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Innovation and Access to Healthcare

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International Standards in support of the dissemination of innovation and better health policies

Access to healthcare is not only access to medicine. It covers in addition the broader issues of the efficiency of and accessibility to health services, such as preventive medicine, early detection and diagnosis, access to safe and efficient preventive and curative medical devices and technologies or the good management of health services, including through the use of information and communication technologies. International Standards of the type developed by ISO may assist on all these issues

1- International standardization in support of positive globalization

Globalization not only of trade, but of many other issues which know no frontiers, such as environmental protection, climate change, security or pandemics, has resulted in a significant acceleration in the need for and production of international standards. International Standards, of the type produced by ISO, are indeed the vehicle for the wide transfer and dissemination of new technologies and good business practices, for interoperability of products and services and to support the security and effectiveness of the global supply chains. The commitments not to create unnecessary barriers to trade, taken in the context of the World Trade Organization or of bilateral or regional free trade agreements, have introduced new relations between the regulators and the standardizers. Making reference to voluntary standards has become an element of good public governance.

ISO is the leader for the production of globally relevant, voluntary International Standards, based on a double level of consensus, amongst stakeholders and across countries. Its network of 156 member countries and its liaisons with more than 680 international and regional organizations, amongst which OECD of course, has delivered a collection of more than 16500 standards, with a current monthly production of 100 new or revised standards, some 50% more than 5 years ago. The scope of ISO is very broad, from basic industries to ICT, from test methods and conformity assessment standards to management systems standards, such as our emblematic ISO 9000 series, from nano- and bio-technologies to the area of services.

2- Health technologies and services: a growing area for ISO

Health and technologies and services are an increasing part of ISO's scope and production, in collaboration with its sister organization, IEC (the International Electrotechnology Commission).

The traditional and still very active area relates to test and analytical methods for the evaluation of the safety and functional aspects of medical devices and dental products. A

simple example to illustrate the relevance of ISO standards: a simple trip to the dentists for a root canal may involve the use of a dozen ISO standards to clean, shape and seal the canal. In total, there are 156 ISO standards for dental products and dentistry alone!

The second and more recent involvement of ISO relates to organizational and management practices. ISO standards have been developed and are now widely used for:

- quality management and competence for medical laboratories,
- application of risk management, clinical evaluation and quality assurance for the development and production of medical devices,
- packaging of medical devices and pharmaceuticals,
- quality management and accreditation of health services.

But healthcare is much more complex than 20 years ago, relying more fundamentally upon knowledge, technology, information, data and their interactions. ISO has therefore also embarked on the development of standards to support interoperability between diverse and independent information systems supporting health services. This relates for example to the "health cards" and "electronic health records" (EHR), as well as to "intelligent" in vitro diagnosis and curing devices which now embed and share data and with external equipment and monitoring, or even the EHR itself, such as pacemakers, insulin pumps or hemodialyzers. ISO has an active technical committee on health informatics. "e-health" policies, from the individual level to the operation of national health systems, need to rely on globally recognized standards for the formatting and exchange of electronic health information.

An emerging subset of "e-health" applications is "tele-health". This term is defined as the use of telecommunications for the purpose of providing telemedicine, medical and health education over a distance. It has a great potential to bring clinicians and care closer to patients and people in remote and isolated communities. There again, ISO standardization is at work, with many partnerships, to deliver the formatting and interoperability of data needed for these developments.

3- International Standards contribute to the effective and fair dissemination of innovation.

International Standards can reduce time to market of new technologies, as well as broaden their markets, thus increasing their economic perspectives and the sharing of their benefits worldwide. A current example may be found with nanotechnologies. Much hope is indeed placed in their use in medicine. Nano-particle based drugs are already commercially available in North America, Europe and Asia. It is the size and tune ability of nano-particles which so particularly suits them for use as medical tools. ISO is already at work to consider the standardization of methods for the characterization of nano-particles intended for medical applications. This could speed up the translation of nano-particles drugs from discovery to development, and facilitate regulatory approval. More generally, ISO provides a tool box of standards for the assessment, clearance and monitoring of new health technologies. Adequate patent policies are in place to enable the fair use and dissemination of patented technologies through International Standards. Close collaboration has been established with the regulators, in particular with the Global

Harmonization Task Force (GHTF) which brings them together with industry, and with the World Health Organization (WHO) and many other fora in the health sector.

4- The development dimension

The development dimension is quite present in ISO's strategy and actions. Developing countries represent 80% of ISO's 156 national members, which have a major role to stimulate and channel the expectations and contributions of stakeholders, as well as to promote their actual take up of International Standards. ISO is implementing a whole set of awareness raising and training actions, and collaborates with international regional and donor organizations which increasingly support the development of the national quality infrastructures, of which the health system is a key component.

5- Some objectives to share

Having thus recalled ISO's major contribution to the quality, safety and efficiency of health technologies and services, I would like to summarize four objectives we could all share and help implement in relation to the theme of this OECD Forum and to international standardization:

- anticipate the needs for international standardization to support and accelerate the emergence and validation of innovative health technologies and good practices: the focus of OECD on innovation will certainly enhance our already active collaboration,
- promote the use of International Standards to optimize the facilitation of trade in medical and pharmaceutical products, the fairness of competition and the efficiency and safety of health services,
- encourage public-private partnerships to support the development of globally and market relevant consensus based International Standards,
- include health services in the support that development programmes dedicate to the quality infrastructures and policies in developing countries

In this way, standardization will increasingly contribute to innovation, growth and equity in the health sector.