

COCIR Contribution to Public Consultation

Expert Panel on Effective Ways of Investing in Health Access to health services in the European Union

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Section Title	COCIR Comment
<p>1. Financial resources are linked to health need</p>	<p>Concerning the Health Care (HC) spending as % of GDP, COCIR draws attention on the distinction between HC systems where long-term care services are included in the HC budget, and those countries where that is not the case. A clear distinction between these systems is necessary to support Member States in making healthcare investment decisions.</p> <p>COCIR strongly supports the concept that financial resources for health systems should reflect a country's health needs. Resources should be deployed to reflect disease burden. In recent decades, the rise of non-communicable diseases (NCDs) has dramatically changed the health landscape. According to the WHO, there were 14.1 million new cancer cases across the globe in 2012, and 8.2 million cancer deaths. Such data demand a reassessment of health resource allocation at the global, national and sub-national levels.</p> <p>COCIR further supports effective use of public funds - healthcare investments that have clear economic benefits; assessed through studies which examine the wider social contributions afforded by increased healthy population productivity and the intrinsic social value of life years saved. A recent Lancet Oncology Commission study demonstrates that investments in radiotherapy capacity would yield a net benefit of at least US\$239.3 billion in upper-middle-income countries (taken collectively) over the next 20 years, due to life years saved. Building radiotherapy capacity thereby epitomizes the type of cost-effective health investment that will yield significant health and economic benefits in the long term.</p>



	<p>COCIR emphasizes that the report should also consider public funding from EU sources, such as the European Structural and Investment Fund (ESIF). COCIR has previously highlighted the need to use the ESIF for health-related projects in its publication "Towards EU Structural and Investment Funds for Health Projects in 2014-2020" and would welcome a consideration in the report on access to health services.</p> <p><u>Specific comments:</u></p> <ul style="list-style-type: none">• 1051: COCIR believes that the report should also focus on the possibility for countries with low public spending to use the provisions of Directive 2011/24/EU on patients' rights in cross-border healthcare.• 1077: COCIR wants to highlight that this evidence should also be considered in the development of the Partnership Agreement and Operational Programs within the ESIF.
<p>2. Services are affordable for everyone</p>	<p>COCIR echoes the principle that patients should not be prevented from using necessary health services because costs associated with use are too high, and that affordability issues often occur where there are gaps in breadth, scope and depth of publicly financed coverage. This phenomenon is prevalent even in developed health systems where reimbursement schemes may be slow to reflect the implementation of advanced techniques despite robust clinical evidence of effectiveness. There is significant clinical literature to support the usage of image-guided radiotherapy (IGRT) for cancer patients in order to enhance precision, minimize side effects, and attain better outcomes overall. Nevertheless, IGRT is not currently reimbursed in the public sector in the United Kingdom, among other countries; resulting in restriction of utilization to those who can afford private insurance or to pay out-of-pocket.</p> <p>Furthermore, COCIR calls on the EU to push forward an EU wide unique methodology assessing the medico-economic benefit of any e/mHealth project. Once a methodology in place is approved by all MS, insurers will be more open to consider the reimbursement of such services, an issue that currently challenges all MS and creates an inequality in accessing healthcare.</p>



3. Services are relevant, appropriate and cost-effective

COCIR industries are best-positioned to support cost-effective investments in the health sector. Over the last century, progressive technological advances have contributed to better clinical outcomes, system efficiencies and increased productivity

The implications of advanced innovations extend beyond improvements to individual technologies and today include broader 'solution offerings' enabling benefits across many clinical pathways and the optimization of workflow and resource allocation. For example, IT-enabled medical technologies are supporting integrated patient-centric care pathways that can enable healthcare professionals to use cost-effective approaches such as performing procedures in outpatient settings instead of hospitals. Technological innovations are catalysing necessary changes across the continuum of care, enabling healthcare providers to enhance cost-effectiveness and clinical efficiency.

Furthermore, the main subject of Interoperability is of utmost importance. COCIR calls on the EU to push for the adoption of an EU wide data hosting Policy to avoid the current fragmentation in Europe and try rather to create a real industrial platform.

Specific comments:

- **1732, 3rd bullet point, 1818:** Many manufacturers of medical devices are unable to produce sufficient quality evidence-of-value to support early market access decisions. If payers & providers were to decide they will not pay for any device until it's undergone an HTA, then market access could be compromised and few non-drug technologies would get through to patients early in their lifecycle. Plus other healthcare benefits (e.g. efficiency savings) would not be realized. Therefore this is not a practicable suggestion for many medical devices.
1827, 1828, 1832: COCIR supports. Attempts so far to unify and coordinate HTA activities both vertically within a country and across member states have failed to have much tangible effect on decision making. Because HTA methods developed for pharmaceuticals have failed to recognize the diverse specificities of medical devices, they are failing to evaluate their full value (clinical, economic, societal), and have failed to recognize and adjust for contextual factors highly relevant for some medical devices that are different from drugs.
- **1836, 1837:** COCIR supports. Methodologies should be developed and HTA used more



for this purpose.

- **1872–1880:** An explicit reference to interoperable EHRs as a key tool in assessing the severity of a person’s condition or need for health care should be made.
- **1964:** If payers & providers were to decide they will not pay for any device until it’s undergone an HTA, then due to the current randomized Clinical trial (*) methodology requirements of HTA any non-drug technologies, would already be obsolete by the time it is fully approved for full release and distribution. The current benefits afforded patients by the use of technologies early in their lifecycle by the current CE marking process, EC/93/42 Directive, would be markedly affected, and the resultant anticipated affect in slowing of innovation and development of technologies within the European setting might also be expected to be impacted.
- **1972–1976** Rather than referring to ‘information systems’, the list of policy responses should explicitly refer to the deployment of interoperable EHRs.

(*) To avoid such delays, Medical Devices should apply new predictive analytics (predict the future by looking back) and prescriptive analytics (decision support) to support HTA studies in collaboration with “EUnetHTA JA3 WP7 - Methodology development and evidence generation”. In Medical Devices, Relative Effectiveness Assessment (REA) implementing sequential prospective cohort studies with standard follow up programs (usually named “Model based SELECTION and VALIDATION method”) are common for comparing new treatment modalities to already applied ones.



<p>4. Well-equipped facilities are within easy reach</p>	<p>EU should support Member States in developing reference networks to ensure access to well-equipped facilities. The reference network model is clinically relevant and cost-effective across disciplines. For example, in oncology, local treatment and delivery centres use a basic configuration that is easy to implement and operate at the sub-regional level. Complex cases are referred to reference centres, which also provide training and education for clinical personnel, and referral centres, which also specialize in treating unique patient groups such as children.</p> <p>The EU should promote health solutions. Studies have shown, in the developing countries, there is no access to many basic needs but almost everyone has a mobile phone which can be way to access basic healthcare, like a hotline to consult, or basic diagnostic of the health condition).</p> <p><u>Specific comments:</u></p> <ul style="list-style-type: none">• 2185-2190: COCIR believes the reference shall be to 'the Internet and wireless connectivity' and should recognize that cost-effectiveness should not be the main rationale for deploying eHealth and mHealth solutions. Consistent evidence on impacts is overwhelmingly positive, resulting in fewer emergency admissions, hospitalisations and bed days per intervention as well as reduced mortality, sometimes dramatically and beyond expectations. See JRC-IPTS (2012), Strategic Intelligence Monitor on Personal Health Systems phase 2 (SIMPHS 2): evidence consolidation – report on best practices and key drivers of success.
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<p>5. There are enough health workers, with the right skills, in the right place</p>	<p>Training and education programs for health workers not only enable the delivery of health services, but also represent an investment in long term sustainability.</p> <p>With its network of clinical partners across the globe and robust education resources, the private sector contributes to healthcare personnel solutions through dedicated training programs, and a range of solutions including integrated software solutions, knowledge-based treatment planning, and partnerships with world-class health institutions to share expertise.</p> <p>Distance learning offers trainees a dynamic and innovative platform for continuing education through online academic content, and local clinical professionals to increase their knowledge base while also minimizing the heavy costs associated with travel for remote training sessions. Education is also available using new innovations in software tools that enable clinicians to capture and share best practices. Such tools can connect local staff with clinical professionals across the globe, thereby creating a community of international and multilingual professionals who can provide feedback and consultations, share new innovative techniques, and provide continuous mentorship via an online network.</p>
<p>6. Quality medicines and medical devices are available at fair prices</p>	<p>COCIR strongly supports the principle that quality medicines and medical devices should be available at fair prices. However, the lack of a globally accepted framework, a clear methodology or indicators to measure access and uptake of medical devices have hampered development of a robust policy framework aimed at improving access and ensuring minimum standards are met. COCIR believes that no HTA measures will be effective if Quality of HC services accessed is not at the center of such assessments. Quality requires transparency about clinical and economic results and how they can be achieved and needs to be complied by all stakeholders. A focus solely on quantitative information is contra-productive in this respect.</p> <p>COCIR supports the EXPH statement: "Yet across and within EU countries, many people find it hard to access necessary medicines, supplies and diagnostic tests. In some countries people face long waiting times for diagnostics due to lack or inappropriate use of equipment and staff." Noting that access challenges also encompass access barriers to treatment systems such as radiotherapy machines, and emphasizes these challenges may be addressed through training initiatives in best practices for the use of medical equipment and staff, as well as through</p>



service and maintenance programs.

COCIR supports the EXPH call to re-think how investment for research and development (R&D) for medicines is funded and rewarded to better address areas of unmet need. Cross-sectoral research efforts will drive successful efforts to prevent, manage, treat and cure disease and disability; medical technologies may enable molecular understanding of disease mechanisms; facilitate patient stratification and monitoring; reduce side effects and costs through targeted treatment; and provide more efficient patient management through electronic medical records.

Specific comments:

- **2499:** The use of medical devices reduces long waiting times
- **2516:** The definition of "Routinely Available Data" is required
- **2517 – 2518:** Specify the relation between the price of medical devices and their use. In what sense does the information on prices hinder the interpretation of existing data?
- **2523:** COCIR does not believe that the purpose of Research and Developments is to ensure fairer prices. Should that be the case?
- **2527/3rd bullet point:** Same comments as per lines 1732, 1818 & 1964.
- **2530:** COCIR fully supports
- **2533:** Instead of "improve", COCIR suggests "EU to setup the required data sharing and data collection infrastructure at EU level in coordination with regional, national levels" in line with what UN is advocating on healthcare data collection and analysis.
- **2537:** COCIR endorses this opinion, and to achieve this, has called to set up a dedicated platform for MEDTECH at the HTA network level.
- **2597-2613:** The contention that patents are designed to ensure Return of Investment (ROI) purely based on cost is incorrect. Moreover, the Opinion mentions a 2014 OECD study on patent and regulatory rules governing generic entry to reinforce this point, but the OECD study has little to do with cost-based Return on Investment (ROI).
- **2676:** COCIR agrees
- **2785 – 2794:** The recommendation is flawed given the premise that patents should only ensure ROI based on cost.



- **2870 – 2871:** COCIR recalls that the Action Plan for Immediate Actions under Existing Medical Devices Legislation was launched by the EC (not the EP)
- **2878 - 2880:** COCIR believes the line should be rephrased as follows: “In the past, transparency, certification, distribution and use might have been issues of concern but with both the adoption of the Action Plan for Immediate Actions under Existing Medical Devices Legislation and the proposed Medical Devices Regulation, these will disappear”.
- **2885:** COCIR recalls that medical devices aim at neither having under-use nor over-use of equipment
- **2899-2900:** The proposed MDR concerning reprocessing (Council vs. EP) is still under discussion.
- **2910:** COCIR contributes to comparable information of medical devices, since 1996 it has closely monitored the ageing of medical imaging equipment and distributed the findings through various publications
- **2960:** Same comment as for the line 2526
- **2962-2963:** COCIR supports this opinion to promote the use of appropriate methods of HTA for different types of medical devices (see comments line 2537)
- **2965** In what way should this be done? What is the definition of big-ticket equipment?
- **2967** What is the objective(s) to improve procurement processes? In what way should this be done?
- **2975:** COCIR is convinced that Managed Equipment Services (MES)* provide healthcare solutions which ensures that devices are used efficiently to optimize investments
- **2988:** change “capacity” with “authority”.
- **2996:** COCIR fully support the reinforcement of information systems at EU level to monitor the medical devices sector.

(*) MES: partnership between one or more healthcare facilities and one or more technology providers over a fixed time During this period, a technology infrastructure is made available against a fee. The provider of the equipment takes responsibility for the availability, quality, and maintenance and upgrading over the lifetime technology, assuring the facility benefits from the future improvements and innovations.



7. People can use services when they need them	Rather than referring to 'e-health systems', the list of policy responses should explicitly refer to the deployment of interoperable EHRs. <u>Specific comments:</u> 3336: COCIR fully supports this opinion.
8. Services are acceptable to everyone	COCIR supports the recommendation to develop a robust framework of indicators relevant to access issues that can be tailored to national contexts. It is crucial for these indicators to measure access to medical devices that support diagnostic, e-health, imaging, healthcare IT, and radiotherapy services. <u>Specific comments:</u> <ul style="list-style-type: none">• 3422-3423: COCIR believes the policy responses should explicitly refer to the deployment of interoperable EHRs.• Page 118/3rd bullet point in left hand column under heading 3: see line 1732, 3rd bullet point• Page 120/3rd bullet point in RH column: COCIR agrees (see above line 1732 3rd bullet point).• Page 120/3rd bullet point in LH column: Same comment as per line 1732, 3rd bullet point