hope
European Hospital and Healthcare Federation

Newsletter

Newsletter N° 213 – July/August/September 2023

The monthly HOPE Newsletter is designed first of all for HOPE Liaison officers. It covers the wide range of issues related mostly to EU institutions that are relevant to hospitals and healthcare services. It is up to Liaison officers to redistribute articles to their colleagues and members.

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Meeting of the cluster "Prevention and early detection" and "Understanding" under the EU Cancer Mission

On 7 September 2023, HOPE was present in San Sebastian for the meeting of two clusters under the EU Cancer Mission: "Prevention and early detection" and "Understanding." HOPE is a partner in the LUCIA Project, part of the two clusters and host of the meeting, and of the DIOPTRA Project, part of the "Prevention and early detection" cluster.

The clusters were created with the scope of supporting the Mission objectives, creating added value and increasing the impact of EU funding. The areas addressed in the clusters are the following: Data Management, Research and Innovation, Communication and Dissemination, Citizen Engagement and Addressing Inequalities.

Link for more information and other partners.

HOPE Projects

Health InnoFacilitator

InnoFacilitator aims to create a community to promote innovative procurement in the field of health through business support, tailor-made training courses, coaching for buyers and solution providers, and the creation of collaborative tools. The overall objective is to raise awareness, increase the skills and knowledge of stakeholders on innovative procurement, and collaborate to co-designate the Public Procurement of Innovative solutions (PPI).

InnoFacilitator is funded by Horizon Europe Programme 2021-2022 European Innovation Ecosystems (EIE).

Join the **Health InnoFacilitator community** and follow its activity on its **website** and on **LinkedIn**.

DIOPTRA

DIOPTRA is a Horizon Europe project, aiming to revolutionise Colorectal Cancer (CRC) screening via a holistic, personalised and accessible method for early detection. Its mission is to use new technologies for CRC risk assessment, screening, and progression while incorporating lifestyle and environmental factors to develop a unified holistic protocol for primary CRC screening using network modelling and Artificial Intelligence-based Decision Support System.

You can now follow DIOPTRA's latest development by **subscribing to its newsletter**!

Visit **DIOPTRA website** and follow DIOPTRA on **Twitter** and **LinkedIn**.

SAFEST

SAFEST (Improving quality and patient **SAFE**ty in surgical care through **ST**andardisation and harmonisation of perioperative care in Europe) is a four-year project funded under the new cycle of the EU's framework for research and innovation, Horizon Europe.

When considering surgical safety, SAFEST looks at the entire journey before, during, and after surgery (often referred to as perioperative safety and care). Especially considering how several studies have shown that most adverse events linked to surgery occur outside the operating room. The project seeks to play a decisive role in improving patient safety and it will do so by (1) identifying and agreeing on a unified set of perioperative practices based on evidence, and (2) promoting their implementation across Europe involving healthcare professionals, patients, and other stakeholders.

SAFEST 10-member consortium is led by Fundación Avedis Donabedian in Barcelona and comprises research institutions, **hospitals in The Netherlands**, **Spain**, **Portugal**, and **Czechia**, and policy organisations. **HOPE** leads tasks on communications and contributes to other Work Packages with surveys, as well as help identify existing perioperative standards as part of a multi-disciplinary group.

Be sure to follow the project on **Twitter** and **LinkedIn**, or **check our website for interesting blog posts, in-depth project information, and news**!

RE-SAMPLE

RE-SAMPLE (REal-time data monitoring for Shared, Adaptive, Multi-domain and Personalised prediction and decision making for Long-term Pulmonary care Ecosystems) is a large-scale European project in which real-world data monitoring and Artificial Intelligence (AI) will be used to improve understanding of chronic obstructive pulmonary diseases (COPD) and comorbidity (two or more chronic conditions).

This month RE-SAMPLE released its summer newsletter, broadcasting the project's videos. **You can discover them here**.

Do you want to know more about the project?

1. **Register to the newsletter**
2. Follow us on **Twitter** and **LinkedIn**

In June, the project released a special newsletter displaying different videos created through the project. **You can view the newsletter here.**

In the end of September, the Consortium met in person in Greece.

LUCIA

LUCIA (LUng Cancer-related risk factors and their Impact Assessment) is a project funded by European Union Horizon Europe Research and Innovation Programme. The project aims to develop a toolbox for studying and understanding the risk factors and causes of lung cancer.

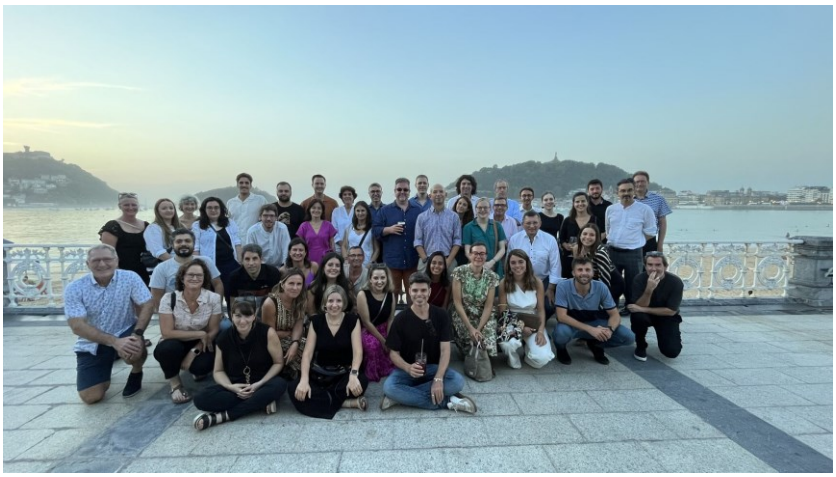
The project website is now ready! You can read all about it **here**.

You can follow the project activities on **LinkedIn**, **Twitter** and **Instagram** or by subscribing to **LUCIA newsletter**!

LUCIA Consortium meeting

On 5 and 6 September 2023, the LUCIA Consortium met in San Sebastian (Spain) on the invitation of Vicomtech. The meeting was the occasion to discuss the updates from all work packages, with the advancements, challenges and possible deviations. A representant from the European Health and Digital Executive Agency (HaDEA) gave a presentation on the main topics to take into account in the project from the European Commission point of view. As

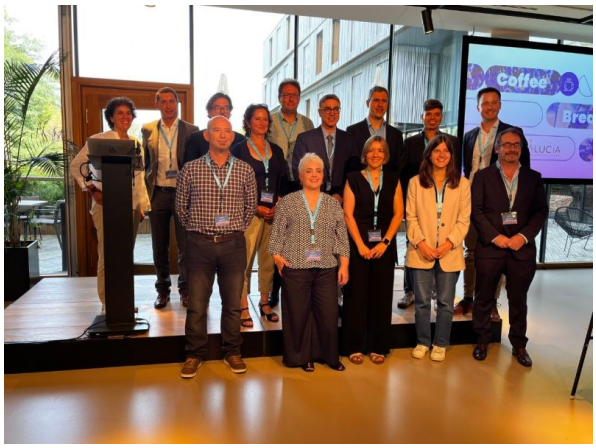
leader of Work Package 6 (Dissemination, Communication and Exploitation), HOPE gave a presentation on the second day.



LUCIA Workshop "Understanding Lung Cancer"

On 5 September, the project hosted its first public workshop. It set up the scene of the project's contributions in the next years to advance in risk modelling, prevention, and early screening of lung cancer. The workshop aimed to:

1. Provide clinical and technical insights about the risk factors, prevention, early detection, and treatment of lung cancer.
2. Share LUCIA's unique contributions beyond the state of art in such fields, in the framework of the EU's Beating Cancer Plan and the EU Cancer Mission.
3. Promote a multidisciplinary community for researchers, industry, policymakers, and practitioners to exchange challenges and solutions to improve the understanding of lung cancer and deliver most effective prevention and screening programmes.



The workshop was broadcasted on the YouTube channel of the hosting partner Vicomtech and is available **here**.

XpanDH

The XpanDH project organised a webinar on 28 June 2023, "**Unlocking the Benefits: Real-World Applications of the European Electronic Health**

XpanDH
Expanding Digital Health through a pan-European EHRxF-based Ecosystem

Record Exchange Format." The EEHRExF represents two important notions in the context of health data exchanges: it is a *set of principles* that should govern access to and exchange of Electronic Health Records across borders in the Union, but also a *process* to take forward the further elaboration of the format.

The first speaker, Esther Peelen of the Nictiz Centre of Expertise for Digital Information Management in Healthcare (Netherlands), talked about the national effort in her country to connect eHealth services with Europe and drive digital health information exchanges, with a new law (*Elektronische gegevensuitwisseling in de zorg* - Wegiz) coming into force in July 2023 that provides standards covering various domains critical to patient care as part of a step-based implementation approach (2023-2028) alongside an ongoing analysis of gaps and similarities undertaken in the context of the European Health Data Space. The domains include patient summary data, nursing discharge reports, medical imaging, medication processes such as prescription and dispensation, medication overviews, lab results for medication, adverse event monitoring, emergency care procedures, and the certification of electronic health record (EHR) systems. This legislation aims to improve the efficiency and quality of healthcare services while ensuring the secure management of patient information.

Kathi Apostolidis representing the European Cancer Patient Coalition (ECPC) stressed that access to patient records was vital as otherwise patients would need to keep and carry around multiple documents. However, she stated interoperability was crucial in this regard as cancer patients were often diagnosed at hospital prior to transfer to specialist cancer centres. She stated cancer patients were willing to share their data for research if privacy protection was safeguarded. Electronic health records should empower patients to engage in better self-management, e.g. by checking, correcting and complementing information. Many medical, technical and human science specialists need to collaborate in cancer care, facilitated by digital solutions. Among the EEHRExF benefits are that it provides a complete set of records; it

enhances privacy and security of patient data; it enables safer, more reliable prescribing; quicker access to patient records; improved patient-provider interaction and healthcare convenience; more effective diagnosis and error reduction. She also noted that training was needed for both patients and doctors; after all, the EEHRExF represented a basic EU infrastructure without which the envisaged comprehensive cancer centres could not function.

Michael Strübin (DIGITALEUROPE) provided the industry perspective, stating that interoperability opens up opportunities and services for new players in healthcare. patient safety comes first, but regulatory constraints and issues pertaining to efficacy and accuracy of health data needed to be tackled. Open, international standards were needed, developed in collaboration with industry. The right incentives were needed e.g., for makers of EHR systems and medical/connected devices, as well as common, robust and stable specifications (data formats, technical specs, standards and profiles), testing mechanisms and conformity assessments. In terms of market demand for EEHRExF, the signals received were still mixed as project efforts have not yet translated into adoption. Collaboration and patience were now required to turn vision into reality. Separate national health data exchange formats needed to be avoided. He expressed confidence that good legislation would translate into actual procurement and unlock investments in the Member States.

A recording of the webinar is available on the **XpanDH project website**.

Follow XpanDH project activities on **LinkedIn** and **Twitter!**

FLASH Project

One of the lessons learnt from the COVID-19 pandemic is the importance of flexibility in funding and organisation of health systems. European countries responded quickly to this extreme event, by expanding the number of financial resources available for health care and reallocating financial and human resources. However, there are several other challenges for health care systems that require efficient and flexible financing mechanisms to be successfully addressed.

FLASH, a 4-year project funded by Horizon Europe undertakes a comprehensive analysis of health care financing mechanisms in Europe and, by employing a wide range of methodological approaches, it provides evidence on the ability of existing financing mechanisms and contracts to address such challenges and study new solutions to achieve more effective, efficient and equitable health care systems.

With a total investment of 4.9 million euros, FLASH project brings together sixteen partners from nine European countries and intends to be a game-changer in the European integrated healthcare system. Nine universities and research centres, one non-profit organisation, and seven SMEs will work together on these research challenges and lead the way to bring innovation to the general public and create a resilient European healthcare system.

Read more and discover **FLASH new website**, and follow FLASH on Twitter **@EUFlashproject** and **LinkedIn**!

European Commission: State of the Union

On 13 September 2023, Commission's President Ursula von der Leyen delivered in the European parliament her State of the Union speech.

Health was definitely not at the core of her presentation. Health policy achievements, such as the Health Emergency Preparedness and Response Authority (HERA) and the mental health strategy were announced in previous State of the Union, respectively in 2021 and 2022.

She mentioned health three times only: "We agreed to buy vaccines"; "we have set the building blocks for Health Union", and the EU's support for Ukraine by ensuring "access to housing, healthcare job market and much more".

The group leaders' speeches only made a few mentions of the pandemic, S&D President Iratxe García and Green leader Philippe Lamberts, taking it as an example of cooperation. And there was a call by EPP's Manfred Webber to be leaders in cancer research.

Health has obviously lost its momentum despite health policy files such as pharmaceutical strategy and European Health Data Space and substances of human origin.

European Council: The Spanish Presidency

On 1 July 2023, Spain assumed the presidency of the European Council. During the first presentation to the ambassadors of Members States, the President of the Spanish Government, Pedro Sánchez, outlined the Council presidency's four priority areas for the next six months. These are:

- Reindustrialising the EU and ensure its open strategic autonomy.
- Advancing in the green transition and environmental adaptation.
- Promoting greater social and economic justice.
- Strengthening European unity

Health ministers

During the informal ministerial meeting (28 July) in Las Palmas de Gran Canaria, EU health ministers discussed the challenges European health care systems face and pledged to make progress on the European Health Union.

Among the issues that require concerted efforts, health leaders included:

- **Digitalising healthcare to improve care**. The digitalisation of healthcare is one of the key priorities for the Spanish presidency in terms of health. Challenges include protecting individual rights over health data and ensuring the ethical use of information.

Potential benefits include large scale development of new services and products for the prevention and treatment of diseases.

- **Strengthening support for mental health**. Health leaders agreed to work on changing the perception of mental illness and fighting stigma, particularly in a context where mental health problems have been exacerbated by the COVID-19 pandemic, increases in the cost of living, among other things.
- **Increasing the production of medicines in the EU.** The pandemic highlighted the importance of having EU-based supply chains to ensure access to essential medicines and health products and reduce its dependence on third countries. This autonomy measure is included in the strategic autonomy (OSA) proposal. The Spanish presidency is finalising the draft to be presented in October.
- Draft Council Conclusions on the transition of care systems throughout life towards holistic, person-centred and community-based models

Link.

Substances of human origin

Substances of human origin: European parliament votes its report

During the plenary session of the European Parliament on 12 September 2023, MEPs adopted the report on new rules governing the use of substances of human origin (SoHO) with 239 amendments to the text of the European Commission.

The report was adopted with 483 votes in favour, 52 against, and 89 abstentions.

MEPs insist that donations of those substances must always be voluntary and unpaid, with donors able to receive compensation or reimbursement for losses or expenses incurred during the donation process. They stress that compensation should not be used as an incentive to recruit donors, nor lead to the exploitation of vulnerable people.

To ensure the EU has its own independent supply of these substances, MEPs want an EU strategy to ensure their availability, an EU list of critical SoHOs, and the establishment of "national emergency and continuity of supply plans".

MEPs are ready to start the talks on the final shape of the legislation, once the Council agrees on its position.

The report adopted is available on: **EP Report on SoHOs**.

Previously on 18 July 2023, the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) had adopted its position. The report by Nathalie Colin-Oesterlé (EPP, French), which proposed amendments to the European Commission's initial proposal, was adopted with 59 votes in favour, 4 against and 4 abstentions.

Link to the compromise amendments adopted: **https://aeur.eu/f/84w.**

Medical Devices

Flowchart to assist decision-making regarding use of medical devices

The Directorate-General for Health and Food Safety has released a flowchart designed to aid manufacturers and other relevant parties in making decisions regarding whether a device falls under the extended transitional period outlined in Article 120 of Regulation (EU) 2017/745 on medical devices (MDR), as amended by Regulation 2023/607.

This flowchart is meant to assist in determining the eligibility, conditions and deadlines for the placing on the market or putting into service of certain devices in accordance with Article 120 MDR. Users of the flowchart are advised to consult the text of the MDR, which takes precedence over the flowchart, and the **Q&A section** regarding practical aspects related to the implementation of Regulation (EU) 2023/607.

Link to flowchart.

Online survey

The European Commission's Directorate-General for Health and Food Safety (DG SANTE), through the European Health and Digital Executive Agency (HADEA), has commissioned the consortium led by Netcompany-Intrasoft to run a communication campaign, to raise awareness on the new Regulations (EU) 2016/745 on medical devices and (EU) 2017/746 on in vitro diagnostic medical devices.

In the frame of this communication campaign, they are setting up a number of tools to keep medical stakeholders informed and engaged, allowing them to stay up to date with the latest news and initiatives in the health sector.

The objective of the online survey is to better understand the information needs around the EU Regulations on medical devices (MDR) and in vitro diagnostic medical devices (IVDR). Particularly, how the changes in the legislation are affecting stakeholders that are directly involved and what challenges you are facing to ensure a smooth transition to the new regulations.

To take part in the survey follow the **link**.

A stakeholder database was created to help communicate in a more efficient way with stakeholders. All relevant stakeholders can register **here**. Once registered, stakeholders will be able to receive all the relevant information about the changes in MD/ IVD regulations through quarterly communication.

To subscribe, please click on the following **link** and enter your details.

Orphan devices

The Medical Devices Coordination Group proposed a new work item: Guidance for manufacturers and notified bodies on the application of clinical evaluation requirements to orphan devices in view of their certification in accordance with the Medical Devices Regulation.

HOPE attended the 7 September 2023 ‘open session’ that followed the 6 September 2023 ‘closed session’ with only competent authorities.

The first topic for discussion was the definition of ‘orphan device’ in continuation of discussions based on current working definition which is: ‘Orphan device’ means a medical device specifically intended to benefit patients in the treatment or diagnosis [or prevention] of a disease or condition that has an annual incidence* of not more than 1 in 37,000 per year in the EU. A second topic was Orphan IVDs with the report from meeting of ‘small group’ on orphan IVDs on 30 August 2023. There were also reports by healthcare professionals about discontinued or ‘threatened’ legacy orphan devices.

In its position paper MDCG 2022-14, the MDCG stated that the Orphan Devices Task Force confirmed that generating sufficient clinical data for devices for orphan devices is challenging due to the epidemiology of the disease or condition to be treated (small patient populations). Meeting the clinical evidence requirements set out in the MDR within an appropriate time will be too burdensome or not even feasible for orphan devices.

The guidance should then address the following:

- definition of ‘orphan device’ for the purpose of the guidance and clarification of the scope of the planned guidance, including whether it should also apply to ‘orphan indications’ for devices intended for broader patient populations;
- clarification of the level of clinical safety evidence considered sufficient for demonstrating compliance with the applicable legal requirements. This should include clarification of what may constitute acceptable gaps in clinical evidence and of strategies to address those gaps within an appropriate time after certification by using suitable methodologies;
- clarification whether different considerations should apply for 'legacy' orphan devices compared to new orphan devices (not previously certified);
- identification of a possible role for expert panels, for example to provide voluntary scientific advice to manufacturers or to notified bodies on manufacturer’s clinical evaluation;
- highlighting the relevance for manufacturers to comply with the MDR requirements, and hence the opportunity to gather sufficient clinical evidence for orphan devices and orphan indications.

First stakeholder consultation workshop

HOPE as observer of the Medical Device Coordination Group (MDCG) participated in the First Stakeholder Consultation Workshop, on 19 September 2023.

This is taking part within the ongoing “Study on Regulatory Governance and Innovation in the field of Medical Devices”, developed by EY on behalf of the European Commission’s DG SANTE and HaDEA, as presented at the latest MDCG meetings on 17 April and 7 June 2023.

MEDTECH Europe open letter

On 14 September 2023 MEDTECH Europe send to the Health Commissioner an open Letter called “Need for comprehensive structural reform to address healthcare access challenges resulting from the EU regulatory framework for medical technologies.”

Considering that delayed access may become reality MEDTECH Europe puts the blame on the existing legislation. MEDTECH Europe considers that there are structural issues in the regulatory framework which cannot be solved simply through its implementation.

For MEDTECH Europe needs a more efficient and fit-for-purpose CE marking system, taking the best of the current framework while improving resource efficiency among manufacturers, notified bodies and authorities. At the same time, it should improve predictability of conformity assessments and requirements over the certification lifetime, so that all actors can plan, prepare, and allocate resources efficiently. Such improvements to the current system should result in reduced administrative burden and costs. The system should be reactive and able to adapt as needed to external changes.

Europe also needs according to MEDTECH Europe a system that supports innovation for medical devices and diagnostics, by incorporating an explicit innovation principle aimed at swiftly connecting the latest medical technologies to European patients and health systems. The EU can achieve this by establishing well-resourced platforms for early dialogue with developers on evidence expectations, and by making dedicated and fast-track assessment pathways available for medical technologies innovations that address unmet medical needs, life-threatening or highly debilitating conditions, and orphan and niche indications.

Finally, MEDTECH Europe considers that to put all this into practice, Europe needs a single, dedicated accountable structure to oversee and manage the regulatory system. It should designate and oversee Notified Bodies. The structure should be empowered to take system-level decisions to ensure efficiency and agility including providing support for SMEs. This includes the implementation of accelerated pathways for innovative technologies, and the enabling of Union-wide derogations in times of crisis to address unmet needs.

Health Technology Assessment

Prior Information Notice on building capacity and knowledge for the implementation of the EU Health Technology Assessment Regulation

On 4 July 2023, the European Health and Digital Executive Agency (HaDEA) released a Prior Information Notice for a call for tender purchase training services in the field of Health Technology Assessment (HTA), to ensure HTA agencies consolidate their knowledge and experience on joint HTA work. These trainings will help build capacity for the implementation of the HTA regulation and improve the availability of skilled personnel to take part in the joint work.

The trainings requested will include online classes, recorded modules, and tutoring. The topics have been pre-identified by the contracting authority but could be amended based on the needs of the HTA agencies and will serve the purpose of further strengthening their understanding of the new HTA Regulations. The estimated budget is €1.000.000.

Link.

Implementing Act on Joint Clinical Assessment for Medicinal Products

The consultation on the main concepts will take place during the 1st Commission Implementing Act on Joint Clinical Assessment for Medicinal Products on 3 October 2023. The meeting is for members and observers of the HTA Stakeholder Network only.

Workshop on oncology and advanced therapy medicinal products

A workshop on oncology and advanced therapy medicinal products will take place on 25 October 2023 organised by the European Commission.

Pharmaceuticals

Council and Parliament agree on flexible fee system

On 25 September 2023, the presidency of the Council and the European Parliament have reached a provisional agreement on a regulation to update and simplify the payment of fees to the European Medicines Agency (EMA). Key elements of the provisional agreement include:

- Cost-based fees;
- Simplifying the current legal framework by merging pharmacovigilance and marketing authorisations);
- Adjusting certain fees to reflect inflation rates;
- Increasing fees for scientific advice and procedures regarding generics; and
- Increasing remuneration for national competent authorities working on EMA-related activities.

The agreement still needs to be officially ratified by both institutions before going through the formal adoption process.

For more information on the rationale for this approach and next steps, **follow this link**.

Pharmaceutical package

Following a long process, the translations of the proposals of the Commission are now available in all languages:

- **EUR-Lex - 52023PC0193 - DE - EUR-Lex (europa.eu)**
- **EUR-Lex - 52023PC0192 - DE - EUR-Lex (europa.eu)**

The European Parliament decided on 14 September 2023 to refer the proposals to the responsible committees:

- **Directive**: ENVI + opinions by BUDG, ITRE, IMCO, JURI
- **Regulation**: ENVI + opinions by BUDG, CONT, ITRE, IMCO, AGRI, LIBE

The ministers for the internal market and industry scrutinised the pharmaceutical package on 25 September 2023 in a session of the Competitiveness Council. This was requested by Germany and Austria. A position paper drafted by industry ministries in Germany and Austria expressed worries for business with the package proposed by the Commission. According to POLITICO considering the progressive line at least of the Austrian ministry of health, this will complicate an already complex negotiation. Austria and Germany presented their concerns with the proposed pharma revision. This exchange is publicly available here **https://video.consilium.europa.eu/event/en/27025**. Some member states, in particular

smaller ones, made comments pointing out their support to the current proposal (Malta, Estonia, Cyprus, Hungary, Ireland and Bulgaria) except Denmark supporting the Austrian/German initiative. Some other member states do not want to duplicate the debates stating that this is an EPSCO topic.

European Medicines Agency: Phasing out of extraordinary COVID-19 regulatory flexibilities

On 6 July 2023, the European Medicines Agency (EMA), the European Commission (EC) and the Heads of Medicines Agencies (HMA) are phasing out the **extraordinary regulatory flexibilities for medicines put in place during the COVID-19 pandemic** to help address regulatory and supply challenges arising from the pandemic. This follows the **end of the COVID-19 public health emergency declared by WHO** in May 2023.

The extraordinary regulatory flexibilities covered different areas, including marketing authorisation and related regulatory procedures, manufacturing and importation of active pharmaceutical ingredients and finished products, quality variations, labelling and packaging requirements and compliance. The EC, HMA and EMA also agreed during the pandemic on a series of measures to mitigate the impact of disruptions caused by the public health emergency on inspections of manufacturing facilities or other sites relevant for medicinal products in the EU. The extraordinary flexibilities ensured the continued availability of medicines while making sure that good manufacturing (GMP) and distribution practice (GDP) standards were being adhered to.

From now on, the regulatory flexibilities that were introduced jointly by the HMA, EC and EMA specifically during the COVID-19 pandemic should no longer be granted. For already approved labelling flexibilities, e.g., the English-only labelling for COVID-19 vaccines, their application will be extended until the end of 2023, to ensure a smooth phase-out and avoid any supply difficulties or other disruptions due to a sudden change in applicable requirements. After 2023, the regular mechanisms foreseen in the legislation in relation to labelling exemptions should be followed.

Concerning on-site GMP and GDP inspections, these have been restarted after being postponed or carried out remotely during the pandemic, however, a considerable number of postponed inspections still need to be carried out. The validity of GMP and GDP certificates has currently been extended until the end of 2023, and the GMDP Inspectors Working Group will issue in the coming months an update on the approach for 2024. This Group has also reviewed experiences with remote working arrangements of Qualified Persons during the pandemic and will issue guidance on how those specific arrangements can be applied in the future.

Experiences gathered during the application of the COVID-19 regulatory flexibilities are being collected by EMA's **Executive Steering Group on Shortages and Safety of Medicinal**

Products (MSSG). They will consider how lessons learned can inform best practices for tackling medicine shortages in case of new and emerging health challenges in the future.

Pharmaceuticals: Transparency directive

HOPE attended on 29 June 2023 the online stakeholder workshop on the state of functioning and implementation of the Council Directive 89/105/EEC relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems, better known as the "Transparency Directive".

This workshop was organised by the EUHealthSupport consortium, in the context of a study launched by the Directorate General for Health and Food Safety (DG SANTE) of the European Commission and contracted to them. The study aims to gain insights into:

- Implementation challenges of the "Transparency Directive" and its requirements in Member States as part of the broader medicine pricing and reimbursement processes;
- Limitations of the "Transparency Directive" to meet the policy aims ;
- Potential future policy actions related to implementation of the "Transparency Directive" to support the Pharmaceutical Strategy objectives, including technical and digital improvements.

The Commission representative (Sylvain Giraud, Unit D2 'Medical products: quality, safety, innovation', DG SANTE) insisted several times that this was not a formal evaluation nor a first step in a process to revise the directive.

The purpose of the workshop was to exchange lessons and information regarding stakeholder (non-state actors) experiences and views on the application/impact of the provisions laid down in the Council Directive 89/105/EEC and/or the functioning of the system it puts in place. This workshop is part of a series of consultations, which will also include a public survey to stakeholders (non-state actors) and Member States.

Court of justice of the EU: University hospital

On 22 June 2023, the Court of Justice of the European Union (CJEU) annulled the decision of the General Court of the European Union (Joined Cases 6/21 P and C-16/21 P) which had found that the experts of the European Medicines Agency (EMA) could have been impartial in the negative opinion issued on the marketing authorisation application by *Pharma Mar* for the orphan drug '*Aplidin*'.

The Court finds a university hospital cannot be considered a 'pharmaceutical undertaking' and its experts can therefore participate in EMA's activities.

In July 2018, the Commission had relied on an EMA opinion to refuse to grant marketing authorisation for this drug developed to treat severe bone marrow cancer. The opinion was

based on the work of several experts, two of whom had been employed by a university hospital that controlled a cell therapy centre. The latter fulfilled the criteria of a 'pharmaceutical undertaking' within the meaning of EMA rules. Employment in such a company is, in principle, incompatible with participation in EMA activities.

Just over two years later, on 28 October 2020, following an appeal lodged by *Pharma Mar*, the Court of First Instance annulled this decision, ruling that the procedure that led to the refusal did not offer sufficient guarantees to exclude any legitimate doubt as to the possible bias of the experts involved in the assessment of the drug.

In its judgment, the Court held that the Court of First Instance had erred in considering that the university hospital constituted a 'pharmaceutical undertaking' solely because it controlled the cell therapy centre in question.

"To consider that all the staff of a university hospital are employed by a 'pharmaceutical undertaking' would be contrary to European Union law," the Court stated, taking the view that a blanket exclusion of this kind could lead to a shortage of experts with sufficient medical knowledge to assess medicines.

In addition, the Court points out, the EU's centralised authorisation procedure also applies to orphan medicines, with a view to harmonising the single market.

Hearing on medicine shortages

During the European Parliament hearing of 13 July 2023 on 'Medicine shortages', Members of the SANT subcommittee held a debate on the role of the European Commission and Member States regarding any necessary action to restore pharmaceutical sovereignty in Europe and local pharmaceutical production, with particular attention to the priority given to essential and strategic medicines.

Five persons were asked to provide feedback. Professor Jerzy Sieńko, specialist in general surgery, oncology and clinical transplantology; Flemming Sonne, CEO of Amgros; Illaria Passarani, Secretary General PGEU (European Community Pharmacists); Professor Tomasz Byrski, head of the oncology and chemotherapy clinic of the Pomeranian Medical University; Charlotte Roffiaen, patient advocate, France Assos Santé (FAS) & European Public Health Alliance (EPHA).

The event was a mix of realism, questioning any ability to buy for 450 million Europeans, mentioning the lack of methodology and collecting information and simplistic views on a common budget for cancer drugs and stockpiling.

Recommendations for actions to avoid shortages of key antibiotics used to treat respiratory infections

The European Commission, the Heads of Medicines Agencies (HMA), and the European Medicines Agency (EMA) issued recommendations for actions to avoid shortages of key antibiotics used to treat respiratory infections this upcoming winter season. These recommendations have been developed by the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) and they complement the process determining the EU list of critical medicines.

If the demand is similar to last year's winter season, the data suggests that supply to the EU of oral formulations of key first and second-line antibiotics for respiratory infections will match demand in the coming winter season.

The recommendations include:

- Increasing the production of key antibiotics.
- Monitoring of supply and demand.
- Raising public awareness and prudent use.

Read more about the context, available data on key antibiotics, and the EU list of critical medicines here.

Pharma package translated in all languages since 14 September **EUR-Lex - 52023PC0193 - EN - EUR-Lex (europa.eu).**

Optimising Public Procurement of Medicines

HOPE participated on 26 September 2023 in Brussels to the workshop presenting and debating the main findings and recommendations from the study on "Optimising Public Procurement of Medicines."

The first session was devoted to Best Practices in Action: country experiences leveraging procurement for security of supply, access, affordability, and environmental protection. The main purpose of this session was to facilitate a comprehensive understanding of the practical aspects involved in implementing specific procurement policies, by highlighting hands-on experiences and presenting concrete examples. Participants gained valuable insights in the challenges, successes and lessons learned during the implementation of procurement policies in different countries.

Three presentations were developed:

- Using MEAT criteria with focus on better security of supply. Multiple winners, pooling our efforts and increasing access (Eirik Sverrisson, Norwegian Hospital Procurement Trust);

- Lessons from Denmark's integration of environmental criteria and lifecycle approach in tenders (Rasmus Syberg Hazelton, Amgros);
- Collaborative procurement in the Baltics: Estonia's experiences and success stories in joint procurement initiatives (Eveli Bauer, Baltic Procurement Initiative).

The second session was on Aligning Procurement Strategies with Supplier and End-User Needs: unveiling key challenges and considerations. During this panel discussion, suppliers and end-users had a valuable opportunity to articulate their challenges and needs to procurers and policymakers. By exploring these perspectives, the session aimed to equip participants with valuable insights for crafting procurement approaches that effectively cater to the requirements and concerns of suppliers and end-users.

This was followed by break-out sessions. Session A on Ensuring Security of Supply: Optimizing Procurement through Multiple Winners Awarding and Supply Criteria delved into the vital aspect of addressing security of supply through procurement strategies. Participants explored the implementation of multiple winners awarding and supply criteria, through practical case studies. This session focused on operational matters and drafting tenders, providing practical insights and best practices to optimise procurement outcomes.

Session B on Lifecycle Approach and Trade-offs: Developing a Robust Strategy for Procurement of Medicines emphasised on developing a comprehensive strategy for procurement of medicines by considering a lifecycle approach and trade-offs. Participants engaged in policy-oriented discussions, exploring how procurement policies can be designed to balance the lifecycle considerations and make informed trade-offs.

Session C on Environmental Criteria Integration in Tenders: Promoting Sustainable Procurement Practices centred around the integration of environmental criteria in tenders, highlighting the significance of sustainable procurement practices. Procurers and policymakers delved into the practical aspects of incorporating environmental considerations into the procurement process, working on concrete case studies. This session provided practical guidance on drafting tenders that effectively address environmental concerns. But the example of Denmark showed that there is limited evidence of an impact on the environment and that it is ten times longer to evaluate.

Session D on Collaborative Procurement: Leveraging the Power of Joining Forces emphasised on the potential benefits of collaboration. Participants delved into the practical aspects of starting and implementing joint procurement, gaining insights into the necessary requirements and key considerations involved. This session aimed to equip procurers and policymakers with valuable guidance and best practices, enabling them to navigate the complexities of collaborative procurement successfully.

Cross-border threats

➢ COVID-19

Parliament adopts roadmap to better prepare for future health crises

On 12 July 2023, the Parliament adopted its Resolution on the COVID-19 pandemic: lessons learned and recommendations for the future which calls for action in four thematic blocks steaming from its mandate, i.e., health, democracy and fundamental rights, social and economic impact and EU and the world. It includes a series of final recommendations on prevention capacity, preparedness, resilience and open strategic autonomy. The text was adopted by 385 votes in favour, 193 against and 63 abstentions.

Over the past year, the European Parliament's Special Committee on the COVID-10 pandemic (COVI) analysed the impact of the crises, evaluated the effectiveness of EU and national measures and made specific recommendations to address gaps and weaknesses in their actions.

Key proposals include enhancing the EU's strategic autonomy for medicines, transparency for joint procurement activities, and stronger parliamentary oversight at both EU and national levels for emergency legislation. MEPs also demand the EU maximise the use of recovery funding to strengthen the single market and want improved global coordination with the upcoming international pandemic treaty.

The detailed recommendations are available **here**.

Link.

Impact of selected non-pharmaceutical interventions on EU adult's work-life balance during the COVID-19 pandemic, 2020-2022

This technical report from the ECDC was published on 9 August 2023. It summarises results from an analysis conducted by the ECDC and Eurofound to understand the impact of selected non-pharmaceutical interventions (NPI) introduced from 2020 to 2022 in response to the COVID-19 pandemic on the work-life balance (WLB) among EU adults.

The study is set in the 27 EU Member States between March 2020 and May 2022. It found that the selected NPIs (stay-at-home orders and recommendations, closure of day-care, primary and secondary schools (closure of educational facilities) and national teleworking recommendations), implemented in response to the COVID-19 pandemic significantly affected the adult work-life balance (WLB).

On the one hand, these NPIs, particularly the closure of educational facilities and teleworking, reduced the pressure of work on personal and family life by decreasing working time and tiredness from work. On the other hand, the selected NPIs, particularly the stay-at-home policies and teleworking, increased European adults' propensity to worry about work outside of working hours and, in some instances, reduced their job concentration and dedicated working time due to family responsibilities.

More information about the report.

➢ HERA

HERA: Civil Society Forum

HOPE participated on 30 June 2023 to the meeting of the HERA (European health emergency preparedness and response authority) civil society forum (CSF) looking at the results of two of the three working groups.

Working group 1 (of which HOPE withdrew) presented an update of their preliminary answers to the three guiding questions posed by the Commission concerning the review of HERA. The working group emphasised the need to further refine and define HERA mandate and tasks, especially regarding enhanced collaboration among EU-level institutions active in emergency response. It was further requested to provide a clearer understanding of preparedness, along with HERA's role and responsibilities in ensuring preparedness. It was highlighted that preparedness entails more than medication and protective equipment availability. The working group preliminary concluded that HERA could become a comprehensive crisis hub for health and could benefit from more autonomy, transparency, funding, fast decision-making and strong cooperation mechanisms with stakeholders.

Following the presentation by the working group, the Chair emphasised the roles of SANTE and HERA, clarifying that SANTE serves as the regulatory body while HERA acts as the operational tool for health emergencies. The Chair reiterated that HERA's main focus is medical counter measures (MCMs), but it remains open to incorporating input from first responders if they identify MCM needs. On the question of HERA form of entity, the Chair underlined that being a separate entity creates more autonomy but may lead to unique challenges, such as diminished political influence. The Chair stressed that in crisis mode, HERA requires rapid crisis response and proximity to decision-makers.

Working group 3 (training and information) led by HOPE aims at providing recommendations to the development of HERA's training programme and communication actions. The second meeting took place in the morning of 30 June 2023 before the main meeting of the CSF, and activities on training and information from ECDC and EMA were presented. HERA also presented an overview of the work of the European Commission on misinformation and disinformation.

Then the Commission gave an update on HERA's health threats approach. The Commission conducted and concluded its first threat assessment and prioritisation exercise in 2022, resulting in the selection of three high-impact threats, notably pathogens with high pandemic potential, chemical, biological, radiological and nuclear (CBRN) threats originating from accidental or deliberate release, and health threats associated to antimicrobial resistance. HERA plans to regularly review and update the list of priority threats to prepare against, according to epidemiological or other contextual evolution. HERA recently shared with the HERA Board a proposal to address more prominently two additional topics, namely environmental health threats and biosecurity and potential dual use/misuse of emerging technologies. As regards environmental health threats, HERA reminded that its mandate is not to prevent the occurrence of health threats of environmental origin by addressing their root causes, e.g., climate change, but rather to mitigate their consequences on human health through appropriate MCM preparedness and response. Therefore, an assessment will be carried out to identify the types of health conditions caused or promoted by environmental factors that are relevant for HERA, i.e., which require EU coordination for MCM preparedness and response.

The Commission gave an update on HERA initiatives on AMR, which are carried under the 2017 EU action plan against AMR. HERA actions concentrate on MCMs that can contribute to not only better treatments for patients infected with multi-resistant pathogens, but also to optimise and reduce the antimicrobial consumption, and thus to prevent the emergence and spread of AMR. By promoting innovation and access to MCMs against AMR, the Commission supports the EU action plan against AMR, including EU policies on surveillance, awareness, stewardship, infection prevention and control. Furthermore, the Commission commissioned two studies to prepare its action on AMR, both publicly available. A strong priority for the Commission is the implementation of direct financial pull incentives, in form of annual revenue guarantee, market entry reward or milestone payments, in articulation with the Commission proposal to include indirect pull incentives in form of "transferable data protection vouchers" in the EU pharma legislation.

The Commission gave an update on the MCM prioritisation exercise. In collaboration with Member States, the Commission has developed an MCM prioritisation methodology including prioritisation criteria. It was used to draw up a list of priority critical medical countermeasures for the 2023 call for stockpiling under rescEU. Later this year, the Commission will focus on establishing a list of a limited number of priority MCMs to guide its supply chain monitoring activities, covering different MCM categories. This work will be enhanced once HERA's ATHINA tool for intelligence gathering and monitoring is in place. A prioritisation of products under development to guide HERA R&D activities will follow. HERA will map promising technologies as well as products in development tackling preliminary identified gaps. In a final step, experts from Member States will be requested to evaluate products on the pipeline list based on prioritisation criteria. This analysis is scheduled for the end of the year.

The Commission presented the Joint Industrial Cooperation Forum (JICF) and gave an update regarding the most recent developments. The JICF has been set up by HERA together with DG GROW to support the work on preparedness and response to cross-border health threats.

Its objective is to identify and, where possible, reduce congestions within and outside the EU, including market failures and supply chain dependencies that could limit the production capabilities of relevant medical countermeasures and access to their raw materials. To ensure wide representation of relevant industry and supply chain stakeholder, 19 organisations have been selected to take part in the Forum following a call for applications published on 28 March 2022. It brings together the Commission, national representatives as well as industrial organisations representing relevant supply chains including pharmaceutical, medical device, biocidal products, Personal Protective Equipment industries and animal health organisations, as well as health procurement and distribution organisations. The JICF is meeting twice a year. HERA informed the CSF members of the main outcomes of the last meeting, which took place on the 26 April 2023.

CSF members made several comments regarding the composition of the JICF, namely the presence of non-Member State members which do not represent industry and the lack of understanding that this forum could also feature non-industry representatives. Members also mentioned that the name does not fully reflect the composition of the forum. Following CSF Members' comments, the Commission will explore possibilities for additional memberships to address current and future unforeseen gaps or new challenges.

HERA: InvestEU

On 12 June 2023, HERA announced the creation of HERA Invest, a €100 million top-up to the InvestEU programme, to support research and development (R&D) in the most pressing cross-border health threats, financed by the EU4Health programme. Currently, European companies find it difficult to access sufficient public and private funding for the development and scaling up of cutting-edge solutions in health and life sciences. Innovation is needed to respond to priority health threats such as pathogens with high pandemic potential or resistance to antibiotics.

The HERA Invest funding instrument is geared towards small and mid-sized companies (SMEs) that develop medical countermeasures addressing one of the following health threats:

- Pathogens with pandemic or epidemic potential
- Chemical, biological, radiological and nuclear threats originating from accidental or deliberate release
- Antimicrobial resistance

Under HERA Invest, the European Investment Bank (EIB) will provide venture loans, covering a maximum of 50% of total project costs. There is a rolling application process. The EIB assesses whether an operation is eligible based on defined criteria and the project's commercial and scientific viability.

More information:

- **Webpage**

- **Press release**
- **Factsheet**

EU Reference Laboratories (EURLs) for public health

HOPE attended on 29 August 2023 the webinar "Meeting on EU Reference Laboratories (EURLs) for public health - Stakeholder Webinar".

Article 15 of Regulation (EU) 2022/2371 states that the European Commission may designate, by means of implementing acts, European reference laboratories (EURLs) in public health or for specific areas of public health relevant for the implementation of the Regulation. These EURLs for public health will provide support to national reference laboratories to promote good practice and alignment on diagnostics, testing methods, use of certain tests for the uniform surveillance, notification and reporting of diseases by Member States.

The network of EURLs for public health will be operated and coordinated by the European Centre for Disease Prevention and Control (ECDC). The EURLs will be designated for at least four years, and grants will be made available under the EU4Health programme to cover for the costs that the EURLs will incur in the implementation of their work programmes.

The purpose of the webinar was to inform stakeholders about the plan of the implementation, and to collect their feedback and additional input on specific EURL aspects. The webinar was focused on stakeholders that have not already been included in any specific consultations in this area and will also address the concept of EURLs in areas other than communicable diseases (e.g., threats of chemical or environmental origin) of relevance for the implementation of Regulation 2022/2371.

ECDC e-learning pilot course on the topic of “Vaccine acceptance and behaviour change”

This is a 45-minute course, designed for frontline health workers involved in the planning, counselling, prescription, and administration of recommended vaccines and who have a role in promoting vaccine acceptance. Its aim is to introduce the concept of vaccine acceptance, the main themes of behaviour change related to vaccine acceptance and to present communication as a supportive tool to help ECDC_pilot_Vaccine. persons to take important decisions for their health. The pilot that will run from 22 June to 14 July 2023. The objective is to collect detailed feedback on the course slides as well as feedback about the overall quality of the course. After the pilot, the ECDC will finalise and launch the e-learning in EVA, making it available in open access. To provide feedback, this is the access in EVA **https://eva.ecdc.europa.eu/enrol/index.php?id=608** and the code.

Good safety profile of COVID-19 vaccine confirmed

On 5 July the European Medicines Agency endorsed a joint statement on the safety of COVID-19 vaccines issued by the International Coalition of Medicines Regulatory Authorities (ICMRA), which brings together 38 medicines regulatory authorities from across the world and includes the World Health Organization as an observer.

Evidence from more than 13 billion doses of COVID-19 vaccines administered worldwide shows that these vaccines aimed at protecting people from severe outcomes of COVID-19 have a very good safety profile in all age groups, including children and people with underlying medical conditions, immunocompromised patients and pregnant women.

The statement also highlights that vaccines reduce the impact of long COVID based on several real-world data studies and that there is no indication from the very large data set suggesting that this condition is a possible side effect of COVID-19 vaccination. It also draws attention to the spread and impact of false and misleading information about the safety of COVID-19 vaccines on public health, as it can result in deaths or severe disease if people avoid getting the vaccines they need.

Read full summary **here** and the ICMRA statement **here**.

EU Network Training Centre page information

The European Union Network Training Centre (EU NTC) platform offers training opportunities (in human and veterinary medicines) to the staff of medicines regulatory authorities in the European medicines regulatory network. It is overseen by the European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA).

The platform can pool resources and expertise in regulatory authorities in different EU countries to develop training programmes for the entire regulatory network.

To learn more about how it works, who has access, and how to use the platform, among other information, **you can consult this link**.

Training and resources for patients, consumers and HCPs/academia

The European Medicines Agency (EMA) also provides training and resources for patients and consumers, as well as their representatives to enable a better understanding of the work of the EMA, and the types of activities they can be involved in.

Click here for more information on the resources, workshops, and webinars for patients and consumers.

Likewise, the EMA has developed training and resources tailored for health care professionals, and for academics and researchers. Information for both can be consulted below.

Information for HCPs
Information for academics and researchers

EMA releases presentation on mis-/disinformation

The EMA has published a presentation on mis-/disinformation about medicines and vaccines, which it first presented at the Patient and Consumer Working Party plenary meeting. This resource can help civil society and other actors combat the spread of misleading and sometimes false medical information.

The presentation can be accessed here.

Future Shocks

European Parliamentary Research Service (EPRS) published in July 2023 its annual 'Future Shocks' called **Future Shocks 2023**.

The European Parliament started monitoring future shocks during the coronavirus crisis and has continued to do so during Russia's unprecedented war on Ukraine.

The annual 'Future Shocks' series reviews global risks, with a focus on specific risks and the capabilities and resilience of the EU system in the face of multiple challenges. It seeks to provide up-to-date, objective and authoritative information on these risks, based on risk literature from a broad range of sources. 'Future Shocks' includes, but is not limited to, areas where the EU has primary competence, and identifies the benefits of concerted action by the EU as well as the ability of its institutions and Member States to find new and effective solutions to deal with major shocks.

The 2023 edition, the second in this annual series, highlights 15 risks related to geopolitics, climate change, health, economics and democracy that could occur in the coming decade, and 10 policy responses to address existing governance capacity and possible ways to enhance capabilities within the EU. Among the options set out are those previously included in European Parliament resolutions, positions from other EU institutions, and policy papers from think tanks and stakeholders.

The health risk presented in the document is the increase in antimicrobial-resistant infections.

➢ Antimicrobial resistance

New OECD report: One Health action generates high return on investment

A policy study by the Organisation for Economic Co-operation and Development (OECD), "**Embracing a One Health Framework to Fight Antimicrobial Resistance,**" released on 14 September 2023, confirms that antimicrobial resistance (AMR) levels will remain very high over the next 25 years if targeted One Health action (focusing on people, animals, agri-food systems and the environment) is not stepped up. As a result, resistant infections will claim the lives of thousands of people in OECD and EU/EEA countries every year, exert additional pressure on hospitals, and increase costs for health systems and economies.

Building on OECD's 2018 report, "**Stemming the Superbug Tide: Just a Few Dollars More,**" the new report looks at the effectiveness and cost-effectiveness of 11 One Health policy interventions and three policy packages. The document highlights worrisome trends regarding antibiotic consumption:

- in human health, despite efforts to optimise consumption, average sales of all classes have been rising by nearly 2% since 2000, and more than one-third of OECD countries do not meet the WHO target for first line antibiotics to make up at least 60% of all antibiotic consumption. If historical trends continue, significant decreases will not occur until 2035;
- In animals, the use of antimicrobials in OECD countries has halved between 2000 and 2019 and could decrease by an additional 10% by 2035. But the majority of sales for animals takes place outside OECD countries and in the G20 could double that of the OECD average by 2035;
- Fuelled by high levels of inappropriate use, resistance proportions across 12 antibiotic bacterium combinations stand at around 20% across the OECD: one in five infections is now caused by superbugs;
- If left unchecked, resistance to last-resort antimicrobials could be 2.1 times higher by 2035 compared to 2005. Health systems will be running out of options to treat patients suffering from a range of illnesses including pneumonia and bloodstream infections;
- AMR remains dangerously high in some countries, including Greece and Türkiye, where more than 40% of all infections caused by the 12 antibiotic-superbug combinations studied by OECD could be resistant by 2035; this could be 90% for certain antibiotic-bacterium pairs such as fluoroquinolone-resistant and carbapenem-resistant infections.

Treating complications due to resistant infections can exceed USD 28.9 billion annually across OECD and EU/EEA countries, with total health expenditure incurred by AMR corresponding to

19% of the total health expenditure due to treating COVID-19 patients in 2020. The document also highlights that, to treat the consequences of AMR, an additional 32.5 million days are spent in hospital per year and that the impact on workforce participation and productivity is estimated to be equivalent to USD 36.9 billion.

OECD stresses that investments across human and animal health, agrifood systems and the environment deliver the highest returns. In addition to implementing National Action Plans against AMR, it will be important to:

- bolster nationwide implementation of programmes for infection prevention and control and for optimal use of antimicrobials in line with international standards and best practices;
- Invest in more robust surveillance systems, particularly in specific areas in human (e.g. long-term care) and animal health;
- Ensure greater compliance with regulatory frameworks, especially to promote prudent use of antimicrobials in animals; and
- Increase R&D investments for new antibiotics, vaccines and diagnostics.

The 11 policy interventions modelled by the OECD are estimated to generate substantial health and economic gains. Among these, the following interventions promise to yield the highest gains: strengthening antimicrobial stewardship programmes, better environmental and hand hygiene practices in healthcare settings (human health), as well as better food safety practices and improved biosecurity in farms.

Scaling up investments in One Health actions is affordable, with a high return on investment (every USD invested in a mixed policy package across the health and food sectors, generates returns equivalent to USD 5 in economic benefits achieved through reductions in health expenditure and increased work productivity).

➢ Cancer

Promises & challenges of EHDS for cancer patients

A policy dialogue organised by the **MEPs against Cancer Interest Group** on 19 September 2023 discussed the potential of the European Health Data Space (EHDS) for cancer patients, concluding that it will be tricky to establish the right balance between safeguarding patients' privacy on the one hand, and spearheading innovation thanks to the secondary use of health data on the other.

Dr Francisco Rodriguez Lozano (Chair, Cancer Patients Europe) stressed that proper legislation balancing patients' rights and research needs will be required for the EHDS to work. He argued that reassuring patients that their health data will be safe was of paramount importance, hence it was particularly vital to communicate clearly about the different purposes of secondary uses – especially regarding disease-specific research. In Spain, with 17 different regional health systems, the EHDS could, for example, facilitate easier access to health data

by enabling less burdensome administrative processes. At the same time, Lozano reported that the “right to be forgotten” was treasured by Spanish patients, indicating there might also be concerns among certain patients about sharing health data for purposes not clear to them, even if cancer patients were generally inclined to share their data.

MEP Tilly Metz (Greens, Luxembourg) highlighted that unambiguous safeguards were required for patients to be able to protect their privacy, which could only be achieved through the introduction of opt-out options regarding certain health data uses, even regarding some primary uses. More stratification might be needed as the current conception of the EHDS includes everybody, regardless of their personal situation and disease status. It was important that the EHDS will benefit patients first and foremost, whether by improving access to certain treatments or enhancing quality of life for certain groups. Moreover, MEP Metz stated that a better balance between public and private sector research was required, e.g., through open science approaches enabling to spread the knowledge derived from patients’ health data and ensuring that patients could really gain access to new treatments in a timely and inclusive way.

Dr Daniel Morales (European Medicines Agency) outlined the benefits of the EHDS for regulatory agencies, explaining that EMA would like access to data to be rapid, wide (geographic coverage) and deep (detailed), to ensure data were comprehensive and reflecting the population of the EU. He stated it will be important to make it more understandable for individuals to understand what they are getting back in return for sharing their health data for secondary (research, public health, regulatory, etc.) purposes as the potential was great for patients in terms of being able to get new treatments.

The need to design a “fit-for-purpose" EHDS, which could instil confidence and trust, was a key point made by Sylvia Maurer, Health Team Leader at the European Consumers’ Union Bureau (BEUC). Firstly, this needed to entail giving individual patients the right to decide who has access to their health data for secondary uses (via opt-out) so that people feel they actually have choices at their disposal; she noted there were noticeable differences between certain categories of patients (e.g., cancer, rare disease or certain NCD sufferers) eager to share their data, digitally literate and engaged in managing their conditions, and other patients with less life-threatening diseases who remained very hesitant. Moreover, she agreed with Dr Lozano on the issue of communication and explanation given the many different purposes and intents of the EHDS proposal. Cybersecurity and enshrining clear rights for individuals in case their health data should be misused was another point that needed to be included in the proposal.

Completing the panel, Nasreen Anjum, Policy Officer at KFW Kankerbestrijding (Netherlands) represented the academic point of view, noting that the EHDS could become a gamechanger for researchers in the oncology field, all the more so as 1 in 5 cancers were rare and at present there were too many obstacles regarding access to health data. Therefore, research projects were often slowed down by one year or more, coupled with issues pertaining to data system interoperability and insufficient channels for collaboration between academia and the private sector to ensure innovation could be brought to the market. Hence, she spoke in favour of rapid verdicts taken by the Health Data Access Bodies and ensuring they will also apply in

other Member States to avoid having to file multiple applications while also supporting transparency and ensuring that technical solutions integrated in the EHDS are safe.

➢ Health equity

European associations working with homeless call on Member States to consider 'housing exclusion' to be major public health issue

On 5 September 2023, FEANTSA (European Federation of National Organisations Working with the Homeless) and the *Abbé Pierre Foundation* presented their eighth annual report on housing exclusion in Europe.

Indicating that no fewer than 895,000 people are currently homeless in the European Union, both organisations are calling on European public authorities to recognise unfit housing as a major public health issue.

"The pandemic highlighted the vital role of housing in debates around health. Given its importance, housing should be considered essential to improving the living conditions of households and as a way to leverage public policies. Combatting unfit housing should therefore be part of all EU measures taken to implement the 'Renovation Wave'."

In addition, the report describes a disparate situation across Europe. If certain international criteria are included in the definition of housing exclusion—such as cramped conditions, poor insulation, or mould, a total of more than 19.2 million people in the EU were affected by severely unfit housing in 2020.

"The rates of severe housing deprivation observed in the different [...] Member States in 2020 show significant disparities [...]. While this deprivation only affects one person in every hundred in Malta and Finland, it impacts a significant segment of the population in Hungary (7.6%), Poland (7.9%), Bulgaria (8.6%), Latvia (11.5%) and Romania (14.3%)."

Northern EU countries also have more housing that has been refurbished more recently, while [social] housing stock in eastern EU countries, due to their Soviet past, or in southern EU countries, for other structural reasons, has housing that is in poorer condition.

In 2020, "more than one in eight Bulgarians (13%) were living in housing without an indoor toilet", emphasised the Abbé Pierre Foundation. "Almost a fifth of the population (18%) [was] living in housing that could be considered unfit [due to mould problems] in France."

The two associations also pointed out the increased risks of fire, illness, and even depression that such precarious housing can cause—recent studies conducted in the United Kingdom having demonstrated a link between housing renovation and a reduction in depression.

Link to the report: **https://aeur.eu/f/8fj.**

Long term care - standardisation

BSI, the British Standards institute, is proposing to elaborate a new international standard on "Care for older persons at home and in residential care facilities" (with as future number ISO 25557).

This future standard would specify requirements and recommendations for the provision of health and social care services for older persons provided by healthcare and social care personnel, irrespective of whether the service is provided in the persons own home or in a care home. The services concerned would also include those offered to older people who do not reside permanently at a care home, such as temporary accommodations. Care services are provided in a variety of settings. While this future international standard would focus on those delivered in care facilities including preventive, responsive, and palliative care, many of the requirements could also be applied to the provision of care services in any setting.

This future international standard would seek inspiration in the already existing Canadian, British, and international standards (CAN/HSO 21001:2022, CSA Z8004). The European CEN/Technical Specification 17500 "Quality of care and support for older persons" – to which the ETUC actively contributed during its drafting - is likely to be a basis for this new international standard.

➢ Mental health

European Commission publishes comprehensive approach to fund mental health flagship initiatives

On 7 June 2023, the European Commission published a new **comprehensive approach to mental health** with 20 flagship initiatives and EUR 1.23 billion in EU funding.

One of these flagships, number 15, aims to support health professionals in the EU through training on mental health. The aim is to train 2,000 professionals across the EU by 2026, resulting in 100 sessions per year on average.

To this end, HaDEA has launched the call for tenders "**Capacity-building on mental health: multidisciplinary training programme and exchange programme for health professionals**."

The contractor will:

- Design, create, pilot, implement and evaluate a multidisciplinary hybrid training programme and an EU exchange programme for professionals working in the area of mental health;
- Develop a study to identify the needs, gaps and obstacles of current knowledge, competences and training needs of health professionals;

- Produce a toolkit on an EU multidisciplinary approach to mental health capacity-building.

Estimated budget: €9.000.000

All interested parties are invited to send their applications by **4 September 2023 16:00 (CEST).**

Learn more and apply on the eTendering portal.

World Mental Health Day conference hosted by the European Commission

Within the framework of World Mental Health Day, the European Commission is organising a high-level conference on **10 October 2023 in Brussels.** Stella Kyriakides, European Commissioner for Health and Food Safety, will host the half-day event, bringing together hundreds of representatives from the EU institutions, national governments, and international organisations, among others. The following topics will be covered:

- Mental health across all policies
- Promotion & Prevention
- Equal access for all

Click here to learn more about the event and register.

Call for tenders: "Capacity-building on mental health"

The call for tenders "Capacity-building on mental health: multidisciplinary training programme and exchange programme for health professionals" under the EU4Health programme is still open for applications. The contractor will:

- Design, create, pilot, implement and evaluate a multidisciplinary hybrid training programme and an EU exchange programme for professionals working in the area of mental health;
- Develop a study to identify the needs, gaps and obstacles of current knowledge, competences and training needs of health professionals;
- Produce a toolkit on an EU multidisciplinary approach to mental health capacity-building.
  All interested parties are invited to send their applications by 4 September 2023 16:00 (CEST).
  Read more on HaDEA website.

EU4Health call for tenders on mental health training and exchange programmes for health professionals (europa.eu).

Call for best and promising practices on mental health

On 12 July 2023, the European Commission published a **call for best and promising practices on mental health** on its **Best Practice Portal**. This call supports the implementation of actions identified in the Commission Communication on a comprehensive approach to mental health.

The Commission calls for best and promising practices aimed at, in particular:

- mental health across policies (i.e., coordination and consistency of measures among policy areas such as health, education, digitalisation, migration, justice, social services, environment, climate, etc);
- addressing children and young people's mental health and psychological wellbeing;
- improving the mental health and psychosocial wellbeing of vulnerable groups;
- addressing links between mental health, inequalities and other key health determinants;
- supporting the development and implementation of prevention initiatives, including against depression, anxiety and suicide, and preventing and mitigating loneliness and social isolation; within and across policies;
- developing early detection, recognition, and intervention strategies in various settings (home, school, institutions etc);
- breaking through stigma and tackling discrimination around mental health and enabling groups with mental health difficulties to develop agency and voice;
- preventing and reducing mental health issues by incorporating green living environments in all life settings (urban environments, hospitals etc.)
- social prescribing (a range of non-clinical services to improve health, and mental health in particular, such as sport and physical activity, arts and culture, nature, and green spaces)
- improving the quality and accessibility of mental health care including through digital solutions such as telemedicine;
- providing multi-disciplinary training, including re- and upskilling, to health and non-health professionals (e.g., teachers, social workers);
- fostering mental health globally.

Read more.

The EESC adopts set of recommendations to improve mental health

Following and request from the Spanish Presidency, the European Economic and Social Committee (EESC) adopted an opinion regarding mental health on 13 September 2023, which consists of a set of conclusions and recommendations on ways to improve mental health in Europe.

The document can be downloaded here.

Social policy

Commission decision sets up the European social dialogue committee for social services

On 10 July 2023 the European Commission announced the decision to set up the European social dialogue committee for social services as part of the follow-up to the **2022 Care Strategy** and the 2023 Social Dialogue Initiative.

The new committee will bring together European employers and trade union organisations of the social sector, who will deliver opinions and recommendations to the Commission on initiatives regarding social and employment policy and the development of European policy.

Priorities of the new committee's draft work programme include working conditions, job evolution, skills, and attractiveness to provide accessible, affordable high-quality social services.

The organisations taking part in the committee will be Social Employers and the European Council of Regions and Municipalities (CEMR), representing European employers in social services, and EPSU. In addition, UNI-Europa and the European Confederation of Free Trade Unions (CESI) will also be part of the workers' delegation to plenary meetings.

The care sector is one of the fastest growing in the EU: in 2022, social services represented almost 5% of the total EU workforce. The number of employees in the sector increased by 15.5 % in 10 years, double the average rate of the whole EU workforce. However, the sector also faces big challenges, especially in terms of growing staff shortages and, at the same time, the increasing care needs of an ageing population, the press release said.

A look at the European Care Strategy: one year after adoption

One year ago, the European Commission introduced the **European Care Strategy**. Since then, and in close cooperation with Member States, social partners, and stakeholders, the strategy has supported actions to improve access to quality care services, as well as improve the working conditions of care workers. The three key areas the strategy targets are:

- **Policy reforms for high-quality affordable long-term care**. Among other actions, Member States appointed national long-term care coordinators/contact points to design and monitor national reforms.
- **Working conditions in the care sector**. Among other actions, care services, education and training providers as well as social partners also set up a large-scale skills partnership for long-term care in April 2023. And on 10 July 2023, the new European social dialogue committee for social services sought to bring together employers and trade unions of the sector.

- **Early child education and care. Among other actions**, the Commission launched (March 2023) a communications campaign to challenge gender stereotypes, which continue to hinder equal-share parenting. The Commission also continues to monitor the implementation of the work-life balance directive 2019/1158 for parents and carers to ensure the correct transposition of its provisions by Member States.

Read more about the initiatives, background documents, and download factsheet here.

European Care Strategy: Council work

The Social Questions Working Party of the Council examined on 5 September 2023 a set of draft Council Conclusions on the transition of care systems throughout life towards holistic, person-centred and community-based models, prepared by the Presidency.

The Presidency hopes that an agreement on these Conclusions can be reached in two meetings.

In the draft the Council would invite member states in accordance with their respective powers, considering national circumstances, and respecting the principle of subsidiarity, to define and recognise the right to care and to be cared for, under equal conditions, as a universal subjective right, promoting reforms, including legal regulations when necessary, that holistically define and ensure the legal right to sufficient, freely chosen, and highquality, person-centred and community-based care; and the right to care, with the capacity to make decisions about how much, and whom to care for, while guaranteeing the right to stop caring when that may conflict with the enjoyment of other rights. This right should be independent of personal and legal status.

The draft text is available here: **https://data.consilium.europa.eu/doc/document/ST-11993-2023-INIT/en/pdf.**

Human resources

➢ Health workforce

Beyond all that applause: How to ensure a sustainable and fair European care sector?

HOPE participated in the event organised by the European Parliamentary Research Service (EPRS) presenting the OECD study 'Beyond Applause? Improving Working Conditions in Long-Term Care.

The roundtable discussion gathered Milan Brglez, MEP, Member of the Committee on Employment and Social Affairs, Sirpa Pietikaïnen, MEP, Member of the Committees on Economic and Monetary Affairs, and on Women's Rights and Gender Equality, Maria Walsh, MEP, Member of the Committees on Employment and Social Affairs, and on Culture.

Beyond Applause? Improving Working Conditions in Long-Term Care | en | OECD.

https://www.europarl.europa.eu/thinktank/fr/events/details/eprs-roundtable-how-to-ensure-a-sustaina/20230726EOT07721.

➢ Safety at work

Psychosocial risks in the health and social sector

On 11 September 2023, OSHA published a report on work-related psychosocial risk factors in relation to workers in the health and social sector.

The health and social care sector is one of the largest European sectors, employing around 11% of all workers in the EU (EU-OSHA, 2022a). The sector has grown steadily throughout the past decade and is likely to continue to grow in the near future, given the ageing of the EU population.

In this sector, more than three-quarters of the workforce are women and a significant proportion is employed in hospitals (EU-OSHA,2022a; Eurofound, 2020a). Other workplaces are nursing and care homes, medical practices, and patients' own homes. Occupations in this sector are very diverse, ranging from highly educated and well-paid doctors to low-wage nursing assistants.

Psychosocial risks at work are factors linked to the way work is designed, organised and managed, as well as to the economic and social context of work (EU-OSHA, 2007). Examples are a high workload, third-party violence and harassment, irregular working hours, and high emotional job demands (e.g., dealing with pain and dying patients). These factors can lead to

stress and serious deterioration of workers' mental and physical health. Consequently, these negative employee outcomes can result in production loss and increasing personnel costs due to absenteeism and personnel turnover at the organisational level (Niedhammer et al., 2021).

The health and social care sector is currently facing a number of challenges. First, due to the ageing EU population, the demand for (health) care activities is growing, whereas recruiting new staff is becoming increasingly challenging. Staff shortages are profoundly impacting health and social care organisations, leading to increased workload and financial expenditure due to stress-related employee absenteeism and turnover (Drennan & Ross, 2019; EU-OSHA, 2014a; Van den Heede et al., 2019; Yu et al., 2019). Also, the health and social care workforce itself is ageing. Attempts to extend working life of the general workforce as a solution for staff shortages (i.e., increases in official pension ages) imply extending health and social care workers' exposure to occupational risks. At the same time, in the coming years more employees (including health and social care workers) are likely to develop chronic health problems while still at work, as the prevalence of chronic health problems increases with age (EU-OSHA, 2016a).

Furthermore, as the sector is dominated by women, this brings about additional challenges in relation to occupational health and wellbeing. These include women being more impacted by having a dual role at work and at home (e.g., childcare, domestic work, informal care (EU-OSHA, 2012a)) and physiological changes that come with age (e.g., menopause) (EU-OSHA, 2016b).

Finally, the health and social care sector is recognised as a high-risk sector (European Commission, 2011), with workers being exposed to a very wide range of risks to their health and wellbeing. The main occupational risks are: biological risks, which include any form of exposure to biological agents such as blood-transmitted pathogens and infectious biological agents (e.g. COVID-19); chemical risks, including exposure to hazardous medicinal products (e.g. treatment of cancer) and disinfectants; physical risks, such as slips, trips and falls, exposure to noise and ionising radiation; ergonomic risks, for example lifting or static postures during patient handling; as well as psychosocial risks, which are at the core of the present article. Being exposed to physical risks is itself a risk factor for stress. For example, musculoskeletal disorders can contribute to stress and mental overload, and vice versa (EU-OSHA, 2021). This interaction is particularly relevant for the health and social care sector, given the high prevalence of both ergonomic and psychosocial risks.

There are several additional contextual factors that can contribute to the impact of psychosocial risks. For instance, due to the globalised economy and increased market competition, health and social care organisations have adopted new management modes to increase their profitability (ETUI, 2022).

The introduction of national and organisational austerity measures (e.g., funding cuts and wage cuts for health and social care workers) and market-like mechanisms (e.g., merging healthcare organisations to accomplish volume growth) have, in turn, led to a deterioration of the working conditions in the health and social care sector. Furthermore, during the COVID-19 pandemic, many healthcare workers were required to continue their jobs on the frontline of the

pandemic. As such, they were exposed to an additional and diverse set of hazards impacting their physical, psychological, and social wellbeing (Franklin & Gkiouleka, 2021; Martinez et al., 2021). The pandemic also accelerated existing digitalisation trends on a global level, giving rise to changes in ways of working and exposure to psychosocial risk factors. For instance, telework and telemedicine are growing rapidly in healthcare work (e.g., Brault et al., 2023; Garavand et al., 2022) and new forms of aggression are emerging (i.e., cyberbullying [La Regina et al., 2021]).

All these characteristics of health and social care work combine to create demands and put pressure on workers. This discussion paper reviews existing literature on work-related psychosocial risk factors and effective psychosocial risk management in the health and social care sector. The literature included mainly focuses on Europe to ensure its relevance for EU working cultures and practices, although research from other parts of the world is included when necessary.

https://osha.europa.eu/sites/default/files/Psychosocial_risk_management_social_care_en.pdf.

➢ Cybersecurity

ENISA report on health cyber threat landscape

At the beginning of July, the European Union Agency for Cybersecurity (ENISA) released its first **cyber threat landscape for the health sector report**. A key finding of the report is that ransomware attacks continue to pose a significant menace, overall accounting for 54% of cybersecurity threats in the health sector.

The analysis – based on an investigation of 215 publicly reported incidents in the EU and neighbouring countries over two years - maps and studies cyberattacks, identifying prime threats, actors, impacts, and trends for the benefit of the healthcare community and policy makers. The report's content is gathered from media articles, expert opinions, intelligence reports, incident analysis and security research reports; as well as through the members of the ENISA Cyber Threat Landscapes Working Group.

Among the key observations are the following points:

1. The European health sector experienced a significant number of reported incidents, and healthcare providers accounted for 53% of the total. Hospitals were particularly affected (42% of incidents reported), other targets being health authorities, bodies, and agencies (14%), and the pharmaceutical industry (9%).
2. Ransomware emerged as one of the primary threats (54% of incidents). However, only 27% of surveyed organisations in the health sector have a dedicated ransomware defence programme. Patient data, including electronic health records, were the most targeted assets (30%). Alarmingly, nearly half of all incidents (46%) aimed to steal or leak health organisations' data.
3. The COVID-19 pandemic increased the number of attacks, with financially motivated threat actors responsible for the majority (53%). The pandemic saw multiple instances of data leakage from COVID-19-related systems and testing laboratories in various EU countries. Insiders and poor security practices, including misconfigurations, were identified as primary causes of these leaks.
4. Attacks on healthcare supply chains and service providers resulted in disruptions or losses to health organisations (7%). Another recent ENISA study confirmed that healthcare organisations reported the highest number of security incidents related to vulnerabilities in software or hardware, with 80% of respondents citing vulnerabilities as the cause of more than 61% of their security incidents.
5. Geopolitical developments and hacktivist activity led to a surge in Distributed Denial of Service (DDoS) attacks by pro-Russian hacktivist groups against hospitals and health authorities in early 2023, accounting for 9% of total incidents.

6. The incidents examined in the report resulted in breaches or theft of data (43%) disrupted healthcare services (22%) and disrupted services not related to healthcare (26%). The median cost of a major security incident in the health sector is estimated at €300,000 according to ENISA.
7. Patient safety is put at risk due to such attacks, given potential delays in triage and treatment caused by cyber incidents.

Meanwhile, the Network and Information Systems Cooperation Group, established by the NIS Directive to ensure cooperation and information exchange among Member States, also released a report on **"Threats and risk management in the health sector – Under the NIS Directive."** This study sheds light on the different cybersecurity challenges in risk mitigation faced by the EU health sector. Together with relevant threat taxonomies and cyber incident data, the report discloses business continuity and mitigation recommendations to limit the likelihood and impacts of a cyber related incident.

➢ Artificial Intelligence (AI)

Civil society organisations share views on ethical AI

After co-signing a **Joint Statement on AI and health inequalities** as a member of a Thematic Network led by Dutch-based Health Action International (HAI) on the European Health Policy Platform earlier this year, HOPE participated in a HAI workshop on 14 September 2023 in Brussels. The purpose of the event was to exchange views among supporters of the Joint Statement – including representatives of European Digital Rights, the European Patients' Forum, EuroHealthNet, European Disability Forum, Global Health Advocates, European Bureau of Consumers' Unions, and Ada Lovelace Institute – on how European digital health policies, and in particular the proposed AI Act, could best be implemented in an inclusive, ethically sound and non-discriminatory way to foster better health outcomes for all people in Europe.

Opening presentations by Hannah van Kolfschooten (University of Amsterdam) on "AI in elderly care in the Netherlands" and Dina Babushkina (University of Twente), who provided her perspective on explainable AI and transparency, stimulated a lively discussion around patients' and ordinary persons' perspectives on AI, the possibility to make AI as explainable as possible to healthcare workers and patients, and what should (and should not) be done with the integration of AI in the health sector.

An important message coming out of the meeting is that all measurable data do not necessarily reflect the real health status of individuals given the inherent bias of any data collected from subgroups of the population (statistics do *not* apply to everybody) and that patients' real needs and requirements are often overlooked, regardless of what the data are indicating regarding the best possible treatments. A good fit needs to be found between health environments shaping population health and the results of AI analyses. Moreover, even if AI is highly

complex, it would be reassuring for patients to obtain as much accompanying information as possible about how their diagnosis has been generated.

In addition, the group mapped current dominant narratives contributing to the ongoing "AI hype" and reflected on how to challenge them as part of future collaborative actions. Examples of such narratives include the notions that data (always) save lives, that Europe is losing the global AI competition against the US and China, that AI is "impossible to understand" yet already "part of everyday life", that not sharing personal health data contravenes solidarity or that the remaining data would not be representative, and that industry self-regulation is more desirable than designing a strong legal framework grounded in fundamental rights.

The next meeting of the group will discuss in more detail how such myths can be challenged, and how a better balance can be found between ethical use of AI, patient and professional needs, and the industry's drive to derive maximum innovation and financial benefits from AI-powered solutions.

➢ European Health Data Space

Swedish progress report, national perspectives, and postponed EP vote

The Swedish EU Presidency wound up at the end of June, prior to which it released a **progress report on the European Health Data Space (EHDS)**. This report provides a brief overview of the two compromise texts published by the Swedish Presidency and the technical meetings during which views were exchanged on topics including, inter alia, the definition and scope of EHR systems, the scope of wellness applications, the possibility of an opt-out for secondary data (a key feature of the ENVI-LIBE Committee report promoted by co-rapporteur Tomas Sokol over the last months), and the possibility for third countries to connect to the EHDS.

The compromises introduced by the Swedish Presidency contain several adjustments to the Commission's original proposal, including making use of the examination instead of the advisory procedure, deleting delegated acts, making definitions more precise, and clarifying the links with the GDPR. New articles were added on the rights of natural persons as regards secondary use of data and to group together existing provisions to give a clearer structure to the text and align provisions on primary and secondary use; the order of articles has also been changed in Chapters II and III. New definitions were added, including for 'anonymous electronic health data' and 'contracting authorities'. New provisions introduced would enable Member States to regulate the use of wellness applications as they see fit and to decide on rules for the enrichment of datasets.

The progress report concludes by noting the need for further discussions and finetuning under the Spanish Presidency that took the helm in July, such as roles and responsibilities in cross-border infrastructures, the need for European central services, and the interplay with other EU legislation including the NIS Directive and Clinical Trials Regulation.

A political opinion released by the French Senate on 5 July 2023 sheds further light on issues deemed relevant by the French, and potentially other, national administration(s). The latter priorities include various points such as ensuring that the MyHealth@EU infrastructure for primary data uses contains a translation feature; limiting secondary uses of health data to purposes with a sufficient link to public health and social security; ensuring an EU budget for the EHDS that goes beyond its mere establishment and includes financing health providers' investments in health data tools and cybersecurity, as well as training; enabling pharmaceutical companies to access health data to meet the objective of the EU Pharmaceutical Strategy, in particular regarding access to medicines and unmet needs; allowing Member States to decide whether or not they wish to employ EHR systems and how to handle patient consent for primary uses of health data; adding medical test results such as electrocardiogrammes and breath tests in the list of priority categories for primary uses; and including patient and health professional associations, as well as health data holders in the national governance structures and the EHDS Board.

Meanwhile, the EHDS Committee vote in the European Parliament has been moved from July to September, and the indicative plenary sitting date is now 2 October 2023.

➢ Other

EU reaches deal on Data Act

Negotiators for the European Parliament and EU member countries reached a provisional deal on the new EU Data Act, regulating who can access and share machine-generated data across the bloc. The new data law aims to unlock non-personal industrial data generated by connected machines and devices such as industrial robots or vehicles. The bill prevents manufacturers from hoarding and monopolising data, by giving users the right to share it, for example with service and repair providers. The regulation proposes new rules on who can access and use data generated in the EU across all economic sectors. It also aims to ease the switching of providers of data processing services, puts in place safeguards against unlawful data transfer by cloud service providers and provides for the development of interoperability standards for data to be reused between sectors.

Main elements of the agreement:

- Scope of legislation
    - The political agreement clarifies the scope of the regulation allowing users of connected devices, ranging from smart home appliances to smart industrial machinery, to gain access to data generated by their use which is often exclusively harvested by manufacturers and service providers.
    - Regarding Internet of Things (IoT) data, in particular, the focus was moved to the functionalities of the data collected by connected products instead of the products themselves.
- Data sharing, compensation and dispute settlement

    - Measures to prevent abuse of contractual imbalances in data sharing contracts due to unfair contractual terms imposed by a party with significantly stronger bargaining position.
    - Additional guidance regarding the reasonable compensation of businesses for making the data available, as well as adequate dispute settlement mechanisms.
- Trade secrets
    - The agreement ensures an adequate level of protection of trade secrets and intellectual property rights, accompanied by relevant safeguards against possible abusive behaviour of data holders.
- Public sector bodies
    - The text provides the means for public sector bodies, the Commission, the European Central Bank and Union bodies to access and use data held by the private sector that is necessary in exceptional circumstances, particularly in case of a public emergency or to fulfil a task in the public interest.
- Benefits for customers
    - The new rules will also allow customers to effectively switch between different data-processing service providers (cloud providers) and put in place additional safeguards against unlawful data transfers.
- Interplay with existing legislation
    - The new text clarifies the interplay between the Data Act and existing horizontal and sectoral legislation, such as the Data Governance Act and the GDPR.

The provisional agreement must now be endorsed by the Council and the European Parliament. The Spanish Presidency intends to submit the text to member states' representatives (Coreper) for endorsement as soon as possible.

2nd WHO/Europe Digital Symposium stresses increased need for investment and inclusion

HOPE virtually attended the **2nd WHO/Europe Digital Symposium on the Future of Digital Health Systems** held in Porto on 5-6 September 2023, hosted by the Portuguese government. The event took place four years after the first symposium in Copenhagen.

In his opening speech, WHO/Europe Regional Director Dr Hans Kluge stressed "it is abundantly clear that digital health is the present and future of our health systems, so we MUST ensure that there are no winners or losers, that everyone benefits, and no one is left behind". The impacts on individuals' health outcomes, reducing the health workforce burden and on data security are important questions that need to be addressed if Europe wishes to assume a leading role in digital health.

Kluge also made two announcements at the event, firstly regarding the opening of a new WHO Country Office in Porto dedicated to Technology, Robotics and Entrepreneurship in Health, secondly launching the publication of a landmark **WHO/Europe report on the state of digital health across the European Region** presented in more detail during another session at the

symposium by Dr David Novio. He highlighted some key points coming out of the report's analysis that would need to be addressed to unleash the full potential of digital tools and interventions. Among the gaps and challenges are the following:

- Only 50% of countries in the Region have policies to improve digital health literacy, leaving millions of people behind; as people with limited or no digital skills are often the ones who stand to gain the most from digital health, this imbalance needs to be urgently addressed;
- COVID-19 accelerated the adoption of digital health tools, but it was uneven and often on an ad-hoc rather than a long-term strategic basis;
- Many countries lack sufficient financial resources to fund the monitoring and evaluation of digital health interventions that is required to improve models and algorithms; only 19 developed guidance on evaluating digital health interventions;
- Despite the rise of artificial intelligence (AI), only 60% of countries possess a strategy regulating the use of Big Data and advanced analytics in the health sector; to ensure fairness and transparency, AI needs to be carefully regulated and managed.

To fully tap into the potential of digital health for health systems, Dr Kluge outlined the crucial importance of establishing connectivity, investment, trust, and cooperation. Reliable, low-cost broadband must be available to everybody across the Region. Second, governments and health authorities must start viewing digital health as a strategic long-term investment that will pay off in time. Third, building trust in digital health is fundamental to its adoption, and everybody concerned must believe their data is safe and secure. Finally, Kluge spoke in favour of increasing international collaboration and knowledge-sharing e.g., around interoperability.

The rest of the symposium offered a broad mix of topics, the latter including making effective use of digital tools for combating noncommunicable diseases and for preparing pandemic response, the potential of telehealth and digital solutions for improved mental health. The meeting also served to discuss the implementation of the **WHO/Europe's Regional Digital Health Action Plan 2023-2030.**

Among the high-level speakers featured WHO's Dr Alain Labrique (Director, Digital Health and Innovation) and Natasha Azzopardi-Muscat (Director, Division of Country Health Policies and Systems), Bart de Witte (Hippo AI Foundation, Berlin), Hal Wolf III (HIMSS President) and a Ministerial panel comprised of representatives from Portugal, Greece, The Netherlands and Armenia who discussed the theme of "trust and transformation of health systems in the digital age."

New WHO Global Initiative on Digital Health

The World Health Organization (WHO) and the current Indian G20 presidency announced a new Global Initiative on Digital Health (GIDH, pronounced "guide") at the Health Minister's Meeting of the G20 Summit hosted by the Government of India.

GIDH will operate as a WHO-managed network and platform to support the implementation of the WHO Global Strategy on Digital Health 2020-2025. WHO serves as the Secretariat for the strategy implementation to converge and convene global standards, best practices, and resources to fast-track digital health system transformation.

To drive forward digital health implementation globally, the GIDH initiative aims to bring countries and partners together to achieve measurable outcomes by:

- developing clear priority-driven investment plans for digital health transformation;
- improving reporting and transparency of digital health resources;
- facilitating knowledge exchange and collaboration across regions and countries to accelerate progress;
- supporting whole-of-government approaches for digital health governance in countries; and
- increasing technical and financial support to the implementation of the Global Strategy on Digital Health 2020–2025 and its next phase.

It will also address challenges such as duplication of efforts and “products-focused” digital health transformation through a focus on four foundational pillars:

1. Country Needs Tracker - facilitating digital health investments to be informed by country priorities;
2. Country Resource Portal: identifying traditional as well as innovative resource opportunities, and promoting transparency, while reducing the risk of duplication for enabling a standards-based prospective and retrospective analysis of resourcing gaps in digital health.
3. Transformation Toolbox: advocating for quality-assured tools and resources that strengthen country capacity and autonomy to manage the national digital health transformation.
4. Convening and Knowledge Exchange - promoting strengthened collaboration and knowledge exchange across global, regional, and national networks in digital health.

Further information:

WHO Press Release
GIDH web page

Environment and climate

Parliament adopts new rules to boost energy savings

On 11 July 2023, MEPs approved plans, already agreed with Council, that set new energy saving targets for 2030, as part of the European Green Deal. They adopted the legislation by 471 votes to 147, with 17 abstentions.

The law will set energy-saving targets in both primary and final energy consumption in the EU. Member States will have to collectively ensure a reduction in energy consumption of at least 11.7% at EU level by 2030 (compared to the projections of the 2020 Reference Scenario). A robust monitoring and enforcement mechanism will accompany this objective to make sure member states deliver on their national contributions to this binding EU target.

By 2030, Member States need to save on average 1.5% per year. The annual energy savings will begin with 1.3% in the period until the end of 2025 and will progressively reach 1.9% in the last period up to the end of 2030.

The saving targets should be met through local, regional, and national measures, in different sectors - e.g., public administration, buildings, businesses, data centres, etc. MEPs insisted that the scheme should cover the public sector, which will have to reduce its final energy consumption by 1.9% each year. Member states should also ensure that at least 3% of public buildings are renovated each year into nearly-zero energy buildings or zero-emission buildings. The directive also establishes new requirements for efficient district heating systems.

It will now also have to be endorsed by the Council of Ministers before it can enter into force.

Link.

Ministerial Conference on Environment and Health

On 5 and 7 July 2023, representatives from the health and environment ministries of countries from across the WHO Europe region met for the Sevent Ministerial Conference on Environment and Health (MCEH). During this session, they adopted the Budapest declaration.

The declaration prioritises urgent, wide-ranging action on health challenges related to climate change, environmental pollution, biodiversity loss and land declaration. It also aims to accelerate the just transition towards resilient, healthy, equitable and sustainable societies.

Countries will use the “Roadmap for healthier people, a thriving planet and a sustainable future 2023-2030”, which is part of the Declaration. The Roadmap comprises a set of actions, to expedite the transitions needed to bring about sustainable communities. The Roadmap

explains why urgent action is needed in a particular area, offers a list of commitments countries can consider, and suggests measures to achieve them.

The Declaration also offers countries the possibility to launch European Environment and Health Process (EHP) Partnerships, a new mechanism to help accelerate the implementation of the vision and commitments made at the Ministerial Conference.

This possibility was used by Ireland, Austria, Belgium, The Netherlands, the UK and Norway which went a set further by signing the EHP Partnership for Health Sector Climate Action. The objectives of this partnership focus around sharing learning and building the capacity of health sectors in the WHO European Region to undertake ambitious climate adaptation and mitigation actions.

It links closely with the COP26 Health Programme launched by the UK in 2021 and aims to empower Member States to further their understanding of the range of links between health and climate through a series of virtual deep dives.

Partners will share a range of experiences on mitigation issues including the built environment, sustainable procurement, greener healthcare, and on adaptation issues such as heatwaves, floods, zoonotic and vector borne diseases. While the capacities and structures of healthcare systems across the Region may vary significantly, this partnership will help inform the development of informed domestic policies.

More information on the Budapest Declaration.

Financing

Late payments: Proposed regulation to revise directive

During its 2466th meeting on 12 September 2023 the European Commission adopted a **Proposal for a regulation on combating late payment in commercial transactions (europa.eu)**;

Article 3 (Payment periods) is stricter than the current Directive's Articles 3 and 4, by limiting the payment period and the duration of the procedure of acceptance or verification to a maximum of 30 days, and by eliminating any reference to the concept of grossly unfair practices and clauses.

Without surprise, the exceptions for a maximum payment period of 60 days for healthcare and public authorities carrying out economic activities, as set out in Article 4(4)(a) and Article 4(4)(b) of the current Directive, are removed.

In the Directive 2011/7/EU of 16 February 2011 on combating late payment in commercial transactions, the article 4 stated that Member States may extend the time limits referred to in point (a) of paragraph 3 up to a maximum of 60 calendar days for:

"b) public entities providing healthcare which are duly recognised for that purpose."

Twelve calls for proposals published under EU4Health work programme

HaDEA has published 12 calls for proposals under the 2023 **EU4Health work programme**. The topics, numbered from PJ-01 to PJ-12, include healthcare access, mental health, NCDs, cancer, Substances of Human Origin and medical devices.

The calls have a total budget of €19.960.000. The deadline for applications is **on 17 October 2023, 17:00 (CET).** For further guidance, a recording of the info session has been made available **through here**. You can consult the list of grant topics below:

- EU4H-2023-PJ-01: **Supporting access to medical devices for cross border health threats (HERA**)
- EU4H-2023-PJ-02: **Supporting stakeholders on the prevention of NCDs in the area of chronic respiratory diseases**
- EU4H-2023-PJ-03: **Preventing NCDs in the area of mental health including actions supporting vulnerable population groups, such as migrants, refugees, Roma people and displaced people from Ukraine**
- EU4H-2023-PJ-04: **Preventing NCDs in the area of dementia and other neurological disorders**
- EU4H-2023-PJ-05: **Supporting the implementation of the strategic agenda for medical ionising radiation applications (SAMIRA) – organisation of clinical audit campaigns as a tool to improve quality and safety of medical applications of ionising radiation**
- Action grants on mental health challenges for cancer patients and survivors:
    - EU4H-2023-PJ-06: **Sub-topic (a): Mental health and Cancer**
    - EU4H-2023-PJ-07: **Sub-topic (b): European Code for Mental Health**
- Action grants on the safety and quality of new Substances of Human Origin (Breast milk, faecal microbiota transplants)
    - EU4H-2023-PJ-08: **Sub-topic (a): Breast milk**
    - EU4H-2023-PJ-09: **Sub-topic (b): Faecal microbiotic transplants**
    - EU4H-2023-PJ-10: **Action grants on Facilitating Organ Paired Exchange**
    - EU4H-2023-PJ-11: **Program on orphan medical devices, in particular targeting paediatric patients**
- EU4H-2023-PJ-12: **Action grants to contribute to the organisations of conference and events**

Link.

Prior information notices on three topics released

Prior information notices (PINs) for calls for tenders have been released on the following subjects:

- On speeding up the development of and access to innovative medical countermeasures; **link.**
- On a study to assess the quality of life of cancer patients and survivors; **link**.
- On capacity building to support the uptake of biosimilars in a multi-stakeholder approach; **link**.

Key information on Horizon Europe implementation to date

The European Commission has published a factsheet to report on key data from the first 2 years of Horizon Europe, the EU's framework programme for research and innovation (2021 & 2022). The factsheet focuses on funding, success rates, and contribution to pillars, among other things. It also reports on the financial allotment for the 5 Missions (incl. Cancer).

Click here to download factsheet.

Ukraine

WHO organises workshop for Ukrainian public health experts

On 31 August 2023, the World Health Organization (WHO) held a workshop for 50 experts from Ukrainian governmental bodies in Bukovel, western Ukraine. Participants are working to ensure affordable health care in the context of war, spare people from financial hardship, and build a path towards universal health coverage.

The curriculum consisted of presentations, practical group exercises, and discussions. Organisers adapted the flagship WHO Barcelona Health Financing Course for Universal Health Coverage to fir the Ukrainian context, integrating the country's current health care challenges.

Financial protection and reform

During a full-scale armed conflict, it becomes challenging for the state to deliver health care services and for its citizens to access them. This leads to growing numbers of people who are likely to forego health care and/or pay out-of-pocket for it.

To diminish the blow on individual households, a complex set of health financing policies need to be in place for the present as well as for future recovery. Getting those policies right will be key to successful health-care reforms and will contribute to ensuring affordable access to health services for the entire population, said Dr Tamás Evetovits, Head of the WHO Barcelona Office for Health Systems Financing.

To this end, Ukrainian policymakers discussed the application of health financing concepts in Ukraine, financial protection, coverage policy, revenue generation and pooling, strategic purchasing, and fiscal governance. Despite the war, policymakers aspire to continue health reforms alongside early recovery.

Link.

Antimicrobial Resistance (AMR) surveillance and control

In line with the Antibiotic Resistance Plan, the WHO Country Office in Ukraine explained in a press release on 22 August 2023 that it has donated AMR surveillance equipment and consumables to 10 laboratories nationwide (including regions close to the frontline), as well as consumables to 11 more laboratories that already possessed the necessary equipment. Among the equipment donated are microbiological analysers, which increase the speed and accuracy of microbial identification. Results can be derived on average in 7 hours compared to 24 hours when the analyses are done manually.

All the laboratories use the European Committee on Antimicrobial Susceptibility Testing (**EUCAST**) methodology, and all are members of the Central Asian and European Surveillance of Antimicrobial Resistance (**CAESAR**) network.

In Dnipro City Hospital, one of many health facilities close to the frontline, the automated replacements will help reduce the workload of the bacteriological laboratory, which is strained due to the full-scale war.

Additionally, the Public Health Center of Ukraine and the WHO delivered trainings on the implementation of the EUCAST methodology in daily laboratory work. WHO has also offered to visit microbiological laboratories to provide onsite technical assistance upon request.

- WHO is also carrying out the work to strengthen AMR surveillance in Ukraine with financial assistance from the European Union (EU) within the EU–WHO initiative on health system development in Ukraine. **Link**.

In terms of policy, Ukraine has developed the legal framework to implement WHO's Infection Prevention and Control (IPC) requirements. In 2017, Ukrainian healthcare facilities participated in a study to assess existing IPC mechanisms. The results indicated that the level of IPC was either dissatisfactory or basic. By 2021, Ukraine launched another study to assess the implementation of new IPC regulations.

With the new decree from the country's Cabinet of Ministers in effect, all healthcare facilities must meet WHO's IPC minimum requirements by 2024, after which it will be a mandatory criterion to receive state funding.

Link.

OECD Health Statistics 2023

On 3 July, the OECD released the online database for Health Statistics 2023. The database is a comprehensive source of comparative statistics on health and health systems across OECD countries. You can consult them via the link below.

OECD Health Statistics 2023 - OECD.

Expert group on health systems performance assessment

The expert group (member states) on health systems performance assessment organised its 30th meeting on 28 June 2023 in Rome.

The Member States' co-chair reported back from the launch event of the HSPA report "**Mapping metrics of health promotion and disease prevention for health system performance assessment**."

At the previous HSPA plenary on 15 February 2023, it was concluded to have a succinct report on low-value care. The European Observatory on Health Systems and Policies had volunteered to appoint a penholder to draft the report on behalf of the group (in conjunction with colleagues from the Technical University of Berlin). The Technical University of Berlin presented the outline of the report and different definitions of low-value care and waste. The group discussed the scope of the report and that the focus should be on health systems, not on the individual health level.

The OECD presented the Patient-Reported Indicator Survey (PaRIS). Several Member States use PaRIS indicators as part of their national HSPA frameworks. The OECD offered that countries which are not already participating in PaRIS can join for the coming cycle and should get in touch. The Member States' co-chair invited the OECD to give a further update on the project at a later stage.

Following the plenary meeting in February where five new topics were chosen, the Commission invited Member States to join working groups to develop the scope and type of deliverables. The Commission received 21 positive replies in total. The strongest interest was triggered by workforce, followed by (in order of interest) HSPA governance, mental health, environmental impact of healthcare and health inequalities. On workforce, the aspects of skill mix, and primary care were identified as main fields of interest. On environmental impact of health systems, there was interest to exchange best practices. Another question might be how climate change can be reflected and integrated into national HSPA frameworks. On health inequalities, the experience with health equity audits, which was the outcome of an EU Joint Action in health inequalities, was recalled and could be the focus of attention as well as follow-up on previous

HSPA work on metrics to monitor access. On mental health, the Commission Communication on "**A comprehensive approach to mental health**" was adopted on 7 June 2023. The HSPA Expert Group is mentioned in the Communication as forum to explore the potential of new technologies for prevention and treatment of mental ill-health. The Expert Group was invited to reflect further on this. Two potential areas for further reflection emerged; the role of primary care in mental health care and prevention as well as innovative tools to measure and monitor mental health. The Commission's co-chair mentioned the new Expert Group on Public Health which also has a subgroup on mental health. It was stressed that the HSPA Expert Group should avoid duplication with other ongoing (EU) projects and do complementary work.

Italy gave two presentations. The first one by the Ministry of Health focused on the assessment of the performance of the Italian regional healthcare systems and the new guarantee system. The purpose of the guarantee system is to ensure that the provision of services and benefits included in the "Essential Levels of Care (LEA)" takes place under conditions of quality, appropriateness and uniformity. There is a LEA questionnaire as part of HSPA. The new guarantee system includes 88 indicators on different areas, which are used to calculate scores to allow comparison between regions. The presentation also made a link to the PaRIS initiative and how it can be implemented into national HSPA frameworks.

The second presentation was given by the Italian National Agency for Regional Healthcare Services (AGENAS) on the National Outcomes Evaluation Programme. It is a tool to assess the effectiveness and appropriateness of treatments, equity of access and safety of care. It has a focus on comparative analysis between providers and local health units. The programme uses 194 indicators. The presentation showcased the results of the 2022 edition and different drivers for improvement.

Belgium gave an overview of the revision of its national HSPA framework and explained the general objectives. Backgrounds for the revision are new concepts in literature (such as the PaRIS initiative) and the need to increase the number of indicators. The updated framework includes 146 indicators under different dimensions. There are new sections on governance, environmental sustainability (no indicators yet) and resilience. Several sections have been updated with additional indicators, such as people-centred care. The next Belgian HSPA report is planned to be published in early 2024.

The Commission's co-chair introduced the European Partnership on Transforming Health and Care Systems, which is co-funded by the European Commission (Horizon Europe) and has a 7-year cycle. Its core activity is to fund and support projects that strengthen research and innovation in health and care. It also aims to intensify cooperation among countries and increase stakeholders' involvement.

The Commission's co-chair explained that the EU's Technical Support Instrument (TSI) has supported several countries in developing their national HSPA frameworks. Estonia presented their national HSPA framework and their experience with the TSI and showcased outcomes of the first national HSPA report. DG REFORM explained how the TSI works and how Member States can request support for the TSI cycle 2024. In particular, potentially relevant flagships such as PACE – Public Administration Cooperation Exchange was highlighted. DG RFORM

also explained that a new database has recently been created where Member States can upload individual support needs to match interests in order to identify areas for multi-country requests. Member States were invited to contact DG REFORM to discuss potential ideas and support needs ahead of the formal submission in October 2023.

Health system performance assessment

On 21 June 2023, HOPE attended the webinar presenting the report on "Mapping metrics of health promotion and disease prevention for health system performance assessment" drafted by the Expert Group on Health Systems Performance Assessment (HSPA).

In 2014, the European Commission set up an Expert Group on Health Systems Performance Assessment to provide EU countries with a forum to exchange experiences in this field and to support national policymakers by identifying tools and methodologies to develop HSPA. The World Health Organization (WHO) Regional Office for Europe, the European Observatory on Health Systems and Policies and the Organisation for Economic Co-operation and Development (OECD) are observers and contribute to the work of the Expert Group. Since July 2022, the Expert Group has an extended mandate which also serves as a forum to discuss and promote strategic innovative approaches to strengthening health systems.

The report covers a survey conducted within the HSPA Expert Group on the indicators used to measure health promotion and disease prevention in Member States.

The report found that the most commonly used indicators to measure prevention activities include cancer screening and vaccination coverage, but some countries also look at lifestyle and risk factors as well as indicators which go beyond the health system such as education or other socio-economic determinants. In terms of data sources, national sources predominated, but also internationally standardised surveys were used.

The HSPA Expert Group members also selected several topics of specific interest which were developed as case studies. These were health literacy, mental health metrics, and Austria's health promotion strategy. The Expert Group also met with stakeholders to look at additional best practices, for instance on social prescribing. The report aims to support Member States in better understanding and strengthening their work in the field of health promotion and disease prevention and how it can be embedded in their respective national health system performance assessment frameworks.

The webinar started with welcoming words by Co-Chairs of the Expert Group Dr. Kenneth Grech, Consultant Post Graduate Medical Training Centre Health-Mater Dei Hospital, Ministry of Health, Malta and Maya Matthews, Acting Director Digital, EU4Health and Health systems modernisation, DG SANTE, European Commission.

The general overview of the report was delivered by Ms. Rachel Greenley, Research Fellow, London School of Hygiene and Tropical Medicine, then presentations included: Indicator case study "Health literacy" by Deidre Coy, Economist, Department of Health, Ireland; Indicator

case study “Mental Health and Wellbeing” by John Cachia (former President of HOPE), Consultant Public Health Medicine & Specialist in Family Medicine, Ministry for Health, Malta; Programme case study Austria on health promotion and health literacy by Robert Griebler, Health sociologist, Austrian National Public Health Institute.

Report: Mapping metrics of health promotion and disease prevention for health system performance assessment.

France: Health system review 2023 (who.int)

The European Observatory on Health Systems and Policies presented on 13 July 2023 its country report on France.

Link

Sweden: Health System review

The European Observatory on Health Systems and Policies presented on 12 September 2023 its country report on Sweden.

Link

HOPE attended the webinar ‘The challenges and opportunities of centralisation or decentralisation: Informing structural reform of the Swedish health system’ on 12 September 2023.

The recording can be watched here.

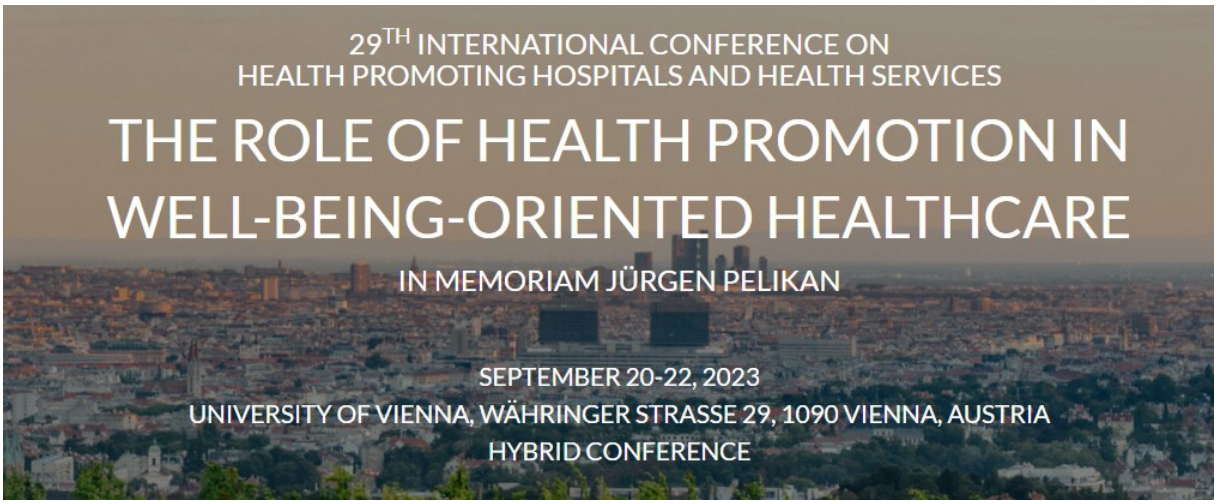
WHO Leadership academy

The third virtual pre-RC73 side event - Supporting health leadership for the present while developing health leadership for the future: the Pan-European Leadership Academy (ELA) - was organised on 18 September 2023.

The side event's purpose was to update Member States on the advancement of the development of ELA and its pilot projects as well as plans for expansion of the Academy in the upcoming two-year period.

29th International Conference on Health Promoting Hospitals and Health Services

Hybrid, 20-23 September 2023



The **29th International Conference on Health Promoting Hospitals and Health Services** took place this year in hybrid format from Vienna, Austria on 20-22 September 2023. The main theme, "Contributions of Health Promotion to Well-being-oriented Healthcare" refers to the **WHO Geneva Charter for Well-Being**, that underlines the urgency for achieving equitable health and social outcomes now and for future generations, considering the impact on the planet. This year's conference was dedicated to Jürgen Pelikan (21.1.1940 – 11.2.2023) who was Chair of the Scientific Committee of the International HPH Conferences, in recognition of his significant role in initiating, implementing, and perpetuating of HPH.

More information can be found by visiting the conference website:
https://www.hphconferences.org/vienna2023/.