## HealthManagement.org

LEADERSHIP • CROSS-COLLABORATION • WINNING PRACTICES VOLUME 23 • ISSUE 2 • € 22 ISSN = 1377-7629

# Medical Device & Al Regulations

#### THE JOURNAL 2023

Anita Sands, Agnes Kijo, Agnès Leotsakos How WHO Strengthens Medical Device Regulation as Machine Learning-Enabled Medical Devices Gather Pace

Stephen Gilbert Improving the Regulation of Medical Devices and Artificial Intelligence

Gabriella M. Racca Digital Transformation in Healthcare Procurement **Penny Pinnock** Growing Pressures Driving the Shift to Healthcare Digitalisation

Elena Demosthenous Standards in Support of the EU Medical Devices Regulations

Susana Álvarez Gómez Effective Management in Times of Health Crisis





### Digital Transformation in Healthcare Procurement

The article explores the potential of AI coupled with digital innovation as it pertains to future healthcare procurement. The importance of interoperability and qualification for the Virtual Company Dossier, and the potential benefits of cross-border procurement and digital platforms are discussed in detail. The article also highlights the need for greater involvement of academia in this and better collaboration between the public and private sectors to achieve innovation, efficiency and safety in healthcare procurement.



#### GABRIELLA M. RACCA

Full Professor, Administrative Law, Department of Management, University of Turin, Turin, Italy

#### Innovation, Collaboration and Digital Trust

#### **1. Innovations in Digital Health Procurement**

The increasing demand for innovative and high-quality medical devices and healthcare services in Europe and worldwide is driving the need for digital innovation in public procurement (Racca, Yukins and De La Rosa 2022).

The recent public health crisis has also strengthened the need of public-private collaboration in the healthcare sector. Procurement under the Joint Procurement Agreement (JPA), the RescEU scheme, the Advanced Purchase Agreements (APAs) for the purchase of COVID-19 vaccines, and the establishment of the new Health Emergency Preparedness and Response (HERA), are evidence of this and highlight the need for digital trust among public buyers and suppliers (Racca and Yukins a).

A different, strategic, approach is required for the procurement of innovative pharmaceuticals and medical devices.

The impact of digitalisation and AI on health

#### key points

- The impact of digitalisation and AI on health procurement should lead to a different process from other procurement sectors and be based on digital and interoperable platforms available to contracting entities and suppliers.
- Digital transformation might provide greater control of purchasing processes and its related data.
- Industry, suppliers and public buyers should work together to develop healthcare purchasing strategies.
- Academic institutions should play a crucial role in the collaboration among the European procurement community and stakeholders.

procurement should lead to a different process from other procurement sectors and be based on digital and interoperable platforms easily available to contracting entities and suppliers (Racca and Yukins 2014). Ongoing research projects by the University of Turin (Master SEIIC) and within international networks (European Commission, Directorate-General for Communications Networks, Content and Technology 2021, European Commission 2020, European Commission 2016), Ehppa (EHPPA), Euriphi (EURIPHI), BBG Procurement Excellence (BBG), CircPro (Interreg Europe), as mentioned by the OECD (OECD 2023) aim to support the effective digital transformation of e-procurement platforms to improve procurement in the healthcare sector (Racca and Yukins b).

#### 2. Leveraging Qualification and Interoperability for Effective Digital Health Procurement

Digital transformation might provide greater control of purchasing processes and the related data, ensuring



transparency and accountability of public choices. This approach is in line with the EU Commission's view to encourage the full use of AI and data analytics in strategic procurement to achieve better value for money (Directive 2014/24/EU, wh. 93) and contribute to a more innovative, sustainable and competitive economy (EU Commission, DG Internal Market Industry Entrepreneurship and SMEs 2023).

The digital transformation of healthcare offers scope for the expansion of e-procurement, which has the potential to increase accountability, transparency and innovation

Industry, Entrepreneurship and SMEs 2020). Digital transformation is driving towards the standardisation of contract models for all phases of the procurement cycle, including need definition, selection, and execution (Racca et al 2011). In addition, "native" digital e-forms for tenders for standardised medical contracts might be carried out on digital platforms by professional and gualified Central Purchasing Bodies through the contractual tools already provided by the EU Directives (Dynamic Purchasing Systems, Electronic Auctions and Catalogues).

The demand for innovative and high-quality medical devices and services is driving the need for digital innovation in public procurement

in procurement (EU Commission, Directorate-General for Health and Food Safety 2021).

The full digitalisation and the interoperability of National Databases collecting the Virtual Company Dossiers of suppliers might facilitate participation as well as the creation of digital platforms supporting joint and cross-border procurement and dynamic purchasing systems for medical products, as well as rapid access to the market for innovative e-health devices (Racca 2022). The issue of interoperability is still a significant challenge, with more than 300 e-procurement platforms and many different qualification systems at EU level (EU Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs 2020, p.14).

The EU TED Platform needs to be improved by means of revised and effective e-forms to facilitate data collection and the re-use of supplier gualifications in a standardised way across different countries. Also, the concept of private platforms collected in the SIMAP website as e-senders should be monitored, and addressed to better connect the TED system to assure effective transparency.

The re-use (Re-usability principle) of the European Single Tender Document (ESPD) and related exclusion and qualification criteria should also be guaranteed to simplify participation.

The economic operator's Virtual Company Dossier, as an evolution of the e-Certis system, should allow for full inter-operability among databases containing the information needed for an effective e-procurement system, applying the Once-only principle (EU Commission, Directorate-General for Internal Market,

#### 3. Cross-border Procurement and Digital Platforms

Industry, suppliers and public buyers should work together to develop healthcare purchasing strategies to promote innovation and market access for disruptive technologies, innovations and services.

Specific platforms might foster pre-commercial procurement and Value-Based Procurement (VBP) as well to select integrated services (EU Commission, Directorate-General for Health and Food Safety 2019). The VBP approach, correctly addressed, might respond to the growing challenges of healthcare systems and actually accelerate the shift to value-based, high-quality, digital healthcare. VPB has already become the default approach applied by the Welsh National Healthcare System (NHS Wales); in addition, Catalonia is using this method in telehealth projects; Dutch authorities are making value-based procurement central in the healthcare supply chain; while in France, Resah ldf has also published a guide on VBP to support a wider use, particularly in the healthcare sector (EURIPHI 2021).

The goals of innovation, efficiency and safety in healthcare procurement require stronger public-public and public-private cooperation (also transatlantic, with U.S. GPOs) based on digitalised networks between CPBs and EU Institutions to address all issues arising in healthcare procurement, especially to face emergencies.

The organisational model of digital cooperation among CPBs could well foster a new system based on public algorithms that can operate according to measurable quality criteria based on benchmarks

99



and deliver fast and transparent outcomes to ensure the efficiency, integrity and sustainability of strategic procurement (Racca and Yukins 2019). community and stakeholders by providing expertise as well as an impartial perspective while safeguarding the quality of innovative and digital transformation of

#### Cross-border procurement and digital collaborative purchasing platforms are needed to foster innovation and market access for disruptive technologies, innovations and services

#### 4. The Role of Academia for a Digital Public Procurement Ecosystem in Healthcare

The common goal of efficient procurement of innovative medical devices, digital services and IT systems through enhanced digital collaboration between industry, health buyers and qualified purchasers can reduce pressure on healthcare budgets and facilitate better value for money and innovation in future digital healthcare.

Academic institutions, assuring free research without external pressures should play a crucial role in the collaboration among the European procurement procurement systems. Academia should continue to play an active role in EU-funded and public-private projects on digital transformation to ensure evidence-based, innovative and high-quality digital procurement practices and platform solutions in healthcare. This involvement will also help industry to develop digital trust, while incorporating academic and research issues to prepare for future challenges for better healthcare.

#### Conflict of Interest

#### references

BBG Public Procurement Excellence Programme. Available from https://ppe.bbg.gv.at/.

EHPPA [European Health Public Procurement Alliance]. Available from https://www.ehppa.com/.

EURIPHI (2021) Resah Guidebook 'Understanding Value Based Procurement: a new approach to purchasing.' Available from: https://www.euriphi.eu/news/resah-guidebook-understanding-valuebased-procurement-a-new-approach-to-purchasing/

EURIPHI [European wide Innovative Procurement in Health and Care]. Available from https:// www.euriphi.eu/.

European Commission (2016) Feasibility study concerning the actual implementation of a joint cross-border procurement procedure by public buyers from different Member States, written by BBG and SKI, December 2016. Available from: https://ec.europa.eu/docsroom/ documents/22102/.

European Commission, Directorate-General for Health and Food Safety (2019) Defining value in 'value-based healthcare': opinion by the Expert Panel on effective ways of investing in Health (EXPH). Publications Office. Available from: https://data.europa.eu/doi/10.2875/148325.

European Commission (2020) ProcurCompEU. European competency framework for public procurement professionals. Available from: https://commission.europa.eu/funding-tenders/ tools-public-buyers/professionalisation-public-buyers/procurcompeu-european-competency-framework-public-procurement-professionals\_en.

European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (2020) Interoperability in end-to-end eProcurement. Publications Office, Brussels. Available from: https://data.europa.eu/doi/10.2873/991386.

European Commission, Directorate-General for Health and Food Safety (2021) Expert Panel on effective ways of investing in Health (EXPH): Opinion on public procurement in healthcare system, adopted on 28 April 2021. Publications Office. Available from: https://data.europa.eu/doi/10.2875/832331.

European Commission, Directorate-General for Communications Networks, Content and Technology (2021) The strategic use of public procurement for innovation in the digital economy: final report. Publications Office, 2021. Available from: https://data.europa.eu/doi/10.2759/936544.

European Commission: DG Internal Market Industry Entrepreneurship and SMEs (2023) Public Procurement: A data space to improve public spending, boost data-driven policy-making and improve access to tenders for SMEs. Official Journal of the European Union. 981, 1-11. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52023XC03 16(02)&from=EN.

Interreg Europe. CircPro [Smart Circular Procurement]. Available from https://projects2014-2020. interregeurope.eu/circpro/.

Master SEIIC. HAPPI Project [Healthy Ageing in Public Procurement of Innovation]. Available from http://www.masterseiic.it/happi/.

NHS Wales, Value-Based Healthcare for Wales. Value Based Procurement. Available at: https:// vbhc.nhs.wales/value-based-healthcare-for-wales/value-based-procurement/.

OECD (2023) Professionalising the public procurement workforce: A review of current initiatives and challenge. OECD Public Governance Policy Papers. No. 26. OECD Publishing, Paris. Available from: https://doi.org/10.1787/e2eda150-en.

Racca GM (2022) Digital Transformation for an Effective E-Procurement. In: Risvig Hamer C, Andhov M, Bertellsen E, and Caranta R. (eds.), Into the Northern Light. In memory of Steen Treumer. Ex Tuto Publishing, Copenhagen, pp. 215-228.

Racca GM, Cavallo Perin R, Albano GL (2011) Competition in the execution phase of public procurement. Public Contract Law Journal. 41(1), pp. 89-108.

Racca GM and Yukins CR (2014) Integrity and Efficiency in Sustainable Public Contracts: Balancing Corruption Concerns in Public Procurement Internationally, Droit Administratif / Administrative Law Collection. Bruylant, Bruxelles.

Racca GM and Yukins CR (eds.) (2019) Joint Public Procurement and Innovation: Lessons Across Borders. Droit Administratif / Administrative Law Collection. Bruylant, Bruxelles.

Racca GM and Yukins CR (a) (forthcoming) Emergency Procurement and Corruption, in Williams-Elegbe S and Tillipman J (eds.), Routledge Handbook of Public Procurement Corruption (Routledge, London, Forthcoming)

Racca GM and Yukins CR (b) (eds.) (forthcoming) Public Procurement and Digitalisation, Droit Administratif / Administrative Law Collection (Bruylant, Bruxelles, Forthcoming)

Racca GM, Yukins CR and De La Rosa S (2022) 1st Pan-European Hospital & Healthcare Procurement Summit, 20-21 September 2022, Brussels. Available from https://www.health-procsummit.com/health-procurement-summit-2022

## HealthManagement Promoting Management and Leadership