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Development and use of genomics and biotechnology for public health

Contents

Executive summary

The unravelling of the human genome has ushered in an era that promises renewed hope for better health for the people of the world at individual, community and national levels. It offers new approaches to bridge the divide between the rich and the poor in health care. During the past three decades, as the understanding of genetics has improved, so has the technology for its applications. Highly sensitive tools have been developed for diagnosing, curing and preventing diseases. The knowledge of disease pathogenesis has improved and the understanding of the impact of environmental factors on diseases has become clearer. The rapid advances in biotechnology have brought significant changes in health care and economies in the industrialized world. Some developing countries are now investing in research and development in biotechnology with the aim of improving the health of their people and for overall national development.

While it is important to embark on biotechnology development, it is equally important to be wary of the dangers it might bring with it. The social, ethical and legal issues, risks to those who are marginalized and vulnerable, and risks to the environment, including plants, animals and microbes, need proper assessment. Public education is crucial to allow people to make informed choices based on risks and benefits, and to put into place necessary regulations to prevent any abuse of biotechnology.

Within the Eastern Mediterranean Region, several countries have fairly well developed genomics and biotechnology facilities. Most of this technology, however, is related to agriculture or other non-health sectors. Health-related biotechnologies in countries of the Region at present are mainly focused on genetic markers to detect monogenic diseases, such as sickle-cell disease and thalassaemia, and highly sensitive diagnostic markers for many common infectious diseases. It is extremely important to ensure that applications of genomics and biotechnology are not undertaken at the expense of existing programmes that are already known to work and to benefit health care. The key challenge therefore is determining how to develop and apply the new knowledge in genomics and biotechnology to supplement what already exists, and how to shape future national health interventions.

The future of genomics and biotechnology depends upon public understanding and support. Investments in education in science and technology are paramount. Member States need to adopt policies and develop national strategies for capacity-building and strengthening of genomics and biotechnology. The focus of research and development should be on priority areas such as diagnostics, vaccine production, biogenerics and bioinformatics. Member States need to create favourable environments for research and development in genomics and biotechnology and facilitate collaboration between partners in developed countries. Lastly, it is crucial to raise and provide funds to support and stimulate development in genomics and biotechnology. Initial investments may indeed be high, but the long-term dividends will be enormous and will include improved health, better economic status and increased equity.

1. Introduction

The scale of the human genome project has been unprecedented in the history of biology. The mapping of the human genome is the culmination of efforts by the International Genome Sequencing Consortium that included hundreds of scientists working at 20 sequencing centres in China, France, Germany, Japan, United Kingdom and United States of America [*1*]. Some equate this feat to the splitting of the atom or to man's landing on the moon. Regardless of the analogy, there is no doubt that this achievement ushers in a new era of science and unveils prospects for bold new directions and research towards improving the lot of humankind.

The world today has been equated with a global village, but one in which the distribution of knowledge, wealth, power and health is skewed. Low and middle-income countries account for 85% of the world's population and 92% of the global disease burden [*2*]. 90% of health research is targeted at problems that affect 10% of the world's population. The rapid pace of developments in the science of genomics[*] and biotechnology in the industrialized world is threatening to widen this gap further. The imperative for developing countries is therefore to reach out now and make use of these technologies to improve the health of their people, otherwise the bridging of the health (and economic) divide in this global village will remain an elusive dream.

Many countries in the Eastern Mediterranean Region have recognized the opportunities that genomics and biotechnology offer in health and related sectors, and are already trying to acquire the necessary skills and expertise on their own. WHO's Regional Office for the Eastern Mediterranean (EMRO), with the support of Member States, has embarked upon a renewed policy for health research and development in the Region. In September 2003, EMRO organized an executive course on genomics and public health policy in Muscat, Oman, in which eminent regional scientists, managers, policy-makers and representatives of civil society participated. The urgent need to make use of the applications of genomics and biotechnology for improving public health in the Region was clearly highlighted at this meeting.

The aim of this paper is to look beyond Muscat and take the message forward. In doing so, the paper examines the role of genomics and biotechnology in improving health care in developing countries. Specifically, the paper focuses both on how these technologies can lead to bridging of the global health disparities and on the possible consequences of failing to utilize these technologies. The case for developing genomics and biotechnology in the Region as a supplement to proven and existing technology for health benefits is made, and the need for Member States to develop sustainable environments and conditions for nurturing these technologies at national levels is highlighted. The paper begins with a historical review of genomics and biotechnology advances, particularly in relation to health sciences, their impact on health and benefits to the society. It describes briefly, the current status of genomics and biotechnology in the Region and draws attention to some key challenges, concerns and constraints. Finally, future actions are suggested with regard to applying genomics and biotechnology for the benefit of the health of the people of the Region.

2. Historical background

In its purest form, the term biotechnology refers to the use of living organisms or their products to modify human health and human environment. Since prehistoric times humans have been unwittingly utilizing biotechnology to their benefit. Our ancestors mastered the art of making bread, wine and beer though the process of fermentation (a natural process), where the biological activity of unicellular

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[*] Genetics versus Genomics

Genetics is the study of heredity and variations in organisms. It focuses on gene structure and possible variations to understand a clear picture of a potential for a condition. Genomics is defined as the study of the genome and its actions. The term refers to DNA contained in the cell, including the chromosomal as well as the mitochondrial DNA. Genomics thus involves the analysis of the full DNA sequence of an organism. The main difference between the two terms is that genetics scrutinizes the composition and functioning of single gene(s), whereas genomics addresses the working of all genes and their interrelationships in order to identify their combined influence on the growth and development of the organism.

organisms plays a critical role. They also found out that, by manipulating the conditions under which the fermentation took place, they could improve both the quality and the yield of the ingredients. Farmers long ago noted that the best plants gave the highest yield, resisted periods of drought and disease and tended to retain their characteristics in future generations. They learned that through careful seed selection they could maintain and strengthen their crops. The first animal breeders learned that different traits could be either amplified or lost by mating appropriate pairs of animals. They consistently engaged in such manipulations to produce the finest domesticated animal breeds to satisfy their interests and needs. In doing so, they mimicked the naturally occurring process in which only those members of a species that are healthiest and best suited to the environment survive.

The evolution of science in human history, especially during the past two centuries, has enabled a clearer understanding of the biological processes that underpin life itself. Mendel's experiments on hereditary traits in peas (in the mid 1860s) paved the way for understanding the genetic basis for heredity, and the benefits of cross-breeding and hybridization became apparent. The scientific basis of biotechnology was thus grounded. Major outbreaks of disease in overcrowded industrial cities led to the development and installation of large-scale sewage purification systems based on microbial processes at the turn of the 20th century. The discovery of penicillin by Alexander Fleming in 1928 derived from *Penicillium* mould was a landmark breakthrough and a legacy of early 20th century biotechnology.

The pace of understanding and knowledge about genetics and genomics advanced exponentially after the discovery of the double helix structure of DNA by Watson and Crick in 1953. By 1973, scientists began unravelling specific gene codes, developed methods for splitting DNA molecules and began inserting genes into bacterial DNA. The modern age of genetic engineering was ushered in. A decade later, the revolutionary polymerase chain reaction (PCR) technique and "genetic fingerprinting", in which individuals can be identified by the analysis of their DNA sequences, were invented. With these inventions, the pace of genetic science and technology development accelerated. The human genome project, launched in 1986 with the goal of sequencing the entire human genome and cataloguing every human gene, was successfully completed a decade and a half later. Scientists are working tirelessly to map the genomes of other species, including microbial organisms, parasites, plants and animals. To date, genomes of over 30 important bacteria have been sequenced, and the number is rising. The primary aim of plant genomics is to identify genes that control important traits, such as growth, high yield and disease resistance. There is evidence that the genetic modification of plants may in the future offer possibilities for effective delivery of vaccines and therapeutic agents.

> The understanding of the structure and functions of genes within a genome, whether human, microbial or plant forms the basis for not only diagnosis, prevention and control of diseases, but also for identifying targets for development (and delivery) of new drugs and vaccines against diseases.

3. Risks and issues in genomics and biotechnology

3.1 Social, ethical and legal issues

Genomics offers an understanding of genetic inheritance and the role of genes in phenotype determination, whether human, animal, plant or microbe. At the same time, it provides the potential to control and manipulate human nature. In order to reap the full benefit of contemporary genetic developments, it is extremely important to avoid unethical concepts and practices. The challenge for contemporary genetics is to ensure that individual rights are not compromised to benefit some greater social good, and vice versa. There is therefore a need for clear definitions of what constitute unethical practices in pluralistic societal value systems.

- Breach of consent or confidentiality. Issues such as informed consent, confidentiality, stigmatization and discrimination are not unique to genomics. However, within the genetic context, these issues need re-examination. This is because of the fact that the genetic information of an individual is predictive of future health not only for the individual in question, but also for his or her entire family. This may lead to serious potential for social discrimination (e.g. in employment, health insurance). New limits of confidentiality therefore need to be defined to reflect this special characteristic of genetic information. Use of genetic information must be adapted within the different social, cultural and religious contexts in the light of controversial practices such as abortion and mandatory genetic testing.

- Discrimination against women. Genetic information can be used to discriminate against or stigmatize women in many ways. For example, it can: a) make women unmarriageable if they are known to harbour genes for diseases; b) harm women both physically and otherwise if they give birth to children with diseases for which they may be deemed responsible; and c) be used to carry out sex selection and prevent the birth of female children. Women may be coerced into undergoing non-therapeutic abortions of female fetuses and be exposed to unnecessary physical as well as social and psychological risks.
- Using human embryos in research. The use of embryonic stem cell research to develop a wide range of adult tissues needed for organ repair raises serious ethical issues that include the status of a human embryo, and the potential for human reproductive cloning. In stem cell research, large numbers of embryos are first created and then are destroyed, because they are used for the purpose of producing different organ tissues. This raises a serious ethical dilemma. Obviously, there is an overwhelming need to develop tissues for organ transplant. A clear distinction must be drawn between therapeutic cloning and reproductive cloning. The latter is currently universally not accepted, as there is no ethical basis for this kind of work.

3.2 Risks in non-human genomics

Genetically modified (GM) animals are being engineered to produce milk or therapeutic agents to benefit humans. GM animals are being produced that stay healthy, offer higher yield and eat less. Insects that spread disease are being genetically modified in a way that renders them incapable of transmitting disease. The potential hazards of these new practices must be carefully evaluated to minimize adverse harm that might occur not only to the GM species but also to humans, adverse effects on environments and ecosystems, and changes in the ability of animals to be reservoirs for human disease. These practices therefore need mechanisms for careful monitoring and control.

GM crops are now grown in developing countries at twice the rate of the industrialized world, and one-third of the world's GM crops are now produced in the developing countries [*3*]. GM crops raise a wide range of safety concerns that include the use of microbial and fungal cells for processing additives and enzymes, potential hazards of introducing foreign DNA into plants, and impact on humans and soil. The need for safety regulations and thorough vigilance against threats from GM food is paramount. Recent research to evaluate the environmental impact of GM crops is ambiguous about whether such crops are safe or hazardous for wildlife. The research showed that GM maize cultivation actually increased wildlife; however, cultivation of GM oilseed rape and beet crops reduced the natural vegetation necessary for wildlife to thrive [*4*]. Application of GM crop technology must therefore be considered on a case by case basis, evaluating rationale, need and evidence.

3.3 Genetic databases

The concept of genetic databases is not entirely a new phenomenon. Many countries maintain national registers or databases for genetic diseases for the purpose of providing necessary services, such as family counselling and disease control. However, genomic databases are different in terms of size, scope and format. Most of the data generated by genome sequencing are being deposited into public databases and made available to scientists all over the world. Researchers in academia and industry continuously scan and mine new troves of genome information for potential application and use. DNA samples from populations are obtained to facilitate research on genetic factors in common diseases. A number of concerns are inherent in the use of such databases, such as privacy, consent for usage of data information, stigmatization of individuals or communities, commercial exploitation and sharing of benefits, and access by third parties such as insurance companies, government bodies, lawyers or even police.

3.4 Biological warfare and misuse of genomics and biotechnology

The use of germs and microbes in war, or ‘germ warfare’, has been practised for centuries, with increasingly lethal consequences as understanding of the science of microbiology has improved. The advent of genomics and biotechnology has enhanced the technology of germ warfare and production of hazardous GM organisms. Molecular-level information on pathogen virulence gathered to combat disease and improve health can be maliciously used to design germs with destructive potential. Stringent regulatory mechanisms are therefore needed to prevent the technology from being misused.

> Although the science of genomics and biotechnology opens up new avenues for improving global health, the potential risks must never be underestimated. Knowledge in this science is still evolving. It is therefore important to understand and assess the risks and the benefits involved, so as to make informed decisions that both allow the new science to thrive and that protect people from possible harm.

4. Potential of genomics and biotechnology for public health in developing countries

4.1 Genomics and world health

The WHO report *Genomics and world health* highlights the need for better and advanced technologies for combating diseases in the developing countries [*5*]. The report argues strongly in favour of the role of genomics and biotechnology in developing future health care and in public health. It explains how the understanding of the structure and functions of genes within a genome, whether human, microbial or plant, are the basis for not only diagnosis, prevention and control of diseases, but also for identifying targets for development of new drugs and vaccines against diseases, as well as for producing high yield crops.

4.2 Genomics and biotechnology in communicable diseases

The burden of communicable diseases in most developing countries is huge, and the impact of traditional and conventional methods of communicable disease control has remained largely unsatisfactory. There is thus a dire need for improved and specific aids and technologies to facilitate reduction of the communicable disease burden in developing countries. There is already ample evidence showing how the advent of genomics and biotechnology is making headway in combating infectious diseases. Examples of beneficial developments include development of DNA-based diagnostics for communicable diseases, such as PCR technology; understanding of drug resistance in organisms such as those responsible for tuberculosis, HIV/AIDS and malaria; development of targets for drugs and vaccines against infectious diseases; and understanding of vector genetics. Already, a new class of anti-malarial drug that is effective against multidrug-resistant parasites, less expensive and easy to store, is being field-tested. Vaccines developed through genetic research against tuberculosis, malaria, and other diseases are in different stages of development, and better diagnostics are evolving against hepatitis, HIV/AIDS, leishmaniasis and dengue fever and for monitoring treatment and control. The potential of the technology to combat new epidemics is well illustrated by the early recognition and halting of the SARS epidemic in 2003.

4.3 Genomics and biotechnology in noncommunicable diseases

The potential of genomics and biotechnology to control chronic diseases has long been envisaged, and global research endeavours have made significant advances in understanding the genesis and causation of a number of noncommunicable diseases, including cardiovascular disease, cancer, diabetes, major psychosis, dementia, asthma, rheumatic diseases and many others. Although the impact of biotechnology on the control of chronic diseases is not yet fully known, knowledge regarding their genesis and causation and methods for control is growing. However, evidence of the

Examples of developing countries engaging in biotechnology for health

- In India, three organizations, the International Centre for Genetic Engineering and Biotechnology, the Malaria Vaccine Initiative and a private pharmaceutical company, are working together to develop a vaccine against malaria (*P. vivax*). The Bill and Melinda Gates Foundation is partially supporting the programme, and the UNICEF-UNDP-World Bank-WHO Special Programme for Research and Training in Tropical Diseases also played a key role in the initial development of this vaccine. The country has announced plans to invest over US$ 85 million in genomics over 5 years, mainly on research and development.
- In Kenya, scientists working on HIV observed that some commercial sex workers were immune to the infection despite repeated exposures. A DNA-based vaccine was developed in collaboration with the universities of Nairobi and Oxford and the International AIDS Vaccine Initiative. Clinical trials of the vaccine have already begun.
- Cuba has a vast and a modern scientific industry. The Finley Institute, which is the leader in Cuban health technology, was established just over a decade ago and now produces a number of vaccines and anti-sera against common diseases. It has produced an anti-meningococcal vaccine to combat type B meningitis that is now being exported to a dozen countries, including Brazil and the Syrian Arab Republic. The country holds over 400 patents, and biotechnology is the third major industry in the country after sugar and tourism [*6*].
- In Mexico, the Institute of Genomic Medicine was established jointly by the National University, health authorities, National Council of Science and Technology and the Mexican Foundation for Health. The Institute is engaged in characterizing the genetic variation of Mexican people and determining how drugs respond to them. The objective is to improve health care in Mexico by focusing on diseases and conditions specific to Mexican people and reducing reliance on imports of unnecessary drugs.
- China and Brazil are two countries that have forged ahead in science and biotechnology. Brazil was able to complete the first complete sequence of a bacterial pathogen within a short period of two years. The country ranks alongside the United Kingdom and the United States of America in research aimed at deciphering the genetic basis of cancer [*7*]. China participated as an active partner in the human genome project. By adopting a national policy for investing in science and research, both countries have shown significant advances in health care and economic development.

beneficial application of DNA technology in monogenic chronic diseases, such as thalassaemia and sickle-cell disease, is strong in both the industrialized and developing worlds. Currently it is estimated that 7% of the world's population are carriers for thalassaemic and sickle-cell diseases, and that many thousands of babies are born with severe forms of these diseases each year [*5*]. With improved nutrition and infectious disease prevention programmes, the mortality rates in early childhood are likely to decline, and more children with genetic disorders will survive long enough to require treatment, putting a heavy financial burden on national health care resources. The burden of thalassaemia in countries of the Region is quite high, and several countries have already begun screening programmes aimed at controlling this disease. Cyprus (which was a Member State of the Region until the end of 2003) began its national thalassaemia control programme in the late 1970s after realizing that if no action was taken, within two and half decades, 40% of the country's population would have to donate blood and the cost of managing the disease would surpass the national health budget [*8*].

4.4 Genomics and biotechnology in drug development

The medical industry, particularly the pharmaceutical industry, is making use of the vast amount of knowledge generated from the human genome project. This knowledge constitutes the basis of pharmacogenomics studies, which combine traditional pharmaceutical sciences with the knowledge and science derived from genomics. It is anticipated that research and development in pharmacogenomics will result in making drug therapy more precise and effective. It will also dramatically reduce the risks of treatment failures and toxic side effects, and the costs to health care.

Advances in genomic technology have propelled the biopharmaceutical industry to a new level in which engineered proteins specifically target diseases with increased compliance and safety in hosts, enhance delivery and retain maximum activity. It has provided the platform for exponential growth and development in drug and vaccine production. During the past two decades, over 75 products including drugs, vaccines, enzymes and antibodies emanating from DNA-based technologies were developed and marketed [*9*]. With the unravelling of genomes, the technologies to screen and produce active molecules have grown tremendously, allowing thousands of new molecules to be developed and tested in a short time [*10*].

While the full potential of genomics and molecular medicine will only be understood and realized over time; at present the applications of these technologies are limited even in the industrialized world but are developing rapidly. Scientists and researchers from many parts of the developing world are increasingly involved in genomics and many developing countries have created their own genomic infrastructure to match effectively international developments in technology. Some developing countries, such as Brazil, China and Cuba, are now competing with industrialized countries in the area of biotechnology. The development and production of a vaccine for type B meningitis in Cuba is a rare example of the transfer of technology from a developing country to the industrialized world.

5. Current status of genomics and biotechnology in the Eastern Mediterranean Region

Investment in biotechnology and genomics in countries of the Region is low, and expertise and infrastructure are generally lacking. Egypt, Islamic Republic of Iran, Kuwait, Morocco, Pakistan, Saudi Arabia, Tunisia and United Arab Emirates are examples of countries of the Region that have invested in developing indigenous expertise in different areas of biotechnology and genomics. However, the focus of these investments has been in sectors other than health. The agricultural sector leads in the acquisition and application of these technologies for research and development (R&D) in most countries of the Region. In many countries, native crops and fruits have been enhanced to produce higher yields and disease resistance. Some countries are already exporting their products to other countries. R&D in veterinary biotechnology is also well developed in some countries; centres for camel breeding in Saudi Arabia and the United Arab Emirates are among the world’s finest. Water desalination, industrial waste refining and oil preservation are well established technologies in some member countries of the Gulf Cooperation Council.

Most countries in the Region are utilizing applications of biotechnology, such as DNA probes, PCR and immunological markers for infectious disease diagnosis, albeit on a limited scale. Access to these technologies is limited and costs are high. A number of countries of the Region now have reasonably well established centres for clinical genetics, and in some cases access to these services is more widespread. Several countries in the Region, including Egypt, Islamic Republic of Iran, Morocco, Pakistan, Saudi Arabia and Tunisia, have now initiated programmes through partnerships and investments that are aimed at developing (and utilizing) biotechnology for public health. Research in developing DNA-based technologies for disease diagnosis, therapy (drug and other product development) and prevention (vaccines) is ongoing. Facilities including infrastructure, equipment and training are growing, and policies favourable to growth of biotechnology for improving health are gradually being put in place. (The existing biotechnologies in countries of the Region are summarized in Annex 1.)

6. Biotechnology and genomics in the Eastern Mediterranean Region: issues and challenges

6.1 Lack of capacities and infrastructure

There is an acute shortage of skilled and trained personnel in the field of health-related genomics and biotechnology in the Region. Favourable national policies are urgently needed to nurture science and technology development in health and to address priorities. The issues and challenges for countries in Region remain as follows:

- building adequate capacity and practical knowledge in genomics and biotechnology, such as rapid and reliable techniques for disease diagnostics, treatment and prevention to ensure their application and benefit to the population;
- ensuring that the applications, when in wide use, provide benefit and cause no harm to patients and communities, are not in conflict with ethical principles and do not create social discrimination against the vulnerable, and that sound legal protection is in place to prevent misuse;
- developing networks and partnerships to share information, resources and skills;
- introducing the new biotechnologies to maximize impact, and complement existing tools and methodologies within the resource constraints and confines.

The main challenge ahead for countries of the Region, like many other countries, is how best to balance the priority needs with the capacities and resources necessary for genomic and biotechnology development, and at the same time ensure that the existing, proven and well-tested interventions that already exist are not compromised. In other words, the challenge is to ensure utilization of biotechnology as a tool in the development of better and more equitable health care and in strategies to reduce the health gap while benefiting societies economically in the long term. Critical questions such as how the new technologies will challenge our identities, right to privacy and freedom from discrimination are some of the key issues that will need urgent attention and resolution. Advances in genetics will only be accepted by the public if their application is carried out ethically with due regard to autonomy, justice, education and the beliefs and resources of each nation and community.

6.2 Lack of research and knowledge generation in science and technology

The contribution of countries of the Region (and the Islamic world in general) to contemporary global knowledge in science and technology is minimal. The regional proportion of publications in the field of life sciences is only around 2.5 % of those made by the United States, Japan and some countries in Europe [*5*]. In the fields of agriculture, biology and environment sciences, India alone produced more publications than the 57 Islamic nations collectively [*11*]. However, evidence is emerging that many countries have substantially increased their science publications over the past two decades. Egypt, Islamic Republic of Iran and Saudi Arabia are among the three largest producers of scientific papers, but an upward trend is noted also in other countries of the Region [*12*]. In the Index Medicus for the Eastern Mediterranean Region, the three top countries contributing to research publications in health are Egypt (44 127 records), Pakistan (16 030 records) and Saudi Arabia (10 159 records). The index includes 87 articles on genetics.

6.3 Biogenerics

Biogenerics (developing pharmaceutical preparations from biologically active substances such as proteins) has transformed rapidly in the last two decades with the advance of genomics and biotechnology. In the latter half of the 1980s, biogenerics technology focused on developing newer and improved methods of product delivery. In the mid 1990s, new avenues such as specific monoclonal antibodies as therapeutic agents opened up. Today’s science of biogenerics is directed towards delivery of highly active, safe and effective agents, “custom designed therapeutic agents”, for disease prevention, control and cure. A number of biopharmaceuticals and related products are currently under development by generic producers. During the next few years, a number of biopharmaceuticals will also lose patent protection. This provides an opportunity and incentive for generic pharmaceutical companies to move into this market. Huge investments will therefore be required from pioneering companies in developing countries to gain access to the market.

6.4 Intellectual property rights in genomics and biotechnology

Genomic knowledge is considered a public health good [*13*], although in practice its use is constrained. Most developing countries (including countries of the Region) lack sufficient expertise needed to put this knowledge into practice. Therefore it is mainly the industrialized world that benefits. Despite the fact that DNA sequences represent naturally occurring information, patents continue to be granted. Patent rights have been awarded to thousands of DNA sequences, and molecules, preventing access to this knowledge by scientists in developing countries. This practice is detrimental to scientific and economic growth in developing countries and may have long-term implications. Many databases are now available in the public domain, but patenting of genes by academic institutions and private firms continues.

6.5 Developing capacities in bioinformatics

Researchers globally are generating (and mining), at tremendous pace, huge volumes of highly valuable genomic data. Much of the data are available for public use and have enormous potential for application in public health. The need to develop regional capacities in bioinformatics is paramount, and can be illustrated by the success story of researchers in a German university, who while screening the sequenced genome of the malaria parasite made an important discovery. They found that the parasite utilized a specific enzyme pathway absent in humans. They knew that a drug, fosmidomycin, was developed in the 1970s that targeted the same pathway. This drug, although well tolerated by humans, was never marketed because it was found ineffective in treating recurrent urinary tract infections, for which it was originally developed. The drug was re-tested against malaria and found to be highly effective. Field trials of the drug are now under way. Recognizing the potential for drugs to target specific enzyme pathways, the research group has established a company to explore and develop therapeutic agents [5].

6.6 Engaging private sector in genomics and biotechnology

The role of the private sector in genomics and biotechnology, and its contribution to economic growth, is well established in the industrialized world. Replicating the experience in countries of the Region is indeed a big challenge which requires not only support to interested partners in the private sector but also national policies conducive to private sector growth. The example of Shantha Biotechnics, a private company in India, shows how entrepreneurship, partnership, collaboration and vision by a group of individuals, linked with university and with investments can result in a highly successful venture. The company is now producing a large number of vaccines and therapeutic agents, mainly for use in developing countries at significantly reduced prices, while at the same time remaining a profitable venture. Within the Region, the Jeddah BioCity biotechnology project is an outcome of a collaborative effort between the private sector, leading businessmen and King Faisal Specialist Hospital.

6.7 Making adequate financial resource commitments to genomics and biotechnology development

The overall global expenditure in health research in developing countries is very low, and the public sector funding on health-related R&D constitutes only 3% of the global R&D expenditure [*14*]. Collectively, the Arab nations spend 0.15% of their gross domestic product (GDP) on research and development, well below the world average of 1.4% [*15*]. It is encouraging to note that the trend appears to be changing, and in spite of declining GDP many countries of the Region are now beginning to invest in science in the hope that it will underpin future economic development. Throughout the Region, spending on R&D is on the rise. In Oman, for instance, despite a 10% decline in its per capita GDP during 1992–1996, the R&D budget increased by 83%. Similarly, Yemen increased its spending in R&D despite suffering significant decline in its per capita GDP during the same period. In Pakistan the budget for R&D has increased significantly and a large programme to develop human capacities in education, science and technology has been initiated [*15*]. Egypt allocates almost US$ 2 million annually for Egyptian scientists to undertake joint activities with US researchers [*15*]. In the Islamic Republic of Iran, the National Biotechnology Commission allocated US$ 5 million in 1997 for research in different disciplines of biotechnology [*16*]. The Sharjah-based Arab Science and Technology Foundation is aiming to raise US$ 150 million in the next 5 years to improve the quality of research in Arab institutes and develop new talent [*15*]. The key challenge therefore is to ensure adequate and sustainable investments in science and technology that are specifically directed towards health biotechnology R&D.

7. Why must the Regional Office pursue genomics and biotechnology development?

At present the well-established centres based in the industrialized world dominate the field of genomics. Many worry that this is leading to a genomic divide and is further exacerbating the existing severe disparities between wealthy and poor nations. Bridging this divide is therefore crucial. Similar opportunities were lost with regard to information technology and agricultural technology, and the consequences for the developing countries are obvious. The opportunity to harness genomic biotechnology must not be lost in the area of human health.

Several countries of the Region have already developed capacities in agriculture, veterinary and environmental genomics and biotechnology, and institutional collaboration and partnerships with science organizations of the North are well developed and functional. Many of the basic techniques in plant or veterinary genomics are similar to human genomics. Although medical genomics is still in a nascent stage, applied medical biotechnology is growing. Diagnosis of common infectious diseases using DNA-based PCR is now the standard in some countries. However, the health sector usually imports commercial kits and reagents. The National Institute for Biotechnology and Genetic Engineering in Pakistan, although primarily established for agricultural research, has established a section for health biotechnology, where it develops its own reagents and diagnostics. Although the initial interests may be commercial, such initiatives stimulate further R&D in the longer run, as the full potentials of the technologies unfold. Several other countries of the Region are in a similar situation.

The scientific institutions and pharmaceutical industries in many countries in the Region have started investment in research and development of biotechnology. In resource starved countries, it is crucial that investments are wisely made. Experts in genomics and biotechnology agree that in order to invest in these technologies, countries must be selective and focus on priorities. These experts recommended a list of 10 technologies that are likely to be most beneficial for addressing public health care in developing countries [*17*].

1. Modified molecular technologies for affordable, simple diagnosis of infectious diseases.
2. Recombinant technologies to develop vaccines against infectious diseases.
3. Technologies for more efficient drug and vaccine delivery systems.
4. Technologies for environmental improvement (sanitation, clean water, bioremediation).
5. Sequencing pathogen genomes to understand their biology and to identify new antimicrobials.
6. Female controlled protection against sexually transmitted diseases both with and without contraceptive effect.
7. Bioinformatics to identify drug targets and to examine pathogen–host interactions.
8. Genetically modified crops with increased nutrients to counter specific deficiencies.
9. Recombinant technology to make therapeutic products (e.g. insulin, interferon) more affordable.
10. Combinatorial chemistry for drug discovery.

In September 2000, at the Millennium Summit of the United Nations, world leaders adopted the United Nations Millennium Declaration, which set eight development goals, known as the Millennium Development Goals (MDGs), to be achieved by 2015. There are already concerns regarding the slow progress towards attainment of these goals. One of the important reasons for this is the lack of partnership between industrialized and developing countries in science and technology [*18*]. The top 10 biotechnologies identified as priority for developing countries fit well in the context of at least six of the eight MDGs [*19*]. In order to help determine how science and technology might be used more effectively to meet the MDGs, the United Nations Secretary-General established a task force on science and technology. Support for tertiary education as a developmental priority and the creation of enhanced science advisory capacities within the United Nations are some of the task force's key recommendations [*20*]. Member States who are signatories to the Millennium Declaration must ensure that the targets are met. The challenge is to determine the action needed now to develop appropriate technologies, and use them widely in order to achieve the MDGs by 2015.

The need to develop genomics and promote applied biotechnology in Member States was emphasized by the Eastern Mediterranean Regional Advisory Committee for Health Research in its 20th session in 2002 [*21*]. In September 2003, experts in biotechnology and related disciplines at the executive course on genomics and public health policy recommended establishing national biotechnology commissions for developing national policies and programmes in genomics and biotechnology application, developing related capacities and integrating genetic and genomic products such as diagnostics, vaccines and therapies within health systems and public health programmes [*22*].

In conclusion, it must be noted that many countries of the Region face problems with disease burden and health care delivery. Funding for health care is limited. The decision to invest in genomics and biotechnology must be carefully weighed and balanced against proven existing interventions and long term objectives and vision. There is already ample evidence that the fruits of R&D in genomics and biotechnology not only enhance epidemiological and clinical approaches to health care and research, but also contribute significantly to overall national economic growth. It is therefore important to ensure that the people of the Region access the benefits of genomics and biotechnology. Sensible approaches to funding genomic research, such as utilizing existing resources, networking and focusing on priorities, are often viable and acceptable options.

> The challenge for countries of the Region is to determine whether to invest now in building capacity for genomics and biotechnology for public health, or wait for further progress. In some countries existing national capacities in genomics and biotechnology can be easily translated to address health priorities and improve health care for people in real need.

8. Recommendations

There is overwhelming global consensus on the potential of genomics and biotechnology for improving health. It also brings hope for many in the developing world that, at last, there is an opportunity for bridging the health gap. At the same time there is growing awareness, both among the industrialized and developing worlds, that the opportunity must not be lost, or else the gap will widen further, and at great pace.

The World Health Organization has been leading from the front in its effort to engage Member States to make use of the knowledge of genomics and biotechnology as it is emerging. In the Statement of the WHO Expert Consultation on New Developments in Human Genetics [*23*] and the report *Genomics and world health*, WHO laid down a clear set of recommendations for Member States as well as for WHO itself for supporting national programmes. In September 2003, the expert panel at the executive course on genomics and public health policy made recommendations to Member States and EMRO on how best to make use of genomics and biotechnology to improve the health of people in countries of the Region [*21*]. The recommendations given below are drawn from the discussions in this paper and from the recommendations made by experts at both global and regional level.

1. Member States should raise awareness of genomics and biotechnology for public health and promote public involvement and support.

   The future of genomics and biotechnology depends on public understanding and support. Public funds can support national investment in scientific research and public opinion can direct policy. The general public also provides the consumers that create markets and the human resources that constitute a skilled workforce.

Public involvement is therefore necessary at every stage to develop science. Broadening the education base in science and developing science and technology institutes must therefore be coupled with general awareness on the subject. This then leads to educated and informed debate within societies, which ultimately paves the way for equitable social development. Countries should therefore begin investing in science and technology education at all levels, i.e. high school, university and post-graduate education. The different stakeholders should have sufficient information and knowledge to enable them to assess needs and make informed judgements that are based on the best options to serve their health needs and interests.

2. Member States should develop national policies for genomics and biotechnology development.

Countries should create national bodies for genomics and biotechnology comprising national experts. This body should develop national frameworks and guidelines for R&D in genomics and biotechnology. It should determine national needs and priorities, define strategies, and develop guidelines and regulations to safeguard the public against potential risk or harm. Science must be allowed to advance, but relevant regulation and legislation should not lag behind.

3. Member States should develop national capacities in genomics and biotechnology for public health.

Countries should articulate national priorities for developing applications in biotechnologies and begin building R&D capacities accordingly. There is consensus on the top ten biotechnologies that can potentially improve public health in countries. Experts from the Region have recommended integration of genetics and genomic products related to diagnostics, vaccines and therapies as key areas for the countries to consider, stressing that preference be given to other national priorities if necessary. Adequate investment in biogenerics is badly needed to enable countries in the Region to enter this field. The field will widen significantly, as patents of many vital drugs will expire soon, and countries of the Region should prepare themselves to enter the competition to produce drugs and therapeutic agents at reduced costs to both individuals and national health systems. While there is need for embracing the technical knowledge, it is equally important for countries to protect themselves against potential harm and exploitation. The need to develop capacities in bioethics, protective regulations and legislation is therefore paramount. Sustainable environments must also be created to retain the skilled and trained workforce, particularly in health related biotechnology, for long-term sustainable development.

4. EMRO and Member States should establish partnerships and develop networks in genomics and biotechnology.

Some developing countries in collaboration with centres of excellence in the industrialized world, have successfully developed their own programmes in genomics and biotechnology. The examples emphasize the importance of developing North–South partnerships that link universities or other academic institutions. These partnerships should be long-term and encompass research areas that are of genuine relevance to the needs of developing countries. Similar arrangements should be encouraged between Member States to stimulate, share and exchange scientific knowledge and resources for mutual benefit.

5. EMRO and Member States should mobilize financial resources to support the development of health biotechnology and genomics.

Genomics and biotechnology require initially high capital investments, but are cost effective in the longer run. Developing countries that have forged ahead in genomics and biotechnology have clearly invested heavily. Some of them are already reaping the rewards in terms of improvement in health of their people as well as earning profits through export of their products. Member States should therefore create a special fund to support the development of genomics and biotechnology. This fund could cover a number of different functions, such as:

- developing infrastructure, capacity building and training in the area of genomics and biotechnology

- buying patent rights for products (vaccines and drugs) that are urgently needed in developing countries to allow ready and cheap access to such products
- commissioning R&D on a priority basis and for priority needs within the Region.

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10. Further reading

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Annex 1

Summary of genomics and biotechnology capacities in (some) Eastern Mediterranean countries

Country	Health biotechnology	Other sector biotechnology	Biotechnology institutes
Bahrain	• Diagnostics: Clinical genetics		Arab Gulf University Ministry of Health
Egypt	• Diagnostics: infectious and chronic diseases (genetics) • Research • Vaccine development • Drug development	• Agriculture • Environmental • Industrial • Bioinformatics • Engineering	Several universities and specialized centres are engaged in genomics and biotechnology Leading research institutes: • National Research Centre • Genetic Engineering and Biotechnology Institute • Mubarak City Informatics and Research Institute
Islamic Republic of Iran	• Diagnostics: infectious and chronic diseases (genetics) • Research • Vaccine development: against several bacterial viral and parasitic diseases • Drug development	• Agriculture • Natural Resources • Industrial • Environment	Several universities and specialized centres are engaged in biotechnology and genomics. Leading research institutes: • Pasteur Institute • Razi Institute • Institution of Scientific and Industrial Research • Organization of Blood Transfusion • Agriculture Biotechnology Research Institute of Iran • Iranian Research Organization for Science and Technology
Iraq	• Diagnostics • Drug production (antibiotics)	• Agriculture • Soil fertility • Water microbiology • Genetic engineering	Due to war and economic sanctions activities have now ceased. Several universities and specialized centres were engaged in genomics and biotechnology
Jordan	• Diagnostics • Research • Drug development: antibiotics, growth hormones	• Agriculture • Food microbiology • Biogas production	University laboratories Research institutes Private companies
Kuwait	• Diagnostics: genetics and infectious diseases • Research	• Industrial fermentation • Water treatment • Veterinary	Kuwait Institute of Scientific Research Kuwait University
Libyan Arab Jamahiriya		• Agriculture: focus on date palm	Agriculture Research Centre
Morocco	• Diagnostics: infectious and chronic diseases, genetics • Research	• Agriculture and food biotechnology	Pasteur Institute King Hassan II Institute of Agriculture and Veterinary Sciences
Oman	• Diagnostics: infectious and genetics		Sultan Qaboos University Ministry of Health
Pakistan	• Diagnostics: genetics and infectious diseases • Research • Vaccine development • Drug development: indigenous plants derivatives	• Agriculture • Industrial • Veterinary	Several universities and specialized centres are engaged in biotechnology and genomics. Leading research institutes: • Agriculture research institutes (several in the country) • Centre of Excellence in Molecular Biology, Lahore • Biomedical and Genetic Engineering Laboratory, Islamabad (KRL Institute) • National Institute of Health, Islamabad • Hussain Ebrahim Jamal (HEJ) Institute of Chemistry, Karachi
Saudi Arabia	• Diagnostics: infectious and chronic diseases (genetics) • Research • Drug development	• Agriculture: local crops, date palm • Veterinary: camel and poultry	King Abdel Aziz City for Science and Technology King Saud University Jeddah BioCity

		• Oil and hydrocarbon Industry: enhancing oil recovery, reducing waste processing hydrocarbons into chemicals of added value	
Sudan	• Diagnostics: infectious diseases	• Agriculture: plant biotechnology	University of Khartoum
Syrian Arab Republic		• Agriculture and food technology:	International Centre for Agriculture Research in Dry Areas Aleppo University
Tunisia	• Diagnostics • Research • Vaccine Development	• Agriculture	National Centre for Biotechnology Pasteur Institute National Institute for Agriculture Research National Institute for Agriculture
United Arab Emirates	• Diagnostics	• Veterinary: Camel reproduction, falcon breeding	Camel Reproduction Centre, Dubai National Aviation Centre, Abu Dhabi