Opinion Paper

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The report of the 1st Turkey in vitro diagnostic symposium results

1.Türkiye in vitro Diyagnostik Sempozyumu Sonuç Raporu

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Abstract: "The 1st Turkish in vitro Diagnostic Symposium" was organized in İzmir between the dates 18–20 February 2016 with cooperation of Turkish Biochemistry Society Izmir Branch and Dokuz Eylul University Institute of Health Sciences. This article presents a collection of the subjects, recommendations and results included in the final report of the symposium. Symposium subjects were analysed under separate titles and evaluated together with results obtained from various reports on medical devices (MD) in the last decade. According to the final report, the subjects to be considered on preferential basis include "configuration of the websites of legal authorities, standardization and accreditation institutions in a way to access work on in vitro Diagnostic (IVD)", "activation of university-industry cooperation", "determination of national standards parallel to international standards" and "carrying out the statistics about IVD-MD in Turkey as immediate as possible". Drawing attention to the fact that there is a requirement for competent man power for every-stage of IVD-MD lifecycle, it is recommended that postgraduate education programmes are founded to serve these fields. Consequently, this symposium enabled to determine the basic problems about the sector by bringing together the stakeholders related to IVD-MD field and to come up with an action plan in accordance with the recommendations.

Keywords: In vitro diagnostic; In vitro diagnostic medical devices; Innovation; National standards; Production.

Özet: "1. Türkiye in vitro Diyagnostik Sempozyumu' Türk Biyokimya Derneği İzmir Şubesi ve Dokuz Eylül Üniversitesi Sağlık Bilimleri Enstitüsü işbirliği ile 18–20 Şubat 2016 tarihlerinde İzmir'de düzenlenmiştir. Bu makalede sempozyum sonuç raporunda yer alan konular, öneriler ve sonuçlar derlenerek sunulmuştur. Sempozyum konuları; ayrı başlıklar altında incelenmiş ve son 10 yılda tıbbi cihazlarla ilgili çeşitli raporlardan elde edilen sonuçlarla birlikte değerlendirilmiştir. Sonuç raporuna göre; "yasal otoritelerin, standardizasyon ve akreditasyon kurumlarının web sitelerinin IVD alanındaki çalışmalara erişilecek şekilde yapılandırılması", "üniversite-sanayi işbirliğinin etkinleştirilmesi", "uluslararası standartlara paralel olarak ulusal standartların belirlenmesi", "Türkiye'deki IVD TC ile ilgili istatistiklerin bir an önce gerçekleştirilmesi" öncelikle ele alınacak konular olarak belirlenmiştir. IVD TC yaşam döngüsünün her aşaması için yetkin insan kaynağına gereksinim bulunduğuna dikkat çekilerek, bu alanlara yönelik lisansüstü eğitim programlarının açılması önerilmiştir. Ayrıca, üniversitelerin meslek yüksekokullarında "teknolog" gibi ara eleman yetiştiren programların yapılandırılması gerektiği vurgulanmıştır. Sonuç olarak bu sempozyum; IVD TC alanıyla ilgili paydaşları bir araya getirerek sektörle ilgili temel sorunların saptanmasını ve öneriler doğrultusunda bir eylem planı oluşturulmasını sağlamıştır.

Anahtar Kelimeler: In vitro diyagnostik; In vitro diyagnostik tıbbi cihazlar; Inovasyon; Ulusal standartlar; Üretim.

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Introduction

All instruments, reagents and related accessories used for research, clinical diagnosis, follow-up and treatment are called "in vitro diagnostic medical device (IVD-MD)". Based on the fact that more than 70% of the patients consulting hospitals go through medical laboratory tests and 85%–90% of these tests are imported in Turkey, "The 1st Turkish in vitro diagnostic symposium" was organized in İzmir on 18–20 February 2016 with 120 participants and with the cooperation of Turkish Biochemistry Society İzmir Branch and Dokuz Eylul University Institute of Health Sciences to determine the definition and scope of IVD-MD, discuss current applications reviewing the role of all stakeholders in terms of production and innovation, generating recommendations for national policies and strategies related to the subject and prepare an action plan to create an interactive online IVD platform. The sessions, stakeholders and speakers at the symposium were determined according to two main sections in IVD-MD lifecycle, namely preproduction and postproduction (Figure 1).

Current status and recommendations on legal authority and compliance evaluation

When an online search is carried out with the keywords "IVD", "in vitro" or "extracorporeal", there is no access to the applications in Turkey. This indicates that the websites of the legal authorities as well as standardization & accreditation institutions are not configured to access the work in this field [1]. In nomenclature, the conformity of logical observation identifiers names and codes (LOINC) match-ups in Turkey with the test codes in LOINC international should be evaluated and results should be published on the relevant websites [2]. MD National information bank (TITUBB) created by Turkish Pharmaceuticals and MD Agency is a significant database for medical device records based on the Global medical device nomenclature (GMDN) and United Nations product and services code (UNPSC). The efficiency of these international codes used in TITUBB as well as the related nomenclature and explanations for IVD-MD should be evaluated and announced. The work in the Ministry of Health (MoH) should be carried out with a holistic perspective and coordination of related agencies and implemented parallel to the applications in the world.

Turkish standardization institute (TSE) should prepare and publish educational video presentations and standards for IVD-MD so they are easily accessible from the website.

Current status and recommendations on IVD-MD lifecycle

The cooperation between universities and industry should be at sufficient and efficient level. Necessary information should be provided and the access should be facilitated for the industrialists for them to take adequate advantage of the endorsement provided by the governmental institutions. "Material resources management systems" agencies

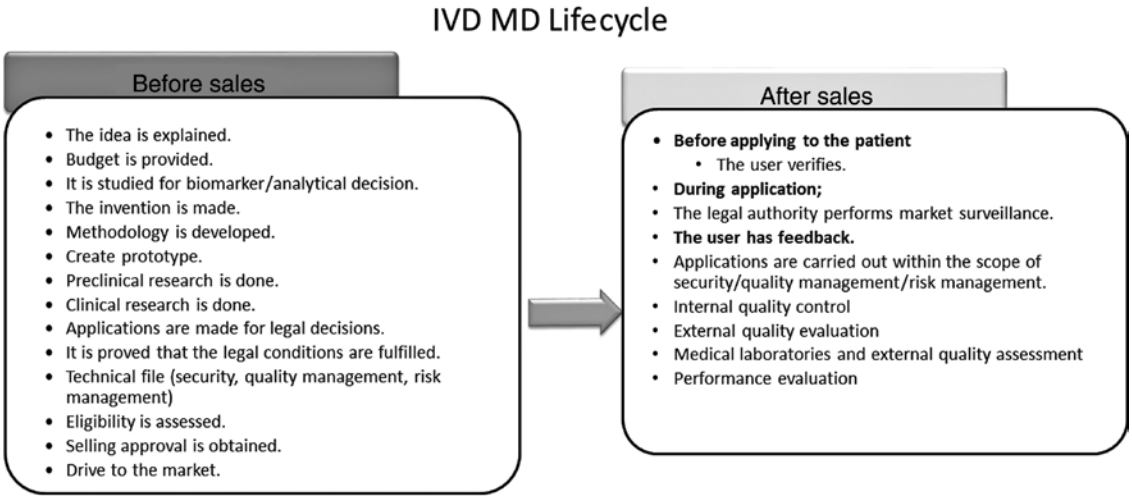

Figure 1: IVD MD lifecycle.

should be founded in all public and private institutions to carry out the statistics about IVD-MD in Turkey. National standards in accordance with international standards should be determined.

In IVD product lifecycle, although both idea improvement and project production are at a promising level and public support is various and sufficient at R&D level, there is an obstruction in validation and quality-risk management levels following the prototype production. The main reasons are lack of knowledge, problems related to project management and insufficient support for the production. Thus, even though technological advancements are followed and innovative ideas are improved, there is no continuity and ideas cannot be transformed into production. An example to this are the problems resulting both from the applications of the MoH and Public Procurement Law in producing diagnostic kits. Thus, support and training from legal authorities are needed [3, 4].

There is need for legal regulations for the encouragement and maintenance of domestic production and the use of domestic products. Establishing and extending "Health Free Zones" is necessary and important to support domestic producers. It would also be appropriate to include IVD-MD issues in "Quality and Efficiency in Health" meetings held by the Ministry of Science, Industry and Technology, and in "Quality in Public" meetings organised by Turkish Quality Association (Kal-Der) [5].

Current status and recommendations on education-training, professional titles and staff

As observed in lifecycle table, there is need for qualified staff in all levels. The only staff assured to work in medical laboratories using IVD-MDs and in laboratories of Medical Schools are those who hold a diploma from the MoH and are medical technicians. There are legal regulations against employing staff graduated from other fields. There should be programmes at vocational schools of universities to train intermediate staff such as technologist. It is important to open and extend graduate programmes related to the field of IVD-MD so as to train expert and qualified work power in laboratory medicine. In-service training activities for the technicians, operators of the state institutions and organisations should be supported by related expertise associations as well as the participation of the MoH and others.

Current status and recommendations on research, development and innovation

The number of people aiming at product development is insufficient. Lack of university-industry cooperation results in not transforming the discoveries into products. Although there is a law (6556) related to supporting research in medical technologies, there are some obstacles in implementation. Restrictions of research-development cooperation in terms of Techno-park and R&D Centres hinder the improvements.

Despite the difficulties mentioned above, it is obvious that there is a real space for the entrepreneurs in the field of medical technologies. Such an attempt can be achieved through state support.

Insufficiency in innovation management is another issue. The Turkish innovation index is 58 in the global scale [6].

Structuring graduate programmes on IVD-MD fields will enable the development of innovative ideas requiring high level of information and equipment as well as ideas possible to put into practice only through multidisciplinary contributions [7].

Current status and recommendations on quality assurance

The requirement to comply with total quality principles, make use of quality instruments and conform to the plan-do-check-act cycle in all applications is emphasized [8].

Overall evaluation

The symposium ensured the gathering of stakeholders of IVD-MD and fundamental problems in the field are highlighted within the context of target outputs of the symposium.

It is decided that an interactive online IVD-MD portal is urgently generated to serve to determine national IVD policy and strategy and ensure the continuous and systematic approach to this subject.

Conflict of interest statement: The authors declare no conflict of interests.

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