEYWORDS: Vaccine production, policymaking, Iran.

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INTRODUCTION

The benefits of immunization as one of the most successful and cost-effective methods in preventing debilitating diseases and disabilities have been clearly demonstrated with an impact on mortality reduction, second only to clean water [1].The basic observation made by the ancient Greeks in 430 BC that recovery from a fatal disease ensured immunity against the same infection, is considered the beginning of vaccination [2]. Furthermore, in the Middle Ages in India, China, Egypt and the Middle East, vaccination was practiced through exposing healthy people to virulent smallpox virus by various means which although effective, was highly dangerous till the milestone discovery by Jenner that the same results could be obtained by a non-virulent microorganism producing attenuated form of the disease [3]. Since then, vaccines have become an irreplaceable tool in the fight against communicable diseases with more than 70 licensed vaccines against nearly 30 microbes [4].The last century saw a burst of activities in the field of

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research, development and production of vaccines, but several challenges have still remained such as effective vaccines for human immunodeficiency virus (HIV), malaria and tuberculosis, with a yearly mortality rate of 4 million worldwide [4]. However, recent advancement in different scientific areas such as immunology and microbiology, the advent of recombinant DNA, genomics, system biology and conjugation technology as well as rationally designed adjuvants may result in better vaccines, allowing better control of the existing diseases. These new technologies may also provide the means for controlling newly emerging infectious diseases and noninfectious diseases such as cancer, neurodegenerative, autoimmune, and metabolic disorders that are the leading causes of morbidity and mortality in modern society [5].

The history of vaccine production in Iran dates back from 1920 when vaccines for smallpox, cholera, typhoid, rabies and BCG were produced in Pasteur Institute of Iran through transfer of technology from France [6]. However, except BCG production, the remaining vaccines have discontinued since smallpox was eradicated and improvement in sanitation made vaccination against cholera and typhoid unnecessary. Animal rabies vaccine is still in production and the institute has been producing recombinant Hepatitis B through an agreement with Cuba in recent years.

Another center that is engaged in vaccine production is Razi Vaccine and Serum Research Institute which was founded in 1924 with a mandate to produce vaccines for veterinary use. However in 1941, Razi Institute manufactured sera and vaccines for diphtheria and tetanus, and added polio to its production list in 1970, then rubella and measles in 1987 which have been continued till present day while it also markets combined mumps, measles and rubella (MMR) as a trivalent vaccine [7, 8].

The history of immunization against smallpox in Iran dates back to 1829 and in 1943, an act for mass vaccination was passed through the Parliament. Although the compliance was not high, the integration of the expanded program on immunization (EPI) in the primary health care system have resulted in>95% immunization coverage with BCG, MMR, DTP (diphtheria-tetanus-pertussis), OVP (oral polio vaccine) and hepatitis B in children under 5 years of age [9].

Vaccine supply crisis in the late 1990s which was brought about by a drop in the number of suppliers, a cutback in vaccine surplus and a gradual change in the type of vaccines used in the developed compared to developing countries, highlighted the need for reliable and secure local production [1]. Therefore, subsequent to the report from the Ministry of Agriculture in 2011 on vaccine production and priorities in the Ministry of Health, it was proposed that The Policy Document for the Science, Technology and Innovation of vaccine production in Iran for the 2025 Horizon, be drafted.

MATERIALS and METHODS

The project was undertaken by the Commission for Health, Food Security and Social Welfare of the Science, Research and Technology Council in collaboration with the Secretariat for the Research and Development of Academic Policies in Health, affiliated with the Tehran University of Medical Sciences. The policy has been outlined with reference to Article A of the "Comprehensive National Scientific Roadmap" encompassing biotechnology, molecular medicine and prevention topics as well as being consistent with the goals set out in paragraph 8 of the section on national science, technology and innovation in health system.

The following processes were undertaken for preparation of the national policy document:

1. Identification of the prerequisites from primary directives in order to identify the priorities laid out in the primary directives as well as the stakeholders' key concerns for the followings were carefully reviewed:

The 20-year vision for the country.

The fifth development plan.

The Comprehensive National Scientific Roadmap.

The Scientific map of Health System.

2. Benchmarking:

Policies of various developed and developing countries including U.S.A., Canada and India as well as related WHO publications and published literature on policymaking were reviewed to obtain data pertaining to the current vaccine landscape, historical and current trends, the challenges and obstacles in vaccine research, development and production as aids to decision making [10, 11].

3. Panel selection:

Participants in drafting this document were selected from vaccine production managers, experts in vaccine production, academia, and executive officers from the Ministries of Health and Agriculture.

Working agenda

The panel during several sessions concentrated on setting out the context of the policy including the vision, mission, goals and expectations from the implementation of the national policy of science, technology and innovation in vaccine production in Iran using a standard methodology. It surveyed the current production status, the strengths, weaknesses of the industry, opportunities and threats and drafted into the policy document, the WHO regulatory policies and orientations.

The first draft was prepared by compilation of data from all the sessions and the prepared document was presented in a one-day seminar for review and assessment by the experts.

RESULTS

The results obtained from the sessions are summarized as follows:

a) Vision

The vision for this national policy was for Iran to become one of the world's scientific leaders of the Islamic countries in the vaccine field by 2025. By that year, the system for science, technology and innovation in vaccine would be a network of dedicated, skilled and innovative researches, linked to strong governmental agencies that forge constructive cooperation with the private sector. Such system would react to environmental changes with foresight and by mastering the key vaccine-related scientific and technological issues and would lead the research and development in the vaccine field in the Islamic world.

b) Mission

The mission was defined as providing the capacity for mass production and development of safe, effective and timely vaccines with national and international marketing standards under the supervision of governmental organizations in order to improve the quality and life expectancy, create wealth, jobs and prevent brain drain.

The expected outcomes of the country's development in vaccine science and technology

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1. Improvement in health, quality of life and life expectancy.
2. Job creation for the graduates to retain our talents.
3. Generating wealth and to increase the gross domestic product.
4. Strengthening the scientific and technological bargaining powers of the country with improvement in negotiating skills.

Founding principles of the system for science, technology and innovation in vaccine production

The system for science, technology and innovation in vaccine production is based on the following principles:

- Cooperation and networking: Mutual respect in cooperation with partners, formation of networks and industrial consortia through association of knowledge-based companies for increased international competitiveness.
- Technology and innovation: Innovation and new technologies are recognized as the key factors for competitiveness; therefore, those involved in this system would embrace new ideas and technologies to sustain a competitive edge in the international markets.
- Human resources: The 4 key elements of technology are technoware which includes tools, machineries and equipment, infoware that provides designs, procedures, standards, and document-embodied knowledge, orgaware is the organizational knowledge needed to operate a given technology and humanware which refers to human abilities needed to use and manage these components. Technology without competent and adequate human resources is rendered meaningless, particularly, soft technology which requires a critical mass of appropriate human resources with necessary skills.
- World-class status in vaccine manufacturing: The aim of the players in the system for science, technology and innovation in vaccine production is to acquire and maintain an international standard of excellence.
- Professionalism: The Iranian Science, Technology and Innovation system is based on Islamic code of conduct and professionalism.

Objectives of the System for Science, Technology and Innovation of vaccines in the "2025 Horizon"

- Inclusion in the list of the top 10 countries in the field of vaccine production.
- Obtaining a 3% share in the sale of vaccines in the world market.
- Establishing two vaccine production facilities with internationally-recognized Iranian brands.
- Obtaining export licenses for all vaccines produced in Iran through acquiring international regulatory approvals.
- Establishing 5 production plants abroad with Iranian brands.
- Formation of at least 60 private knowledge-based companies in the field of vaccine.
- Reciprocal interaction and cooperation with international regulatory agencies.
- To achieve high performance in all the indicators of vaccine science and technology in the Islamic world.

Policy recommendations for development in vaccine science technology and innovation by 2025

The following categories of policy guidelines outlined in this document are in line with the governing policies of the Science, Technology and Innovation System of the National Health.

1. Policymaking, management and laws:

   - Coordinated management and leadership in the vaccine field.
   - Strengthening national regulatory systems and optimization of SMART-based evaluation system for development, production, control and export of vaccines in order to ensure product safety and licensure by World Health Organization.
   - Legislating the intellectual property laws and regulations, covering all aspects of vaccine production.
   - Stabilization in specialized management policies of vaccine research and educational institutes.
   - Policy shift towards focus on solving country's strategic problems.
   - Supportive policies for private sector participation in the field of vaccine.

2. Financial resource allocation, incentives and financing strategies for increased investment funds:

   - To form supportive channels (fiscal and non-fiscal) for vaccine-related companies.
   - To offer facilities to vaccine exporters, especially to Islamic countries.
   - To establish a fund in support of vaccine science and technology.
   - To attract special support from country's supportive funds.
   - To adequately support all those involved in value chain of vaccine development.
   - To attract funds from other countries.

3. Knowledge production:

   - Expanding basic and applied research in vaccines for non-infectious diseases.
   - Building capacities for knowledge management at vaccine production centers.
   - Research collaboration with countries with technology in priority vaccines.
   - To strengthen and support country's mission–oriented research institutes.
   - To establish a National Vaccine Research Network.
   - To develop, renovate, reconstruct and upgrade vaccine development and production facilities.
   - Transfer of up to date and advanced technology for 10 prioritized vaccines.

4. Publication and knowledge sharing:

   - To support specialized publishing in vaccine topics and to establish the country as a regional reference center in vaccine production.
   - To identify and to transfer existing technologies from public to private sector through vaccine techmarts.

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5. Human resources:

- To develop appropriate human resources with necessary skill sets in multiple sectors and at different levels.
- To develop human resource pyramid for vaccine with focus on research leaders training.
- Human resource sharing with countries with advanced vaccine science and technologies.

6. Expansion in product manufacturing and services:

- To monitor market needs in vaccine production and ancillary products/services of the regional countries to expand exports.
- To produce tailored vaccines (mono-component, multi-component and/or combined) and related products/services for export especially to Islamic countries.
- To create product-based research groups at research centers.
- To support the stability and establishment of national trademarks in the vaccine field.
- To support trade organization of vaccine producers.
- To develop, accelerate and facilitate authorization processes for manufacturing- distribution of locally-produced vaccines in compliance with international regulations with the aim of obtaining international licensure.

7. Entrepreneurship:

- To grant special facilities for commercialization of modern vaccine technologies.
- To create required facilities to place companies actively engaged in development of vaccine value chain in related science and technology parks.
- To encourage academic members of the universities and research institutes to establish knowledge-based small and medium vaccine enterprises.
- To create a guaranteed market linked to safety and efficacy standards by government advance purchasing, to reduce risks to the investors.

8. Communication:

- To promote active membership in regional and international vaccine networks.
- To establish and support vaccine scientific associations.
- To support vaccine patenting for Islamic world researchers in Iran.
- To fully engage in specialized corporation of Islamic countries in the vaccine fields under the supervision of Islamic Organization Conference (IOC).
- To enforce the interrelationship between vaccine-oriented organizations through networking, signing memorandum of understanding (MOU), information technology-oriented structures and multi central studies.

Implementation and evaluation

The "Special Committee for Vaccine Development" established in the Ministry of Health will take the responsibility of implementation and evaluation of this national policy**.**

Target audience

The primary audiences of this document are the senior executives of the Ministries of Health, and Agriculture as decision makers and organizations involved in vaccine manufacturing.

DISCUSSION

The success of vaccination in alleviating human suffering and mortality due to infectious diseases has been unprecedented [4]. The benefits of immunization and advances made in medicine, biotechnology, human immunity and microbiology has increased the potentials for improving the existing vaccines and developing new ones for communicable as well as non-communicable diseases. Although vaccines are a highly cost-effective health measure, in recent years the manufacturers in developed countries have been reluctant to invest in vaccines against diseases predominant in the developing world [10]. The changing global economy and the uncertainties and inequities brought about by a changing vaccine market have reemphasized the need for a national strategy for strengthening the local capacity for vaccine research and development. Iran has recently joined the Developing Countries Vaccine Manufacturers Network (DCVMN) which is a non-governmental voluntary association of vaccine manufacturers aiming to supply affordable good quality vaccines to developing countries. However unfortunately, the production has not been able to supply the local demand which has been supplemented through procurement from other members of the network [10].

The guidelines outlined in this national policy draws attention to major challenges that impede the establishment of an economically viable industry in the short to medium term. These challenges which include insufficiency of trained technical staff, reliance on imported raw materials, absence of policy consistency, inadequate quality control and regulatory measures and substandard infrastructure make timely and affordable vaccine development and production improbable. It has been estimated that developing a new vaccine costs between US$163 and $518 million to which additional costs on the road to licensure is added amounting to an upward of $500-$1billion and taking a minimum of 15 years [12]. Therefore, for most developing countries such an undertaking has been considered unrealistic, making the technology transfer a more attractive option. Iran became an observer member of World Trade Organization (WTO) in 2005 and currently is engaged in the first level of negotiation for the accession [8]. Joining WTO puts certain constraints on vaccine industry since for the approved vaccines, specific processes might be subject to intellectual property, requiring alternative production methods. Furthermore, for recent and future vaccines, the intellectual property would be a barrier to the technology transfer which would become a greater problem after 2016 deadline for enforcing pharmaceutical patents in WTO member countries comes into effect [10].

It has been estimated that the global vaccine market will be around US$ 84.44 billion by 2022 from around US$ 32.05

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billion in 2012, resulting from the introduction of new products and rise in the demands [13]. Presently, the market is dominated by the developed world and the share of the developing countries is estimated at around 20%; however, it is anticipated that the collective share of India, China, Brazil, the Russian Federation, Republic of Korea, and Turkey (all members of the DCVMN) to become larger than the developed markets by 2020 [13].

In view of the changes in the global vaccine market, it is imperative that the vaccine industry in Iran should change since remaining a supplier of traditional vaccines to the domestic market in the face of increasing competition from the emerging manufacturers is not a viable option [14]. The published consensus for becoming a successful player in the global vaccine market is mainly those that have been outlined in this draft. Meanwhile, criticisms recently leveled at policymaking in science and technology in Iran, state that many issues raised by the policymakers are mainly fashionable ideas despite their socio-economic relevance and are based on insufficient methodological studies and critical reviews. These criticisms however, overlook the complexity and uncertainties inherent in the relationship between policies and implemented programs and how the macro world of policymaker is integrated with the micro world of individual implementers [16]. Furthermore, the association between planning and execution is non-linear, multi-factorial and highly context-dependent and this complexity should be taken into account in policy evaluations.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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