

Stakeholders' Targeted Consultation

EU4HEALTH & 2022 WORK PROGRAMME

Key insights of the consultation's results

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1. BACKGROUND INFORMATION

The Programme regulation (EU) 2021/522, in Article 16 states that the Commission shall consult with relevant stakeholders, including representatives of civil society and patient organisations, to seek their views on:

- (a) the priorities and strategic orientations of the annual work programme;
- (b) the needs to be addressed through the annual work programme and the results achieved through it.

In addition, recital (43) indicates that the implementation of the Programme should be supported by extensive outreach activities to ensure that the views and needs of civil society are duly represented and taken into account.

The Commission has to organise the consultation and information of stakeholders at least once a year, in the six months preceding the presentation of the draft work programme to the Committee. Each year, prior to the last meeting of the EU4Health Steering Group, the Commission has to present to the European Parliament the outcomes of the proceedings of the EU4Health Steering Group and the consultation of stakeholders.

1. OBJECTIVES OF THE TARGETED CONSULTATION

The targeted consultation took place between 02 July and 28 August 2021.

This targeted consultation aimed to seek feedback from stakeholders on the priorities and strategic orientations and on the needs to be addressed through EU4Health annual work programmes. It focused in particular on input that could facilitate reflection for the 2022 EU4Health Work Programme and possibly beyond. Replies have been collected for all the questions proposed and contributions have been gathered for describing needs, challenges and potential solutions.

The outcomes of the targeted consultation and the most elaborated contributions were presented and discussed during the webinar organized on 10 September 2021 and will feed into further work on the EU4Health 2022 work programme and beyond.

Results overview

Outreach:

- The consultation has successfully reached a broad range of stakeholders.
- The number of replies is considered satisfactory.
- The largest number of replies has come from Belgium, reflecting the involvement of the “European bubble” in the health policy challenges. It is worth noting a high participation from Italy and Spain.
- The civil society organization had a very active participation to the survey (representing almost 30% of total replies); respondents identifying themselves as “individual” have actively contributed to the consultation (almost 20%); followed by Health care professionals (13%) and private companies (11%).
- Member States, including national, regional and local levels, had a relatively lower participation (overall representing 7% of participants).

Inputs:

- All the questions received complete replies and 184 additional proposals (Question 4) have been provided.
- Participants have indicated their views on needs and objectives and have shared their experience on the possible actions.
- *Disease prevention and health promotion* appears as being considered by the majority of participants to the consultation as a priority strand for intervention. It responds to the current needs and challenges, as well as to the most important longer term objective of the Programme.
- Other specific objectives considered of high importance are: Strengthen health data, digital tools & services, digital transformation of healthcare (Specific objective 6); followed by Enhance availability, accessibility & affordability of medicinal products, medical devices and crisis-relevant (Specific objective 3) and Prevention, preparedness & response to cross-border health threats (Specific objective 2).

2. OUTREACH

During the 8 weeks of consultation, 413 replies have been received.

The geographical coverage has been good and at least one participant has been recorded in each EU country, with the exception of Lithuania. Around 5% of participants come from non-EU countries. Belgium, Italy and Spain recorded the highest participation.

Figure 1: Participation to the consultation by country (as a % of total participants)

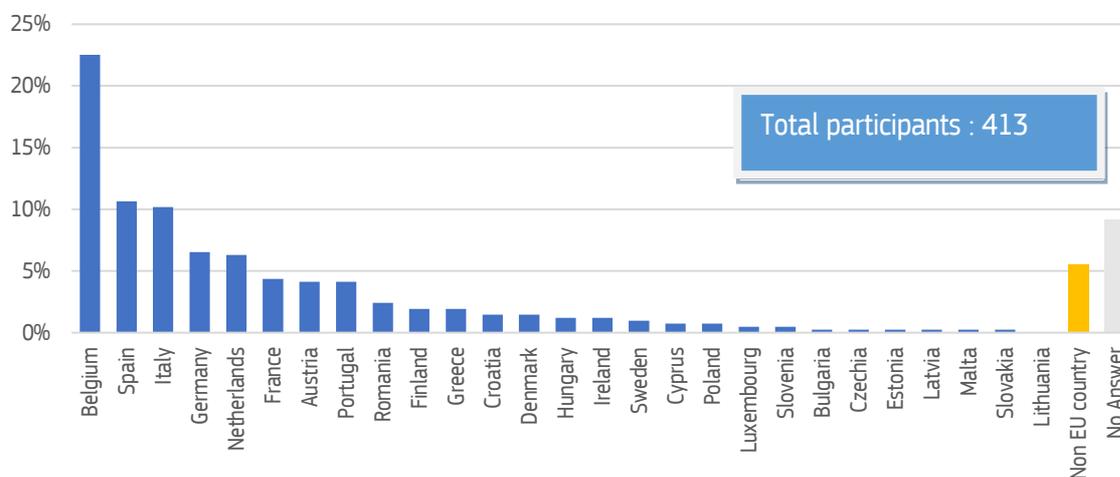
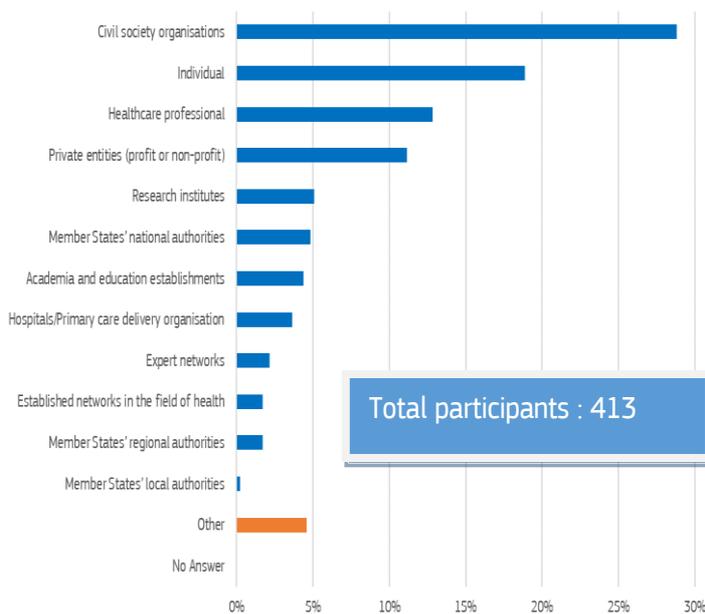


Figure 2: Participation to the consultation by category of respondent (as a % of total participants)



The consultation was addressed to a broad range of stakeholders. Replies have been received from all targeted categories of stakeholders including individuals, professionals, Member States, organisations representing patients, civil society, private companies, and other parties active in public health and social issues, academia and research institutions. All the targeted stakeholders have participated.

Individuals and civil society organisations (including associations, foundations, NGOs and similar entities), have been the most active respondents, together representing almost half of the total number of participants to the consultation.

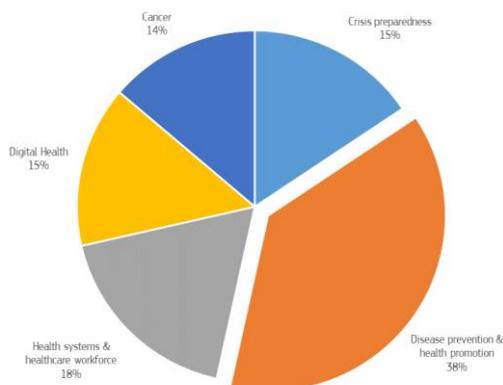
3. KEY FINDINGS

3.1. STRAND OF ACTIONS COVERING THE MOST URGENT NEEDS IN THE HEALTH FIELD

Question 1: The 2021 EU4Health Work Programme's strategic orientations have been designed along four priority strands of actions and one transversal action (cancer). In your opinion, what are the most urgent needs to be addressed in the next programming (2022 and beyond)? Score from 1 (strand with fewest needs to be addressed) to 5 (strand with most needs to be addressed).

A common perception amongst respondents to the consultation appears to be that the most urgent needs to be addressed in the next programming (2022 and beyond) are in the area of Disease prevention.

Figure 3: Strands of actions indicated as covering the most urgent needs to be addressed (as a % of total replies scoring highest for importance i.e.5)

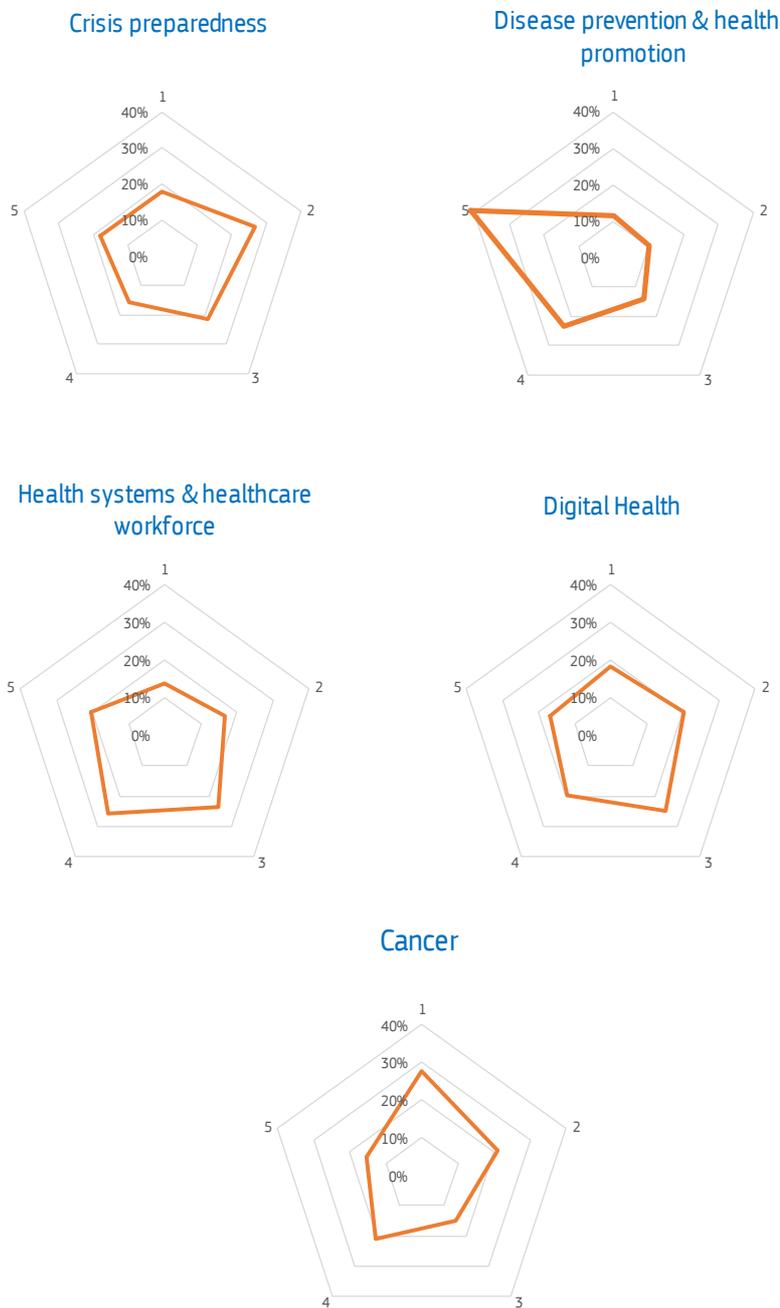


The 2021 EU4Health Work Programme's strategic orientations were designed along four priority strands of action and one cross-cutting priority (cancer). Participants have been invited to score those strands from 1 to 5; with 5 as the indication that such strand covers the most urgent needs to be addressed.

Comparing the number of replies indicating which strands are considered as covering the most urgent needs (strands scoring 5 in the survey), the consultation shows that the majority of respondents indicate *Disease prevention* as the strand where health needs should be more urgently tackled.

The radar chart below allows for a synthetic view of the opinions expressed via the consultation, illustrating the share of replies for each score. The shape of the line is also an indication of the distribution. The most irregular line indicates the most distinct preference.

Figure 4: Prioritization of Programme specific objectives (% of replies by score)



Note :

The radar charts allows for a synthetic view of the opinion expressed via the consultation, illustrating the share of replies for each score.

The chart show the share of each score per objective. 1 stands for lower priority and 5 for the highest priority.

The shape of the line is also an indication of the distribution. The most irregular line indicates the most distinct preference.

For example, in the case of preference expressed for the strand Disease prevention & health promotion, the shape indicates a strong consensus for attributing high importance to this strand.

3.2. MOST IMPORTANT OBJECTIVES TO BE ADDRESSED BY EU4HEALTH FUNDING

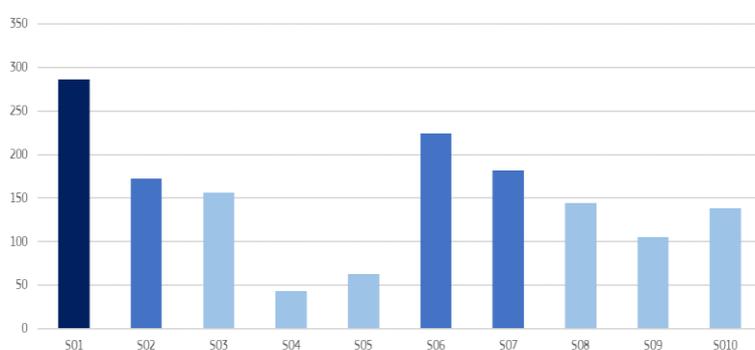
Question 2: According to your knowledge and relating to your sector, which are the most important objectives to be addressed by EU4Health funding? Please choose up to five of the objectives listed below (Article 4 of Regulation (EU) 2021/522).

In line with the previous question, the consultation replies indicate that the *Specific objective 1: Disease prevention & health promotion* is the most important to be achieved.

Another objective indicated as of high importance is *Specific objective 6: Strengthen health data, digital tools & services, digital transformation of healthcare*.

Specific objective 7: Enhance access to healthcare follows in importance as well as *Specific objective 2 Prevention, preparedness & response to cross-border health threats*.

Figure 4: Relative importance attributed to each specific objective
(Number of preferences recorded)



Participants have been invited to indicate the most important objectives to be addressed by EU4Health funding (up to five), according to their knowledge and relating to their sector.

Article 4 of Regulation (EU) 2021/522 establishing the EU4Health Programme, lays down ten specific objectives of the Programme.

S01: *Disease prevention & health promotion*

S02: *Prevention, preparedness & response to cross-border health threats*

S03: *Enhance availability, accessibility & affordability of medicinal products, medical devices and crisis-relevant products*

S04: *Complementing national stockpiling of essential crisis-relevant products*

S05: *Establish a reserve of medical, healthcare & support staff*

S06: *Strengthen health data, digital tools & services, digital transformation of healthcare*

S07: *Enhance access to healthcare*

S08: *Development & implementation of EU health legislation & supporting evidence-based decision-making*

S09: *Support integrated work among MS health systems*

S010: *International health initiatives & cooperation*

3.3. ACTIONS CONSIDERED POTENTIALLY MOST EFFECTIVE FOR ACHIEVING EU4HEALTH SPECIFIC OBJECTIVES

Question 3: According to your experience, which possible actions (from Annex I of Regulation (EU) 2021/522) can be the most effective for achieving specific objectives?

NB: respondents could express more than one preference for each specific objective.

Annex I of Regulation (EU) 2021/522 provides a list of possible actions that are eligible for funding under the EU4Health Programme with a link to each specific objective. The participants have been invited to indicate which of those actions are considered as the most effective, based on their experience and for all objectives the majority of

replies have converged on a few actions (3 or 4).

Here below the actions receiving more attention (at least the 50% of the preferences) have been listed. These are linked to the specific objectives of the EU4Health Programme and are limited to the eligible actions listed in Annex 1 of the Programme Regulation.

Figure 5: Number of preferences expressed for actions eligible for funding under EU4Health specific objective (actions representing at least 50% of the preferences)

Specific objective 1: Disease prevention & health promotion	Preferences for actions eligible for funding
Policies and actions to reduce health inequalities and inequities in relation to healthcare.	69
Assisting and support the Member States to improve health promotion and disease prevention.	77
Surveys, studies, collection of comparable data and statistics, methodologies, classifications, microsimulations, pilot studies, indicators, knowledge brokering and benchmark exercises.	77
Health promotion and disease prevention throughout the lifetime of an individual and by addressing health risk factors, such as obesity, unhealthy diets and physical inactivity.	87
Promoting life-long health: put in place healthy and safe urban, work and school environments, to enable healthy life choices, promote healthy diets and regular physical activity, taking into account the needs of vulnerable groups at every stage of their life.	116
Specific objective 2: Prevention, preparedness & response to cross-border health threats	Preferences
Training and educational programmes for the upskilling of healthcare and public health workforces, and temporary exchanges of staff, in particular with the aim of improving their digital skills.	41
Preventive actions to protect vulnerable groups from health threats and actions to adapt the response to and the management of health crises to the needs of those vulnerable groups such as actions to secure basic care for patients with chronic or rare diseases.	54
Foster Union-wide health crisis prevention and preparedness, and the management capacity and response capacity of actors at Union and national level.	60
Strengthening the critical health infrastructure to cope with health crises, by supporting the setup of tools for surveillance, forecast, prevention and management of outbreaks.	90
Specific objective 3: Enhance availability, accessibility & affordability of medicinal products, medical devices and crisis-relevant products	Preferences
Encourage the development of innovative medicinal products and vaccines to meet rising healthcare challenges and patients' needs, and of less commercially profitable products such as antimicrobials.	49
Strengthen laboratory capacity and the production, research, development, and deployment of health products and crisis-relevant niche products within the Union.	50
Support clinical trials to speed up the development, market authorisation and access to innovative, safe and effective medicinal products and vaccines.	63
Enhance the availability, accessibility and affordability of medicinal products and medical devices.	65
Specific objective 4: Complementing national stockpiling of essential crisis-relevant products	Preferences
Ensure consistent management of stockpiling of essential crisis-relevant products at Union level, in a manner that complements other Union instruments, programmes and funds and in close coordination with relevant Union bodies.	21

Specific objective 5: Establish a reserve of medical, healthcare & support staff	<i>Preferences</i>
Exchange of best practices between existing national reserves of medical, healthcare and support staff.	19
Preparatory work for mobilising and training at Union level a reserve of medical, healthcare.	28
Specific objective 6: Strengthen health data, digital tools & services, digital transformation of healthcare	<i>Preferences</i>
Support a Union framework and the respective interoperable digital tools for cooperation among MS and cooperation in networks, including those needed for Health Technology Assessment cooperation.	81
Deployment, operation and maintenance of mature, secure and interoperable digital service infrastructure and data quality assurance processes for the exchange of, access to, and use and reuse of data; supporting cross-border networking, including through the use and interoperability of electronic health records, registries and other databases; developing appropriate governance structures and	114
Support the digital transformation of healthcare and health systems, including through benchmarking and capacity building, for the uptake of innovative tools and technologies such as artificial intelligence, and supporting the digital upskilling of healthcare professionals	126
Specific objective 7: Enhance access to healthcare	<i>Preferences</i>
Strengthen primary care and reinforcing the integration of care, with a view to providing universal health coverage and equal access to good quality healthcare.	142
Specific objective 8: Development & implementation of EU health legislation & supporting evidence-based decision making	<i>Preferences</i>
Knowledge transfer actions and Union level cooperation to assist national reform processes towards improved effectiveness, accessibility, sustainability and resilience of health systems, while linking available Union funding.	43
Implementation, enforcement, monitoring of Union health legislation and action; and providing technical support for the implementation of legal requirements.	48
Expert groups and panels providing advice, data and information to support health policy development and implementation, including follow-up evaluations of the implementation of health policies.	59
Studies and analysis, health impact assessment of other Union policy actions and the provision of scientific advice to support evidence-based policymaking.	68
Specific objective 9: Support integrated work among MS health systems	<i>Preferences</i>
Support the functioning of European Reference Networks and the establishment and operation of new transnational networks as provided for in Union health legislation, and supporting MS' actions to coordinate the activities of such networks with the operation of national health systems.	41
Cross-border collaboration and partnerships, including in cross-border regions, with a view to transferring and upscaling innovative solutions.	49
Transfer, adaptation and roll-out of best practices and innovative solutions with established Union level added-value between MS, and in particular providing country-specific tailor-made assistance to the MS, or groups of MS, with the greatest needs, through the funding of specific projects including twinning, expert advice and peer support.	62
Specific objective 10: International health initiatives & cooperation	<i>Preferences</i>
Contribute to the objectives of the programme presented by the WHO, as the directing and coordinating authority for health within the United Nations.	30
Support collaboration among Union institutions, Union agencies, and international organisations and networks, and supporting the Union's contribution to global initiatives.	60

4. IDEAS PROVIDED IN VIEW OF ACHIEVING THE SPECIFIC OBJECTIVES OF THE PROGRAMME PROVIDING AND EU ADDED VALUE

Question 4: Do you have ideas or any other suggestions in view of achieving the specific objectives of the Programme and that would provide an EU added value? If YES, please use the format below to briefly describe other needs, challenges and the possible solutions to address them, that differ from the ones indicated in the previous section

The targeted consultation provided the possibility to contribute by proposing alternative ideas that could support the fulfillment of the Program's objectives. Participants were requested to describe needs, challenges and potential solutions different to those laid down in Annex I of the EU4Health Programme Regulation defining objectives, specific outcomes and EU added value as well as their link to the specific objectives of the Programme.

184 alternative ideas were provided during the consultation, representing 45% of respondents. The suggestions provided were either of a general nature or linked to the strands of the programme.

The **general input** received from several organisations and individuals were touching upon different topics such as:

- Several NGOs raised the need to restore operating grants to ensure sustainability of civil society organisations in order to support achievement of various EU4Health's objectives.
- Promote legislation based on scientific evidence.
- Offered different products or services.
- Support the creation of international reference centers in EU.
- Support self-care from citizens to enable them to take care of their own health.
- Propose greater liability from private companies e.g. due to vaccine damage regardless their profit.
- Setting up of databases and repositories to reduce potential patient harm.
- Requested more research to have access to new diagnostic and therapeutic approaches.

On **crisis preparedness**, contributions received touched upon: antimicrobial resistance; building resilience into pharma and medical devices supply chain; monitoring the shortages and increase availability of medicines, medical devices and crisis relevant products; COVID 19 vaccination strategy and immunisation programme; use of non-pharmaceutical intervention; global crisis response capacity and effectiveness; improve surveillance systems during health emergencies; increase awareness of the population and scientific communication during the crisis; and strengthening EU preparedness for cross border health threats.

On **disease prevention**, contributions focused primarily on: mental health and mental disorders; cancer care and combination therapies including specific types of cancer (e.g. prostate cancer, liver or oral cancer); pediatric patients; rare diseases; obesity; nutritional care; cardiovascular disease; sepsis; hepatitis, liver disease; Alzheimer disease and HIV and AIDS.

On **health systems**, contributions received highlighted the following topics: therapy for the Neurodegenerative disease and Amyotrophic Lateral Sclerosis; medical needs in the aging population; alternative therapies (e.g. homeopathy and spa therapy); European autonomy and self-sufficient plasma products; access and affordability of medicinal products; implementation of the medical devices and *in vitro* diagnostic medical devices regulations; strengthening health systems; strengthening sexual and reproductive healthcare (SRH); complementary medicine for health care; home care-giving; ERNs; shortages of healthcare professionals; poor adherence to drug therapies; improving primary care; dissemination of best practices in healthcare; improvement of health parameters of the population by country/region; and promoting health for migrants.

On **digital**, the main areas covered by the contributions received were: digitalisation applied to specifically medical disciplines or health challenges (e.g. mental health, dentistry artificial intelligence); digitalisation of medication management in EU hospitals, digital tools for chronic patients and patient care; increase the interoperability between services and networks in Member States, taking into account regional and local levels; strengthening digital health literacy of EU citizens; digital transformation of health(care); digital solutions for consumers; and improvement of MyHealth@EU.

5. OUTCOMES OF THE DISCUSSION WITH STAKEHOLDERS DURING THE WEBINAR ON 10 SEPTEMBER 2021

On 10 September 2021, the Commission organized a Webinar for discussing with stakeholders the outcomes from the targeted consultation. The discussion during the webinar was organized in 4 clusters, representing the strands of the actions in the EU4Health Work Programme 2021 and 2022: Disease prevention; Crisis preparedness; health system; Digital. Here below the key messages are reported.

CRISIS PREPAREDNESS

The crisis preparedness session had about 50 participants.

The most elaborated proposals have been received from a variety of stakeholders including competent authorities, NGOs and private companies. The presentations and further discussion touched upon similar topics, and the main areas identified by the participants where intervention is considered to be needed are summarised below:

Fostering Union-wide preparedness for cross border health threats which can be addressed by multilateral cooperation at EU level and integrated emergency response:

- By reinforcing of the regulatory angle facilitating some regulatory flexibility in times of crisis, harmonising also logistical requirements;
- strengthening critical health infrastructure to cope with crisis, by the setup of tools for surveillance, forecast, prevention and management of outbreaks including an EU monitoring system for early detection;
- promoting convergence of national systems performance through common indicators and stress tests; and
- enhancing patient care during crisis and communication channels including mobile clinics.

Increasing resilience of pharma and MCM manufacturing and supply chain which can be achieved by improving EU monitoring systems and information feeding back to the public and private decision makers:

- securing access to critical medical countermeasures as response to emergency situations for all EU citizens and also invest in sustainable digital health and biotechnology innovations
- enhancing information on needs, capabilities and available resources during crisis, including the responsibility of manufacturers to report signals of shortages
- mapping and enhancing manufacturing capacity of medicines, medical devices and PPE, investing also in less commercially profitable and niche products
- preventing shortages by improving and interconnecting monitoring systems throughout the supply chain
- establishing an EU strategic stockpiles to respond to crisis BUT relying on existing infrastructures and expertise, including buffer stocks held by distributors, and
- integrating EU procurement structures with global supply to increase sustainability and predictability.

Fighting antimicrobial resistance and emerging pathogens by early cross-sectoral collaboration that will ensure that we are prepared for the next crisis:

- supporting One Health approach against antimicrobial resistance especially the European One Health action plan against AMR;
- strengthening collaboration between human, animal and environmental surveillance systems; and
- collaborating with other initiatives in terms of prevention, risk assessment and response.

Improving the vaccination strategy and immunisation programmes by strategic programming and financing of immunisation to increase vaccination coverage rates and secure timely access to vaccines:

- supporting vaccination programmes at national level, including guidance and best practices on funding to increase understanding and autonomy on immunisation financing;
- improving coordination and reduce fragmentation of vaccination programmes;
- increasing awareness and communication about vaccination to fight disinformation; and
- coordinating and gathering knowledge by all different actors and support to low performing areas.

Enhancing coordination of non-pharmaceutical interventions which can be achieved among others by empowering individuals to bring high quality data to decision makers. Preparedness and early interventions could contribute to avoid pandemics if flow of information can be ensured but there is a need to support national competent authorities infrastructure to ensure interoperability. Supporting targeted non/pharmaceutical interventions based on real data will encourage citizens to share to receive tailored feedback and information.

Other needs mentioned were:

- the need to organise coordinated international solidarity clinical trials for medical countermeasures and vaccines
- the need to establish a coordinated, sustainable and reliable testing strategy, across sectors including human and animal testing capacities

DISEASE PREVENTION

The disease prevention session had about 97 participants.

The most elaborated proposals have been received from a variety of stakeholders including members of civil organisations, international organisations, academic institutions, industry groups, individuals and patient groups. The presentations and further discussions touched upon several topics, with some general comments as follows:

- To move towards a more health-oriented health system with an emphasis of empowering individuals to respond to their health risks
- The importance of continued preventive and care services during crisis situations and the need to address inequalities in access to such services
- To ensure that individuals and patients are placed at the centre of preventive and care services and are empowered to manage their health
- To rebuild patients' trust in the healthcare system
- To focus on vulnerable groups and integrate appropriate services for these groups
- To accelerate the use of digital solutions in health, in particular to enable continuous care.
- To ensure EU added value by innovative approaches such as creating EU partnerships
- To look for collaborative synergies in screening efforts for disease risks to avoid fragmentation of efforts, e.g. when addressing risk factors for chronic diseases
- To gather national data to ensure a good evidence base to guide policy making and monitoring

1st area where interventions are needed is on cardiovascular diseases and related risk factors. The prioritisation of cardiovascular diseases with a focus on prevention, early detection and screening can be achieved by:

- ensuring a continuum of care for cardiac patients to avoid a negative impact on patient outcomes and reduce inequalities in cardiac care.
- supporting the Member States in reaching their goals in reducing the impact of cardiovascular diseases
- using innovative tools and approaches, such as paediatric screening programmes
- improving the understanding of cardiovascular diseases and the role of early detection

- identifying best practice solutions and collecting data on impact on patient outcomes to ensure continuous cardiac care during crisis situations
- patient awareness on the importance of medical care by partnerships with patient organisations
- disseminating and sharing best practices on the prevention and early detection of cardiovascular diseases
- supporting the prevention of alcohol-related harm by for example capacity-building projects, alcohol labelling, fiscal policies and better communication to the public on alcohol harm
- coordinating action at national level to eliminate tobacco use and ensuring coordinated civil society action
- supporting a Joint Action that focuses on early detection of cardiovascular diseases
- supporting knowledge sharing and capacity-building

2nd area where interventions are needed is on mental health. Tackling the mental health consequences of the COVID crisis can be achieved by:

- increasing the public debate on mental health
- investing in mental health as a resource for building up social resilience
- creating a European Mental Health Observatory to assess mental health policies and establish knowledge and experience flows
- improving awareness on mental health among national authorities
- promoting early detection of mental health issues especially amongst children and youth

3rd area where interventions are needed is on empowering cancer patients. Ensuring patient-centred care can be achieved by:

- by means of a wider, multi-partner and multi-stakeholder promotion approach
- ensuring that patients have a greater understanding of their rights when it comes to treatment and care
- increasing awareness activities on the rights of patients such as equal access to affordable and optimal cancer care
- developing an app for newly diagnosed cancer patients to provide links to information sources and organisations

Other needs mentioned were as follows:

- On eliminating hepatitis by 2020 in line with global health strategies and commitments, there is a need for more political will and funding for hepatitis initiatives; potential solutions included creating a transnational network to share good practices across countries, gathering better national data to monitor elimination programmes, informing on the prevention of hepatitis transmission risks, applying lessons learnt from the COVID pandemic on testing and surveillance, and integrating services for vulnerable groups.
- Addressing other diseases such as liver and kidney diseases, HIV/AIDS, dementia and related illnesses by supporting best practices, awareness-raising and exploring synergies with other conditions.
- Implementing the One Health approach by integrating wildlife conservation and habitat protection into human health policy and planning.

HEALTH SYSTEM

The health system session had about 120 participants.

The most elaborated proposals have been received from a variety of stakeholders including patients, member of civil organisations, international organisations, and trade unions. The presentations and further discussion touched upon several topics, with some general comments as follows:

- to interlink the actions throughout the different strands of the EU4Health programme;
- to invest money by creating synergies with other EU programmes by opening to Partnerships;

- to ensure the coordination between the EU institutions and the cooperation between Stakeholders by promoting dialogue and building community together;
- to get information available in particular to citizens which need to receive as a clear message that EU actions are important for their lives;
- to keep patients at the centre of the whole health systems.

Areas where interventions are needed and were presented at details:

Neurodegenerative and rare diseases

The strengthening of health system for people affected by neurodegenerative and rare diseases can be achieved by:

- creating EU network of people affected by rare diseases for networking and awareness raising and having Member States to work together by also creating centres of excellence for example for regenerative medicines and newborn screening for rare diseases;
- creating centre of excellence for new therapies in particular on gene therapy;
- allowing the access to drugs in experimental phase;
- accelerating the EU procedure for the marketing authorisation;
- strengthening and provide major support to European Reference Networks and integrate them in the national health systems;
- providing a clear mechanism to integrate rare disease patients in the national health system for an equal access to specialised care;
- increasing the collaboration between Member States for advanced therapies.

Medicines and patients

The improvements of the health status of the patients can be achieved by:

- more efficient and effective public interventions on the accessibility to medicines by focusing on some priorities such as clinical trial data, transparency on prices and intellectual property protection;
- increasing the awareness of patients to follow the prescriptions provided by their practitioners in order to allow a better monitoring the efficacy and the safety of the medicines during the treatments;
- spreading information and raising awareness to improve the health status of patients especially in elderly population and ensuring their adherence to therapies;
- providing resource allocation, training, guidance and digital tools to achieve the changes in the society and patients are facing as patients are at the centre of the health system;
- implementing the Pharmaceutical Strategy for Europe and better surveillance and monitoring of stocks and shortages of medicines through digitalisation;
- improving access to medicinal products by making them, especially prescription medicines, available for patients to order online or by the support of e-pharmacies, regardless in which EU Member State the person lives;
- supporting a publicly funded comprehensive European Pharmacovigilance system to collect data on the safe use of medicine in and during pregnancy.

Accessibility to healthcare services and the need for healthcare workforce

This can be achieved by:

- strengthening the assistance at home for those suffering from disabilities and elderly;
- incentivise home care model and ensuring good training of caregivers in all the regions in Europe;
- ensuring that national and European plans deliver, facilitate and promote equitable access to healthcare to migrants and mobile population which are also part of the vulnerable population;
- addressing the shortage of healthcare workforce by investing in training, recruitment and retaining the health workforce;

- helping upscaling skills like on digital health for nurses.

Other needs mentioned were:

- Strengthening data collection and reporting of health data are essential for evidence-based and informed decisions. Need to involve patients' representatives in the HTA processes and to provide funding and capacity building support to patient organisations in order to be equal partners in deciding the right type of care. In the diabetes community, patients are oftentimes driving the innovation agenda and if provided with the right tools and support, they can contribute meaningfully to the HTA cooperation.
- Addressing Sepsis through an early detection, developing new cures and having in place a Sepsis registry for patients from different countries in Europe.
- Addressing Lyme diseases, through diagnosis, by collecting information based on a special questionnaire, by providing framework for future doctors and by having a platform to share the medical knowledge.

DIGITAL

The Digital session had about 40 participants.

The breakout session discussed of the digital transformation of healthcare and health systems, that from the consultation appears as considered as a major objective, second only to disease prevention & health promotion.

Among the actions to achieve this objective capacity building, the uptake of innovative tools and technologies such as artificial intelligence, interoperability, cooperation among Member States have been identified as most effective actions for achieving the objective of the digital transformation of health data.

Stakeholders have put forward proposals touching a wide range of issues of topics and representing different perspectives from international organizations, private companies, national authorities and academia.

A first area of interest discussed focused on the **role of digital transformation to enhance the access to health care** (specifically mental care) and in particular on the use of artificial intelligence.

A second area of discussion was on how the **interoperability** can be a challenge for the modernization and strengthening of health systems. In particular a presentation illustrated the challenges of interoperability and cooperation between levels of government (vertically) and different sectors (horizontally), and as how those challenges are one of the biggest obstacles to effective transformation of health systems.

As well the challenge for MS **promoting organizational sustainability in (e)health cooperation** in the EU was discussed. Networking, establishing routine processes, Ecosystem [and nodes] have been identified as potential solutions to enhance the interoperability and security of national health systems and to support the secure exchange of health data, together with capacity building, enhancement of digital tools, sharing best practices and developing guidelines and recommendations.

The discussion also highlighted how **exchange of data and the uptake of digital tools can bring easy and rapid solutions to tackle health challenges**. A case was presented for heart diseases in aging population, illustrating how digital tools can improve understanding and early detection of age-related heart diseases and reduce premature mortality and incidence.

The challenges for **exchanging data and at the same time protecting data privacy** was underlined and in particular the role that the EU can play for enhancing cross-border exchange of data and for creating virtual workspaces that could allow exchange and study of data under secured systems.

Data have been a central topic of discussion. Participants noted that for data exchange the **attention should not be limited to information on non-healthy people, but information on healthy people is essential for cure**

and for prevention. Digitalization can help to reach data sources outside the healthcare sector and in particular for the use of survey or interviews for collecting data.

As well, the **issue of sharing information** was raised: sharing of personal data, ownership of the information, the ability to control the use; the necessity of an audit trail for checking when, why and by whom the data have been shared or used. All that is needed for citizens to trust digital systems. EU4Health Programme is expected to play a fundamental role in advancing citizens and patients engagement in sharing data.

Also a **Human-centric approach to the digital transformation of health care** has been indicated as an important element to focus. Stakeholders indicated the necessity to start by the basics: digitalised healthcare settings, and specifically support for medication management.

Digitalisation of medication management was discussed, highlighting the lack of standard and harmonised data on treatments, data for evaluating the quality of life after treatments, to select the right treatment, and difficulty to administrate medication of patients who are vulnerable.

Stakeholders supported the idea that digital transformation could provide **solutions for ensuring transparency of supply chain and prevention of (cancer) medication shortages**, in addition to better management. Shortages negatively affect cancer patients and the sustainability of the healthcare systems. As well, medication errors are a leading cause of injury and avoidable harm in health care systems, and the promotion of medication traceability systems will be key to significantly reduce such errors and, ultimately, protect patient safety.