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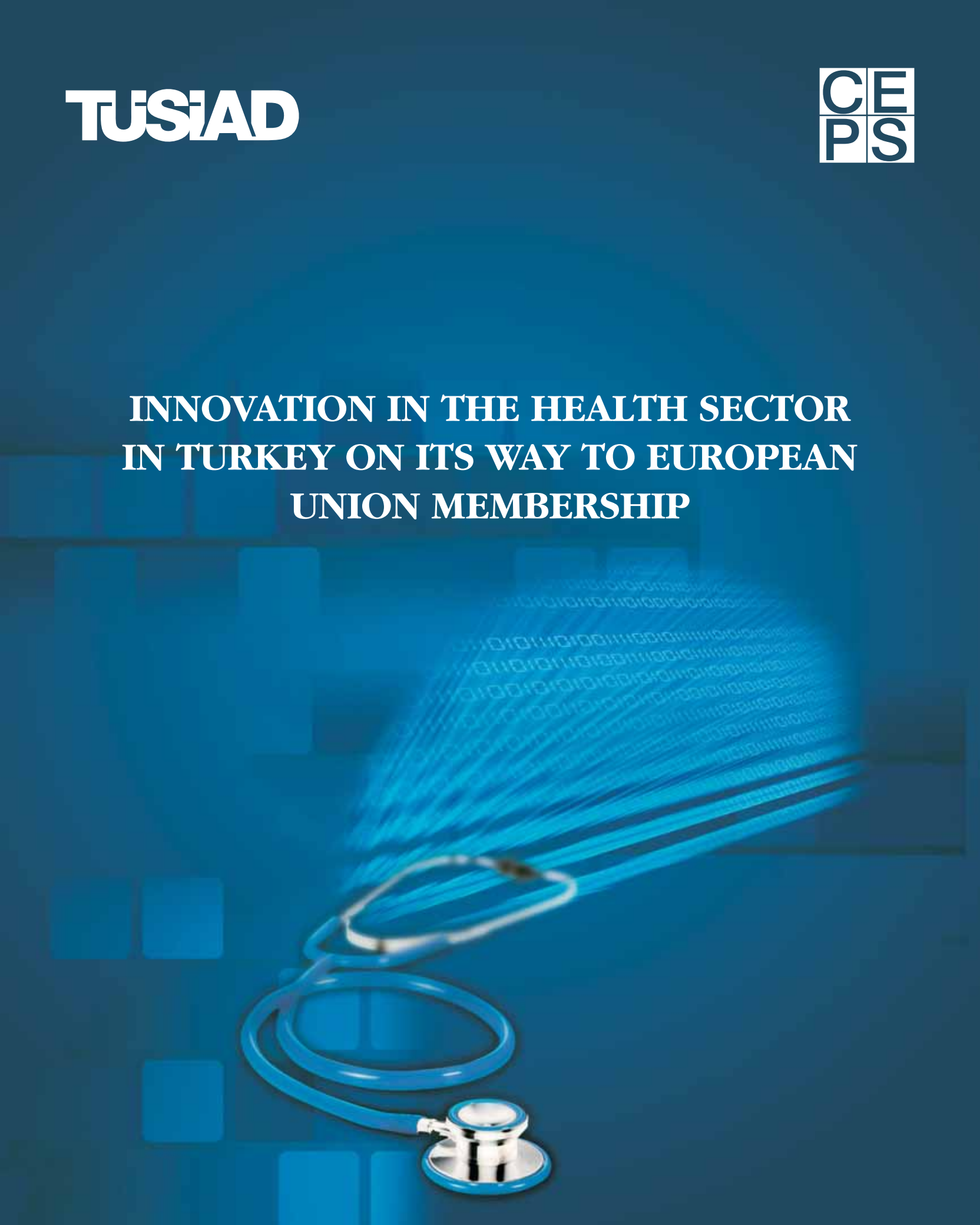

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INNOVATION IN THE HEALTH SECTOR IN TURKEY ON ITS WAY TO EUROPEAN UNION MEMBERSHIP

Z. Güldem Ökem

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Meşrutiyet Caddesi, No. 46 34420 Tepebaşı/İstanbul
Telefon: (0212) 249 07 23 • Telefax: (0212) 249 13 50

EXECUTIVE SUMMARY

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An increasing and ageing population shifts the burden of disease in a society, which in turn changes health care needs. The demand for better health care increases with a higher income level, improvements in technology and expanding health insurance systems, which aim at covering the entire population in many societies. Health expenditures that rise with the demand for health care bring the need to control the costs and improve the efficiency of health services. Innovative products and processes that come with the developing technologies improve early diagnosis and treatment capabilities that pre-empt future costs and hence improve the overall efficiency of the health services in the long run.

Social policies and health systems mainly aim at expanding the accessibility of health services. Innovation enhances accessibility.

Governments need to improve the access to better health care brought by technological improvements, while they have to reduce the financial burden incurred by these new services. Public authorities generally see the innovative diagnostic and treatment procedures as costly. Restricting choices to old and cheap technologies to reduce costs may bring solutions to financing problems in the short term. However, containing costs without improving efficiency may impede accessibility. Diseases that are not diagnosed and treated at early stages may later require greater financing for more costly services. Innovative products and services will bring sustainable solutions by improving efficiency. Their assessment should necessarily involve an economic evaluation and hence, they must be encouraged in line with their contribution to efficiency and benefits for the patient. It should follow that sustainable solutions must also be sought in financing innovation.

The innovation process can be defined as transforming scientific knowledge into products with a market value. Facilitating the interaction of research, production and marketing in the innovation process will ensure the availability and accessibility of new products to people. Accessibility is the basic principle of social policies and the most important objective of the health system.

The health sector is one of the largest service sectors in advanced economies. Innovation in health services contributes to sustainable economic growth.

In advanced economies, the overall value of goods and services generated by the health sector corresponds to almost 7% of GDP and the share of this sector in overall employment reaches around 10%. Total health expenditures as a share of GDP is expected to rise to 16% by 2020. A rapidly growing health sector is one of the largest sources and consumers of innovative technologies.

The end-user of innovation in health is the individual and technological advances directly affect human life and its quality. The ultimate product of the health sector is a healthy population. This would augment the productive capacity and volume of the workforce. Innovative products and services boost the competitiveness of innovating companies and nations and improve their export prospects, while enhancing diagnostic and treatment procedures. Owing to the higher intensity of technology and the knowledge it involves, the research and development (R&D) and innovative capacity of the health sector diffuses into other sectors with which it interacts. Expanding production and exports increase employment and quality of life, as well as the sustainability of growth.

Turkey has important opportunities ahead with respect to the innovative products and services that the health sector can generate. With a growing call for health services due to the size of its population and expanding insurance coverage, its geographical proximity to world markets and technological infrastructure, Turkey is a significant source of demand for innovative products and services from the health sector. Supporting innovation will contribute to the health sector and the economy as well as to the overall health status of the population.

Innovation does not just happen intuitively by itself. It is government policies that stimulate the innovation drivers in the health sector.

Health services are a public good in essence. Therefore, a government's regulatory and supervisory role is imperative. In countries with advanced social security systems, the public sector acts as the principal buyer of health services on behalf of the citizens. Licensing, market authorisation, pricing and reimbursement decisions by public authorities are crucial for the utilisation and accessibility of a new medicine or treatment. Policies and incentives adopted by the authorities who plan and implement these procedures shape decisions concerning the key innovation drivers in the health sector, i.e. R&D, investment and production.

Turkey needs to stimulate its innovative potential, based on its social and economic resources.

Turkey currently ranks among the lowest in Europe in its performance on key innovation indicators, including R&D expenditures as a share of GDP (with a public and private sector distinction), human resources, patenting, etc. R&D expenditure as a share of GDP was 0.73% in 2008, far below the EU average of 1.90%. The share of public sector (including the higher education sector) in Turkey was 0.43% (compared with the EU average of 0.64%) and that of business R&D expenditure was 0.30% (the EU average was 1.19%). While in 2005, the number of patent applications (per million population) at the European Patent Office was 114.9 in the EU, the figure in Turkey was only 2.7. Although, some improvements was recorded in R&D indicators in 2009 (the R&D expenditure as a percentage of GDP increased to %0.85, the full time research personnel per 10.000 employed reached to 73.500) the figure is still far below the level of the EU average and the developed countries.

This report discusses recommendations for the realisation and enhancement of innovation environment in the three main areas of the health sector, i.e. pharmaceuticals, medical devices and eHealth services, in view of the specific features of their innovation structures and processes.

Pharmaceutical Industry

In the pharmaceutical industry innovation is followed by generic production. Both processes should be supported in line with their needs.

The discovery of a new medicine or an active ingredient takes more than ten years and a costly research process. Patent and data protection mechanisms ensure the protection of this innovative process and privileges concerning market access. In this way, the research-based companies retrieve the cost of their long and expensive research activities based on their privileges in the market.

The generic drug producers, entering into the market at the end of a patent and data protection period, develop production processes and forms, doses and combinations. The generic drug producers play an important role in the development of pharmaceutical production capacity and know-how. Infrastructural investments, cross-sector links, supply networks for raw materials and final product markets are fostered by generic production. The production structure emerging from a complementary mixture of innovative and generic industries in a dynamic process leads to the build-up of the infrastructure and human capital needed for innovation. In this context, the incentives for the development of generic production can also be regarded as preparing the groundwork for the innovative processes. Without an innovative drug, however, generic production will not exist. Hence, the two production processes should be supported to complement one another vigorously.

Turkey has important and growing market potential in the pharmaceutical sector. It also has substantial export potential due to its location. Turkey should benefit from these advantages by increasing its limited R&D capabilities.

The pharmaceuticals market in Turkey reached $10.4 billion in 2009, ranking 12th in the world. It is estimated that by 2013, Turkey will be among the fastest growing countries ('pharmerging') together with China, Brazil, India and Russia. Given the growing demand for health services stemming from the size of its population and expanding health insurance coverage, its geographical proximity to international markets and technological capabilities, there is remarkable potential for innovative health services and products. Considering the expected value added in investment, production, employment and exports, Turkey should make the most of this potential in order to support its sustainable growth.

Currently in Turkey, the drug formulation, development and phase II-IV trials are undertaken within a limited scope. R&D activities and expenditures, and the number of pharmaceutical R&D personnel remain behind the world average. In 2009, only 521 of a total 72,615 clinical trials in the world were carried out in Turkey. The number of clinical trials (per million population) was only 4 in Turkey, while this figure was 191 in the US, 86 in western Europe and 22 in Eastern Europe. The share of R&D personnel employed by research-based companies in Turkey was 8 per 1,000 (of around 25,000 total employed) in 2009. The share of pharmaceutical companies operating in Turkey represented less than 1% of overall national patent applications and registrations. Research-based companies have so far allocated $38 million to R&D activities in Turkey. This accounts for only 0.042% of the global R&D expenditure of $90 billion. Considering that these companies devote 18.7% of their revenues to R&D, their investments in Turkey remain negligible.

Research-based companies are expanding their innovative activities on a global scale. Turkey should take part in this global transformation. The harmonisation process with the EU will facilitate such transformation.

Integration into the research-based pharmaceutical industry requires effective protection of intellectual property rights. Turkey has aligned its legislation to a large extent with the World Trade Organisation agreements and the EU acquis (by means of the Customs Union). In terms of its provisions for data protection, however, there is continued expectation of Turkey's full compliance with the EU standards. In this context, Turkey may consider utilising supplementary protection certificates, which extend patent protection for a maximum of five years, as an incentive for R&D investments.

Turkey should fully institutionalise its national market in the pharmaceutical sector.

With a share of approximately 80%, the Social Security Institution (SSI) is the largest buyer in the pharmaceutical market, which has been consolidated by the recent social security reform. In order for this setting to function properly, further institutionalisation is needed in the licensing, pricing and reimbursement processes. In addition to necessary structural enhancements, such institutionalisation should bring further transparency and predictability as well as cooperation among the stakeholders. These new arrangements should be in line with EU practices and any new market anomalies should be avoided.

The licensing process should be facilitated and expedited.

The duration of the licensing process, which has been aligned with the EU standard, should be limited in practice to 210 calendar days. Provision should be made to allow recognition of EU licenses. Inspection and certification requirements for good manufacturing practice (GMP) should be aligned with the guidelines of the European Medicines Agency (EMA) and the US

Food and Drug Administration (FDA). The GMP certificates of other authorities, such as the FDA and the EMA, should also be accepted by the Ministry of Health.

Pricing and reimbursement decisions should be predictable; the decisions with respect to new medicines should be transparent and expeditious.

Interventions induced by financing deficits in social security systems should not be allowed to adversely affect market stability and predictability. The 90-day limit for finalising reimbursement decisions, as harmonised with the EU's standards, should be observed in practice. Pricing and reimbursement decisions should be predictable. Policies must be considered utilising the pricing and reimbursement processes to support new medicines, provided these are created in Turkey. The innovative nature of the new medicines, clinical research, production and export opportunities for Turkey should be taken into account in these decisions. Innovative research and investments will increase employment and improve the experience of the research personnel.

Pharmaceutical innovation originates from the private sector. This process needs an effective public–private partnership. Universities are the facilitators of this partnership.

R&D resources are almost entirely utilised by the private sector in pharmaceutical innovation. Re-organisation and prioritisation of innovation in the pharmaceutical sector as an industrial project will offer a vector for the incentives and resources. Public–private partnership becomes crucial at this junction. In this vein, the resources supporting innovation in the pharmaceutical sector can be used effectively and allocated to projects with measurable targets. A public sector fulfilling its regulatory functions will facilitate project selection and funding. The government may use its principal buyer position to support the offset investments and funding of the R&D phases.

Innovation is an outcome of R&D activities, which primarily include basic and applied research as well as experimental development. The ability to commercialise the products from the basic research carried out in the universities and techno-parks is vital, particularly in the pharmaceutical sector.

R&D legislation should be revised with a view to supporting industrial priorities. A critical research mass should be formed as part of overall human capital.

The innovation stages spreading on a global scale are performed by young companies that typically employ fewer than 50 R&D personnel (and up to 500 full-time equivalent), the minimum required by the R&D legislation for support to innovative firms. These incentives, which are specific to technology zones, should be extended on a project and company basis.

There are 70,000 scientists employed in Turkey. In order to mobilise this capacity towards innovation priorities and objectives, experience needs to be developed in relevant research projects. In addition, a more flexible approach could be taken as to the value added that could be expected from foreign researchers, including facilitated 'R&D visas' to obtain work permits.

Medical Devices

The medical devices sector is one of the most resourceful and dynamic with respect to innovation, owing to the wide spectrum of products.

Innovation in medical devices involves new production and application methods and procedures as well as new products or the modification of existing ones. The innovation process in medical devices is incremental as their performance and safety can be continually improved, withering the innovative nature of a product. The development process is intimately connected with the practical use of a specific device. The economic utility and benefits of medical devices materialise as their utilisation expands. For this reason, decisions concerning the utilisation of new products in health services as well as the users themselves determine the direction and pace of the innovation activities. Medical devices often require 'lead users' to facilitate their effectiveness. As such, the relationship between products, suppliers and health-service delivery organisations assumes a more integral role.

Simultaneous expansion of the domestic market and imports should be seen as an important opportunity for innovation in medical devices.

With a market volume of $2 billion in medical devices, Turkey ranked among the 30 largest markets in the world in 2009. The government's decision to purchase services from the private sector has enabled investments in medical devices and technologies by the private health institutions. This tendency points to a continued expansion of the medical devices market. The medical devices sector currently ranks 13th in terms of the value added it has created and has a 0.9% share of overall employment.

Imports enjoy a greater share of the market vis-à-vis locally manufactured goods. As such, investment and intermediate goods have also been imported. This situation, when combined with the cost of qualified labour, renders domestic production uncompetitive. Yet overall production, exports and imports have been growing with the market. Production and exports will not exceed imports under the current circumstances. Hence, for the existing potential to be realised, some critical steps may be required concerning the institutional and legal setting, capital and human resources, and production and marketing areas.

Manufacturing will be able to focus better on innovation if more rational tax arrangements for stimulating local production towards innovation are accompanied by incentives targeting projects rather than companies.

Importers have the potential to transform into manufacturers, depending on the availability of adequate incentives and tax benefits for innovation. Such incentives and benefits can also direct foreign exporters towards investing or searching for partnerships in Turkey. The current rate of VAT on imports is 18% for intermediate goods, whereas it is only 8% on manufactured products. This encourages the import of manufactured goods rather than local production and innovation.

Venture capital funds to support innovative manufacturing could be augmented by increasing the 'techno-enterprise' funds made available by the R&D legislation. Also, funding support for small and medium-sized enterprises can be made available in this vein. The R&D Law requires companies to have a dedicated R&D unit and employ a minimum of 50 R&D personnel in order to be eligible for incentives. This criterion does not allow for the structural and functional flexibility needed for innovation in the sector. The law should be amended accordingly, given that innovation is mostly resourced by the small and medium-sized enterprises and it generally occurs at the earlier stages of a firm's commercial life.

The institutional structure and legislation should be completed, including the establishment of a 'Turkish Drug and Medical Devices Institution' to ensure the predictability and transparency of the market.

Turkey has largely satisfied the requirements concerning its harmonisation with the EU in assuring quality standards as well as market access for medical devices. With the establishment of the Turkish National Drug and Medical Device Databank (TITUBB), further steps have been taken towards institutionalisation. Rather than remaining a simple 'databank', the TITUBB's services should be enhanced by strengthening its supervision and monitoring functions. This body can assume the functions of a national drug and medical devices authority. The establishment of the long-awaited 'Turkish Drug and Medical Devices Institution' could be made integral to the existing TITUBB structure. It is recommended that the services and objectives of this institution should go beyond the routine aspects and also cover planning for innovative product development.

Interdisciplinary projects must be supported as a crucial element in the innovative processes. The recruitment and mobilisation of human capital requires long-term planning and guidance.

The number of the qualified personnel employed in R&D projects should be increased and their continuity should be ensured. The sector needs experienced specialists in medicine, biomedicine, nanotechnology, electronics, mechanical applications, physics, materials and software engineering. The human resource needs should be defined in detail by a sectoral assessment of skills and capabilities, which should feed into curricula development in undergraduate and graduate programmes. A reversal of brain drain must be encouraged.

The mobilisation of human capital also requires structural adjustments in the provision of services. As such, rather than just providing routine health services, university hospitals should be supported in their research efforts. In this way, the existing qualified human capital would be released and this capacity would accumulate better research experience.

The university–private sector partnerships should be facilitated within the techno-parks and industrial clusters. Academic and clinical practitioners should be encouraged to participate in industrial R&D processes without disengaging from their existing careers.

Innovation in medical devices is inspired by medical practitioners. In Turkey, however, there is little encouragement for the practitioners to participate in the interdisciplinary projects outside clinical services (especially owing to the current performance-based reimbursement system). A significant step forward in ensuring the continued supply of human resources needed in the innovation process would be the introduction of an arrangement that would allow academic and clinical practitioners to become involved in industrial R&D processes without disengaging from their existing careers. Through such amendments in the higher education legislation, these experts could be offered project-based, flexible and special contracts that would allow them to provide critical input into industrial R&D processes. They could even add any innovative product or patented discovery to their individual career files for academic promotion.

Government criteria for pricing and reimbursement should ensure that innovative products are taken into consideration, while predictability and transparency should be improved in pricing and reimbursement. This will help firms better plan their investments in innovative processes.

The government is the largest buyer in the medical devices sector. The conservative reimbursement criteria induced by the funding shortages should not effectively constrain innovative diagnosis and treatment, and hence suppress innovation. Since innovation in medical devices is incremental, their benefits will only materialise when they are utilised, which should in turn lead to further innovation. Therefore, reimbursement decisions must be based on transparent criteria, which also takes into account innovation. The government would contribute further to predictability of the market if it were able to plan its procurement needs for the long term. Further harmonisation with EU and the US standards will improve quality, expedite certification and thus market access. Health authorities should be more involved in random controls and supervision in the market. This will support the quality and safety of especially the locally manufactured products, and hence credibility of products.

eHealth

eHealth applications improve the accessibility of health services, and enhance their quality and efficiency.

Information and communication technologies facilitate the sharing of patient and medical data and their utilisation. Monitoring the cost of health services will improve their quality and efficiency. It will become easier for distant services to be made available and help meet demand, enhancing health service capacity and its accessibility. eHealth forms a foundation for policy-making based on information and it widens the prospects for innovation.

The sectoral formation of eHealth applications is fragmented. There is a need for public regulation.

eHealth applications in Turkey have gained pace since 2004. There is currently a need for both strengthening the infrastructure and incentives to foster market practices.

The main challenges in the deployment of eHealth systems include the absence of an agreed set of definitions, the lack of interoperability in sharing patient and medical data, gaps in the relevant legislation and financing difficulties. In addition, there are uncertainties in the procurement and reimbursement of eHealth services, inadequacies in information for service providers and users, and impediments in the electronic transfer and conversion of service workflows and procedures.

The public-to-public partnership should be given priority to ensure continued political commitment to eHealth. This should be institutionalised through enhancing interoperability. The institutionalisation should be complemented with the public-private-university collaboration.

Although perceived as primarily a domain of the Ministry of Health, eHealth closely relates to the work of the Social Security Institution, the Ministries of Interior, Labour and Social Security, Industry and Commerce, and Finance, and other relevant public institutions. An *eHealth Coordination Council* could be established to plan for the infrastructural improvements and expansion necessary to bring to fruition the benefits of eHealth applications. The tasks of the Council should be planned and implemented in collaboration with universities, the private sector, professional associations and non-governmental organisations as well as related Ministries.

A considerable amount of data has been gathered by the public sector through Sağlık-NET and Medula concerning the patients and services provided. These two systems are effectively designed and relatively good in their performance. However, there is an acute need for interoperability between the two parent organisations (i.e. the Ministry of Health and the Social

Security Institution) in the collection, storage and sharing of the data. This information should be conveyed accurately and adequately, most importantly with respect to the planning and decision-making processes. In this vein, a joint *monitoring and evaluation system* could be established.

All service providers together with the general practitioners and public hospitals should submit information to the Ministry of Health. Institutions that ensure data accuracy and quality can be rewarded by prioritised reimbursement. In some countries such as Denmark, the administration makes some reasonable payments to health institutions in order to promote the transmission of accurate data.

Planning and implementation processes should involve all stakeholders through public-private-university cooperation.

In health services today, there is a growing tendency towards decentralisation, which foretells a prominent role for the private sector. Any marginal improvements induced by innovative products and services will affect all stakeholders including the practitioners, hospitals and all service providers, insurance companies and patients throughout the health system. These changes will need to be integrated into the information systems. Therefore, novel applications brought by eHealth should be discussed on a larger scale, with the participation of the stakeholders. A *'proof of concept'* approach is recommended to ensure adequate support by the stakeholders for these new applications and regulations.

Interoperability: Public–private–university cooperation

The divergences in the perception of concepts and the absence of commonly defined services in eHealth as well as legal shortfalls in data protection and sharing impede public–private–university collaboration.

The problems involved in data sharing are not exclusive to inter-departmental affairs. Society in general (and notably companies, individuals and researchers), needs to be provided access to these data, albeit at differential levels of permission. An efficient sharing of the data collected will help stimulate the potential for developing new drugs and medical devices. Therefore, it is important that the government defines the rules for data sharing and acts prudently to actually share the eligible data among government departments and with other actors. R&D projects should be encouraged to use these data.

The deployment of eHealth applications in health services should be qualified as a major infrastructural investment. Adaptation by health service providers to this new infrastructure should be supported.

Public institutions are both the primary users and providers of eHealth systems, such as health information systems and telemedicine. Interoperability and data safety will provide the critical input in the establishment of the basic infrastructure in eHealth. Its implementation, however, will incur extra costs for service providers. Reimbursement rules may encourage and support 'data-producing' services.

Turkey should follow EU practices and standards in eHealth and utilise potential market opportunities.

Turkey's harmonisation with EU practices and standards will facilitate the servicing by Turkish private providers of the demand expected from cross-border patient mobility, which is currently on the EU agenda.

The deliverables under the eHealth application Smart Open Services for European Patients (epSOS) should be closely monitored in order to adapt its interoperability standards and datasets to Sağlık-NET. In view of the objectives of harmonising with the EU, the rules concerning the protection and sharing of patient data must be defined by law. Interoperability opportunities for the private health care providers in Turkey should be explored with the European health insurance systems.

A proposal for an Innovation Strategy in the Health Sector in Turkey

The success stories in Ireland and Israel are based on strategic prioritisation and supporting institutional arrangements.

The successes achieved by Ireland and Israel in pharmaceuticals and medical technologies respectively, involve good practices but do not constitute a model of achievement for Turkey, where different conditions and dimensions apply. The good practices common to Ireland and Israel involve a strong conviction that innovation is an industrial project and the relevant strategies are supported by necessary legal/institutional arrangements. Such a setting has enabled both countries to prioritise among the sectors where success is to be encouraged, and hence to steer the resources accordingly.

Innovation, with its economic and social outcomes, is an industrial project. There is a need for an innovation strategy that supports innovation within industry, and for the health sector to be a key part of this strategy.

The government's programmes and policy documents emphasise the importance of innovation and aim at increasing the resources allocated to R&D activities. The assessments and recommendations should also involve sectoral prioritisation with respect to these policy objectives.

The Strategic Importance of the Health Sector.

Innovation in Turkey should be perceived as an industrial project geared towards the market, which goes beyond merely scientific and technological development. This project must have strategic priorities. Policies must indicate preferences: because of its technological intensity and the growing demand, the health sector has critical importance under the innovation strategy.

Strategic Institutionalisation

There is a need for an institutional structure to coordinate between scientific and technological R&D activities, and the public bodies supporting the innovation and its implementation. In this vein, a *health research and investment programme* could be established. This programme could plan for innovative activities, steer resources towards priorities in pharmaceuticals, medical devices and eHealth, and foster cooperation among the stakeholders. This structure could also serve a good example to the coordination of a *"National Innovation System"* in the future.

Vector and Functionality

The innovation strategy must effectively stimulate resources and stakeholders. The vectoral relation from innovation to investment, production and the market must function effectively. This relation must be traceable backwards starting from the market. This process must be expeditious, flexible and transparent. Measurable targets and steps must be set.