

# Strategic Plan 2020-2024

DG Health and Food Safety (SANTE)

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#### INTRODUCTION

This strategic plan outlines the political priorities and planning assumptions for DG Health and Food Safety (SANTE). The starting point for all planning for the 2020-2024 cycle is President von der Leyen's six headline ambitions, as set out in her Political Guidelines and further developed in her mission letter to Commissioner Kyriakides. This strategic plan translates these priorities into concrete and operational strategies that will shape the work of DG SANTE for the duration of the mandate of this Commission.

In the Political Guidelines and mission letter to Commissioner Kyriakides, President von der Leyen has placed strong emphasis on modernising the way the Commission works, for example through digitalisation, collaborative methods and an increased focus on the sustainability of our activities. This plan therefore covers not only DG SANTE's strategy to deliver the political priorities, but also to modernise the way the administration of the DG functions and improve efficiency. It also describes DG SANTE's contribution to the recovery plan for Europe, notably through the new EU4Health programme to strengthen health systems and prepare for future health crises.

The strategy is expressed through general objectives (the headline ambitions) and Specific Objectives (reflecting the specific contribution of DG SANTE). This plan includes defined indicators for objectives to allow performance to be tracked against set targets.

Part 1 of this plan sets out how DG SANTE will deliver on the two general objectives to which it will contribute. Part 2 will clarify how DG SANTE will modernise the administration to achieve the greatest possible levels of efficiency and sustainability.

#### PART 1. Delivering on the Commission's priorities

#### A. Mission statement

DG SANTE strives to protect human, animal and plant health, promote a high level of food and animal feed safety, contribute to the Union's efforts to ensure sustainable food systems and enable the health and food sectors to achieve their full economic potential.

Our mission supports the Commission's priorities for sustainability, growth, and competitiveness in two of the EU's most important economic sectors – health and food.

It will contribute to two of the general objectives set out in President von der Leyen's Political Guidelines - A European Green Deal and Promoting Our European Way of Life. Health and safety are of paramount importance.

We play a leading role in managing health crises at EU level, such as the COVID-19 pandemic, and in preventing and managing the EU's response to food safety crises and threats to human, animal and plant health.

In public health, we help EU countries to manage and prepare for crises, such as COVID-19, improve public health and access to healthcare, and strengthen their health systems, in line with the EU Treaty's rules on proportionality and subsidiarity. In medicinal products, we ensure a functioning internal market and high standards for safe, high quality and effective medicinal products. We also develop expertise on health systems and support actions to prevent and reduce the impact of ill-health on individuals and economies to improve the quality and effectiveness of public expenditure and boost prosperity and social cohesion. We encourage and support innovation and the uptake of modern technologies to deliver better care and cost-effectiveness and reinforce the sector's global competitiveness. We promote patients' rights in cross-border healthcare and better health through, inter alia, actions linked to tobacco control and vaccination. The importance of global health has been amplified by the COVID-19 pandemic. DG DG SANTE will continue to work closely with partners such as the World Health Organisation, OECD and with G7 and G20 to address global health challenges such as health security and antimicrobial resistance.

In food and feed safety, we work to modernise and simplify well-developed EU rules in line with Better Regulation principles and ensure they are correctly applied. We strive to uphold world-class standards of animal welfare, animal and plant health, safe and trustworthy products, and an efficient internal market, with confident consumers and business operators. We base our work on international standards and scientific assessments. Our priority for 2020-2024 is to accelerate the transition to sustainable food systems that have a neutral or positive environmental impact, can adapt to or mitigate climate change, ensure food security and make healthy diets the easy choice for EU citizens. We will address increasing global challenges linked to food safety – like antimicrobial resistance, e-commerce and food fraud. We will also promote the EU Sanitary and Phytosanitary (SPS) system, working with non-EU partner countries, international organisations and other stakeholders, to help maintain the EU's competitive position and uphold its internationally acknowledged reputation on food safety.

#### **B.** Operating context

DG SANTE's activities are directly shaped by the Treaty on the Functioning of the European Union (TFEU) and principally linked to Articles 168 (public health), 43 (agricultural policy), 114 (internal market), 207 (trade in goods) and 13 (animal welfare). Article 168 stipulates that a high level of **human health** protection is ensured in all Union policies and activities. EU action supports disease prevention and health promotion, and cooperation between Member State health systems. EU rules also cover cross border health and cooperation on e-health, rare diseases and heath technology assessment, medicinal products and medical devices, tobacco control and substances of human origin (such as blood, tissues and cells). In **food safety**, the EU designs, implements and enforces a common policy and set of rules that apply across all Member States, and to imports, which impacts our trade partners too.

In both policies, the EU plays an important supporting role, providing guidance and tools to promote cooperation and help national systems operate more effectively. It helps EU countries tackle key challenges such as antimicrobial resistance and health system reform; it ensures safe, effective and high quality medicines and food safety, and prepare for and manage health threats, crises and disease outbreaks. We also contribute to the EU's progress towards the global Sustainable Development Goals. Effective EU action depends on Member States' and businesses to implement and enforce EU rules correctly.

DG SANTE works closely with the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA), which implements the EU Health Programme and the Better Training for Safer Food initiative. The current expectation is that CHAFEA will close and its activities will be transferred to another executive agency. The new EU4Health programme will be managed by the new agency. However, until its closure, CHAFEA will continue to manage the current programme. We are also a partner DG to five decentralised EU agencies: the European Medicines Agency (EMA), the European Food Safety Authority (EFSA), the European Centre for Disease Prevention and Control (ECDC), the Community Plant Variety Office (CPVO) and the European Chemicals Agency (ECHA). DG SANTE is also committed to close consultations with citizens and stakeholders on health and food safety as part of the Commission's Better Regulation Agenda, which helps ensure that our work is transparent, accountable, and effective.

Our work supports stability, growth, innovation and sustainability in two of the EU's most important economic sectors: public health, and food and drink; they make an important contribution to EU employment and economic growth: food production and processing accounts for 7.5% of employment and 3.7% of total value added in the EU¹. Health spending is now 9.9%² of GDP and the health sector accounts for 11% of employment³. The pharmaceutical sector is a knowledge-intensive sector with 715,000⁴ direct jobs and EUR 91 billion trade surplus in 2018. Significant resources go to implementing and

<sup>&</sup>lt;sup>1</sup> Agri-food trade in 2015: China boosts EU exports, Monitoring Agri-trade Policy, MAP 2016– 1, Eurostat, p. 3.

<sup>&</sup>lt;sup>2</sup> Source: Companion report State of Health in the EU 2017 page 10

<sup>&</sup>lt;sup>3</sup> This includes employment in following activities: human health, residential care and social work without accommodation, source: Eurostat, figure for 2016.

<sup>4</sup> EU27 figure. Where available, figures in this document reflect EU27 data.

enforcing our legislative *acquis*. This involves a high number of decisions, notably market authorisations for food and medicinal products. We also carry out over 200 audits per year to check EU rules on food safety and some human health areas are properly implemented and enforced. DG SANTE's Better Regulation activities aim to ensure the legislative framework remains fit-for-purpose in an ever-changing environment and based on the best available evidence.

#### C. Strategy

Europe's health and food sectors make an important contribution to the EU economy and the Commission's objectives to improve citizens' health and quality of life, care for nature and leave no one behind. Regulation in these sectors is a pre-condition to protect human, animal and plant health, to ensure food safety and foster the transition towards sustainable food systems.. DG SANTE aims to provide an appropriate framework to ensure the internal market in these sectors can thrive and citizens can confidently engage in it.

Although DG SANTE contributes indirectly to almost all of President von der Leyen's six headline ambitions, it will contribute to two in particular: A European Green Deal and Promoting our European Way of Life.

The principles and requirements of the Commission's reinforced Better Regulation framework are central to the human health and food safety policy making cycle. Without compromising human health and food safety, SANTE will try to simplify its legislative acquis and offset administrative burdens where possible. These efforts will be monitored by the indicator "Proportion of proposed legislative revisions that include burden reduction measures" in the following specific objectives 1.1 Food and feed safety; 1.2 Sustainable

food systems – the 'Farm to Fork' strategy; and 2.2 Patients' access to safe, innovative and affordable medicines and medical devices.

**Funding** for DG SANTE's activities is fixed within the EU's 2021-2027 Multiannual Financial Framework. At time of writing, the proposed MFF would see spending on activities linked to "Food and Feed" allocated under the Single Market Programme (proposed allocation of EUR 1.68 billion), while activities linked to "Public health" would fall under the new EU4Health Programme (proposed allocation of EUR 9.4 billion).



#### **General Objective 1: A EUROPEAN GREEN DEAL**

DG SANTE's work on safe and sustainable food will play an important role in the European Green Deal, helping to make Europe the first climate-neutral continent by 2050, supporting sustainable and inclusive growth that leaves no one behind, boosting the economy, improving people's health and life quality, and caring for nature. Safe food is essential for public health and food security and a crucial part of the EU's action on food sustainability.

The EU's food safety policy ensures the internal market in this sector runs smoothly and that citizens are well-protected and confident within it. Food and animal feed are subject to a complex yet well-developed legal framework throughout the EU. This ensures a high level of safety and quality and encourages free and safe trade, investment and innovation.

EU food safety standards are amongst the highest in the world. They constitute an internationally recognised and respected "trademark" representing safety and quality. This

allows European producers and processors to occupy a strong position on the global market.

In addition, DG SANTE ensures EU imports also respect these standards, and works with non-EU countries to prevent sanitary and phytosanitary (SPS) measures being used as trade barriers.

#### Specific Objective 1.1: Food and feed safety

Food and feed safety, animal health and welfare, and plant health contribute significantly to the European Green Deal. As requested by President von der Leyen in her Mission Letter to Commissioner Kyriakides, DG SANTE focuses on implementing and enforcing the extensive legislation in the areas of food safety and animal and plant health.

In food and feed safety, while the EU is directly responsible for designing and implementing a common policy framework, its success depends on EU countries implementing and enforcing the rules correctly, on farmers, food and feed business operators complying at all stages of production and trading, and on trading partners to ensure that imports to the EU comply with our standards. Any weaknesses compromise our policy's success.

DG SANTE monitors the application of the legislation closely. It will continue to work closely with EU countries and the authorities responsible for controls in non-EU countries to ensure our food safety standards are adhered to. DG SANTE carries out over 200 audits and on-the-spot visits per year to verify that EU rules on food and feed safety, animal health, animal welfare, plant health and some areas of human health are properly implemented and enforced in EU countries. It also ensures non-EU countries exporting to the EU have systems in place to ensure their exports meet EU standards.

In this context, DG SANTE will also continue to coordinate input into the enlargement and neighbourhood processes including support for capacity building, training and other initiatives linked to implementing EU standards and rules.

These activities support the development of evidence-based policies and reassure consumers, producers, processors and traders that EU rules are properly implemented. The "Better Training for Safer Food" programme complements this work by training EU and non-EU official control staff to recognise fraud and non-compliance.

A high number of human diseases are linked with the food and feed chain – they can seriously affect consumers' health and confidence in food safety. Past crises, such as Fipronil in 2017, had serious economic consequences for the agricultural and food production sectors due to the sudden loss of citizens' confidence and difficulties maintaining the EU's trade flows with international partners.

There is a need to coordinate an EU response to outbreaks of foodborne pathogens, to consistently fine-tune the EU's rules, and for close, effective management of evolving situations. Day-to-day management will focus on preventing and reducing the incidence of animal diseases and plant pests and minimising the impact of any outbreaks on public health and the economy.

Better Regulation is an important part of our work in this area. The planned evaluation (2022) of the rules for feed hygiene and manufacturing feed will look at ways to improve the current provisions and contribute to sustainable feed production – in particular to ensure good feeding practices meet the new sustainability requirements and help to mitigate the impact of livestock farming on the environment.

Ensuring animal health as well as managing and isolating outbreaks of major animal diseases

The EU must pay full regard to animal health in key policies such as agriculture, the internal market and research. Under the EU Animal Health Law, DG SANTE manages requirements to prevent and control animal diseases transmissible to animals or

EU animal health law protects animal health and welfare, human health and food safety and promotes a smooth and safe internal market..

humans. Its work supports the EU livestock sector and promotes a competitive and safe EU market for animals and their products. DG SANTE will pursue the implementation of thelegislative framework adopted in 2016 (Regulation (EU) 2016/429), before - and after - its entry into force in 2021.

One of DG SANTE's most important tasks in animal health policy is to ensure we can rapidly isolate and eradicate outbreaks of major animal diseases, the most important of which are currently African swine fever and highly pathogenic avian influenza.

When outbreaks occur, they impact across the industry from primary producers to trade and export restrictions. An effective crisis management policy allows us to mitigate potential damage and ensure the internal market for live animals and animal products continues to function smoothly and safely and international trade continues unrestricted. This requires continuous fine-tuning of numerous animal health rules and close management of evolving situations.

Our success in this area will be measured against *Result Indicator 1.1.A - Increase of the officially free areas from certain zoonoses*. Our success depends on Member States implementing EU rules properly and stakeholders complying with them.

#### Preventing plant pests

Globalisation of plant trade has substantially increased the risk of plant pest infestations in the EU. EU countries currently notify over 200 plant health outbreaks every year.

DG SANTE manages the Plant Health Law (Regulation (EU) 2016/2031) which is designed to protect crops, fruits, vegetables, flowers, ornamentals and forests from harmful pests and diseases. These rules cover the movement of plants and plant products within the EU and impose a strict regime on imports of plants and plant products that might host dangerous pests. It also encourages a proactive approach to early detection, notification, containment and eradication of these pests if found in the Union territory.

Our success in preventing, containing and eradicating plant diseases will be measured against *Result Indicator 1.1.B - Number of phytosanitary programmes successfully implemented/total number of phytosanitary programmes approved.* Whilst the current plant health crisis management system is effective, success depends on the Member States' financial and administrative capacity to introduce relevant survey programmes.

#### Ensuring market access to safe substances and products

Thousands of substances are used in the agrifood sector and may be included in food and feed. As they may pose risks to health and the environment, they are regulated at EU level. With the support of the decentralised

EU policy promotes safe food and animal feed and aims to encourage sustainable food production.

agencies responsible for the risk assessment process, DG SANTE manages the legal framework for placing them on the EU market (authorisation, prohibition, limits, conditions of use and labelling) for food-related uses.

It also provides risk communication. In particular, we manage a substantial number of approval processes for substances used in the production and processing of food including food additives, flavourings, enzymes and food contact material, genetically modified food and feed, novel foods, biocides, and products used at farm level, e.g. pesticides, feed materials, feed additives and veterinary medicinal products.

All these approvals contribute to innovation and are needed to help the EU agri-food sector remain competitive. The legal framework provides, in most cases, clear deadlines for the approval processes. It is DG SANTE's responsibility to monitor and make sure these deadlines are observed by all actors (e.g. Member States, Agencies) to ensure predictable market access and guarantee that any product entering the market can remain there as long as it meets safety requirements.

DG SANTE also manages the establishment of levels, such as maximum residue limits, to ensure food safety and harmonised enforcement. It provides the relevant information to enforcement authorities to detect non-compliant products so that appropriate measures can be taken to protect the EU consumer. This ultimately contributes to the safe movement of products within the single market, as well as imports.

Even though approval processes are largely dependent on DG SANTE, implementation and enforcement is down to Member States as well as farmers, feed and food business operators, who are ultimately responsible for applying the rules at source.

#### Performing effective, efficient and reliable controls

Strict enforcement of the EU's rules on food safety, animal health, plant health and animal welfare is essential to ensure that our high standards are not compromised and that industry can operate on a level playing-field. It is crucial that the legislative framework for official controls across the food chain functions well to ensure businesses and consumers benefit and profit from it.

Audits are crucial to ensure EU rules for food safety are complied with and that official controls respect EU law. They also enable DG SANTE to verify that food imports meet our safety standards. Following an audit, DG SANTE makes recommendations to EU or non-EU countries to address any shortcomings via an action plan which it then evaluates and monitors. Its analysis and verification of control systems also feeds into policy development and best practice initiatives.

Our success in enforcing EU rules on food and feed safety will be measured against *Result Indicator 1.1.C - Percentage of DG SANTE's recommendations following its audits that Member States (MS) have satisfactorily addressed with corrective action.* 

Pursuant to the Official Controls Regulation (Regulation (EU) 2017/625), DG SANTE will continue to adopt further implementing rules with regard to agri-food chain aspects of the legislative framework for official controls.

Official control systems must be accompanied by a strong training strategy. The 'Better Training for Safer Food' programme, which will soon be evaluated, aims to keep official control staff in EU and non-EU countries up-to-date with the relevant EU legislation.

#### Maintaining well-developed rapid alert systems

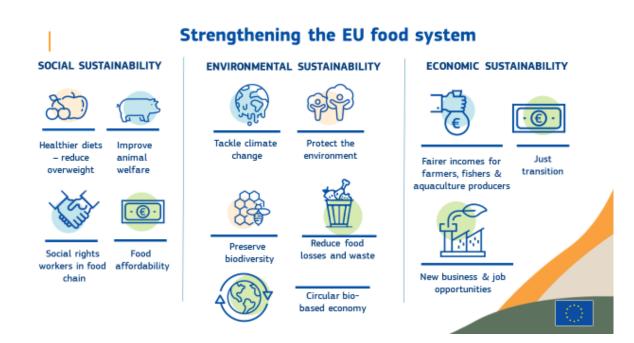
Crisis management in each of DG SANTE's sectors is supported by a series of well-established mechanisms, notably the EU's rapid alert systems, which aim to identify problems early and allow rapid information sharing, response and effective cooperation. These mechanisms are – and will remain – subject to regular simulation exercises to identify gaps and strengthen the system outside of crisis situations.

While it is up to Member States to take control measures, the EU plays a key coordinating role in cases of high-profile, multinational outbreaks of foodborne pathogens. At the same time, audits performed by DG SANTE assess contingency planning in Member States for food-borne emergencies and promote constant improvement of control systems.

#### Specific Objective 1.2: Sustainable food systems — the 'Farm to Fork' strategy

As tasked by President von der Leyen in her Mission Letter to Commissioner Kyriakides, DG SANTE leads on the new Farm to Fork Strategy for sustainable food. The Strategy lies at the heart of the European Green Deal. It seeks to address the challenges of sustainable food systems in a comprehensive and holistic way, recognising the essential links between healthy people, healthy societies and a healthy planet.

To achieve a fair, healthy and environmentally friendly food system, the Commission has proposed an integrated approach covering the entire food chain with ambitious targets in priority areas. DG SANTE will also propose a legislative framework for sustainable food systems by 2023 with clear sustainability standards for products placed on the EU market. Robust evidence will underpin any evaluation and impact assessment work, as necessary.



#### Reducing dependency on and promote the sustainable use of pesticides

Chemical pesticide use in agriculture contributes to soil, water and air pollution and can negatively impact on non-target plants, insects, birds, and mammals. DG SANTE will continue to work towards reducing dependency on chemical pesticides and stimulate the uptake of low-risk and non-chemical alternatives for plant health protection.

It will pursue actions set by the Farm to Fork Strategy to reduce the use and risk of chemical pesticides by 50% by 2030, and reduce the use of more hazardous pesticides by 50% by 2030. By the end of the strategic plan in 2024, we aim to reduce the risk and use of chemical pesticides by 30% (Impact indicator 1 – Pesticide risk) and the use of more hazardous pesticides by 30% (Result indicator 1.2.A – Use of more hazardous pesticides).

Concretely, and based on an evaluation of the current legislation to be conducted back-to-back with an impact assessment of possible options for change, DG SANTE will propose the revision of the Directive on the Sustainable Use of Pesticides.

This will enhance provisions on integrated pest management and promote greater use of alternative methods of crop protection, improve the availability and usability of sound data

and statistics on pesticide use in the EU and reinforce evidence-based policymaking. It will also facilitate placing on the market of plant protection products containing biological active substances and the substitution of pesticides containing hazardous substances.

"Reducing the use and risk of pesticides by 50% by 2030 is a central objective of the Farm to Fork Strategy. To succeed, the support of all partners is vital."

Commissioner Kyriakides, June 2020

#### Improving the effectiveness and efficiency of the pesticides legislation

DG SANTE will address the inefficiencies of the pesticides legislation identified during the recent REFIT evaluation<sup>5</sup>. This showed, amongst others, that Member States do not respect the procedural deadlines for conducting risk assessments in the context of active substance approvals and product authorisations, and that cooperation amongst them, in particular for mutual recognition of product authorisations, is insufficient. On the other hand, Member States grant too many emergency authorisations.

DG SANTE will propose actions to curb delays in the various processes, and to address the other shortcomings identified, where necessary by changing the existing legislation.

#### Reducing use of antibiotics in animals to contribute to the fight against AMR

Antimicrobial resistance (AMR) - linked to the excessive and inappropriate use of antimicrobials in animal and human health - leads to an estimated 33 000 human deaths in the EU each year and significant economic costs. The wide range of measures provided for in the EU's new rules on veterinary medicinal products and medicated feed will frame DG SANTE's proposed actions to reduce overall EU sales of antimicrobials for farmed animals and aquaculture by 50% by 2030.

Our success will be measured against *Result Indicator 1.2.B - Sales of antimicrobials in farmed animals and aquaculture*. To address the environmental angle of AMR, and in line with the actions foreseen in the EU communication on pharmaceuticals in the environment<sup>6</sup>, we will look into the feasibility of a review system based on active pharmaceutical substances to support the environmental risk assessment of veterinary medicinal products, including antimicrobials.

#### Fostering the use of innovative and more sustainable feeds

60% of EU greenhouse gas emissions from agriculture are linked to animal farming. To reduce the environmental and climate impact of animal production, DG SANTE is evaluating the feed additives EU legislation to assess its fitness for purpose and to make it easier to place sustainable and innovative feed additives on the market to reduce the carbon footprint, water and air pollution and methane emission of livestock farming.

The evaluation will also examine EU rules to foster the replacement of critical feed materials (e.g. reduce dependency from imports) by more sustainable feed materials such as insects, marine feed stocks and by-products from the bio-economy, and reduce dependency from imports. A revision of the feed additives Regulation 1831/2003 is foreseen following the ongoing evaluation and upcoming impact assessment.

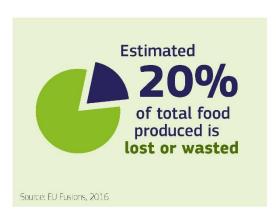
<sup>&</sup>lt;sup>5</sup> https://ec.europa.eu/info/law/law-making-process/evaluating-and-improving-existing-laws/refit-making-eu-law-simpler-and-less-costly en

<sup>&</sup>lt;sup>6</sup> European Union Strategic Approach to Pharmaceuticals in the Environment: COM(2019) 128 final

#### Reducing food loss and waste

The Commission is committed to reaching the United Nations Sustainable Development Goal Target 12.3 to halve per capita food waste at retail and consumer levels by 2030, and reduce food loss across the supply chain, through more focused, joined-up action. Through EU-level coordination, the Commission will help drive and reinforce action at national level, notably to curb consumer food waste, guided by the recommendations of the EU Platform on Food Losses and Food Waste. Our progress will be measured against the *Result Indicator 1.2.C - Number of Member States that have put in place national food waste prevention strategies*.

### In the EU...







Following the introduction of an EU methodology to measure food waste and based on the data expected from Member States in 2022, efforts will be made over the course of the implementation of the Farm to Fork Strategy to set a baseline and propose legally binding targets to reduce food waste across the EU. This links to the work in the context of the new Circular Economy Action Plan, another important strand of action under the European Green Deal.

DG SANTE will also propose the revision of EU rules on date marking to avoid misunderstanding and misuse leading to food waste in the supply chain. DG SANTE will contribute to investigating the extent and causes of food losses at the production stage and to explore ways of preventing them.

#### Ensuring a sustainable food production that improves the welfare of animals

Good treatment of animals is integral to sustainable food production. Better animal welfare is an ethical imperative, improves food quality and animal health and decreases the need for medication. Welfare-friendly farming practices also help to preserve biodiversity.

DG SANTE will complete the evaluation of the Animal welfare Strategy 2012-2015. It will also carry out a Fitness Check of the animal welfare legislation, including animal transport, and the slaughter of animals to assess its fitness for purpose, in light of the latest scientific evidence and the evolution of societal and ethical expectations and consumer demands. This will feed into the reflection process on how the current rules may be improved – and an eventual revision of the legislative framework as foreseen in the Farm to Fork Strategy.

The Commission will continue to promote European standards globally and push for cooperation on animal welfare in the EU's bilateral trade agreements.

The Commission will monitor the compliance of Member States with animal welfare legislation based on verified corrective actions taken by Member States in response to DG SANTE audit recommendations in this area (*Result Indicator 1.2.D*).

#### Fighting against food fraud

Combating food fraud is a priority to ensure EU food products are safe and of high quality, consumers are protected, and the EU food system is sustainable.

The Commission has built a dedicated network to fight food fraud and facilitate actions between EU countries and European and international bodies.

DG SANTE will continue to work with the Member States and all relevant bodies, including the European Anti-Fraud Office (OLAF), to enhance coordination and cross-border cooperation on food fraud. It will also propose stricter dissuasive measures, better import controls and examine the possibility to strengthen coordination and investigative capacities of OLAF.

Empower consumers to make sustainable and healthy food choice through the provision of food information

DG SANTE will work towards improving consumer information, notably by looking at ways to address demands for more visible, complete and non-misleading information, especially on the health and sustainability of food products.

Food information is an integral part of the transition to sustainable food systems and healthier diets.

To improve the EU food environment and facilitate shifting to healthier diets, DG SANTE will consider options to restrict the promotion of foods high in fat, sugar and salt through nutrition or health claims and assess the relevant impacts of such measures based on robust evidence.

DG SANTE will assess policy options to empower consumers to make healthy and sustainable food choices. It will introduce mandatory front-of-pack nutrition labelling and consider extending mandatory origin indication to certain products. DG SANTE will also examine and assess the impacts of measures to harmonise voluntary green claims. Finally, in the medium term, DG SANTE will coordinate preparatory work to support the assessment

of available options towards the establishment of a sustainable food labelling framework integrating nutritional, climate, environmental, ethical and social aspects.

We will also explore the possibility of appropriate labelling schemes, including an EU sustainable food label, to incentivise commercial partners to make sure that food imported into the EU has been produced in a sustainable way.

Supporting innovation in the food chain, especially via the promotion of novel foods, plant reproductive materials and innovative techniques

The sustainability challenge calls for measures to strengthen the protection of plants from emerging pests and diseases and to foster innovation. On the one hand, this links to DG SANTE's work on plant health, and in particular to the planned adoption of EU rules to reinforce vigilance on imports of plants and surveillance of the Union territory under the Plant Health Law.

On the other, new innovative techniques, including biotechnology, may help to increase sustainability and productivity provided they are safe for consumers and the environment and bring benefits to society as a whole.

In response to the request of the Member States, DG SANTE will deliver a study to assess the potential of new genomic techniques, including how they could improve sustainability and productivity in agriculture and along the food supply chain. Once completed, possible follow up in this area will be considered.

Farmers need to rely on seed security through a diversity of quality seeds for plant varieties adapted to environmental and climatic pressures. DG SANTE will explore measures to facilitate the registration of seed varieties, including for organic farming, and to ensure a lighter market access of traditional and locally adapted varieties. This will fit into the implementation of yet another important European Green Deal strand of action, the Biodiversity Strategy. It will also respond to the request of the Member States, which asked the Commission to submit a study on the Union's options to update the existing legislation on the production and marketing of plant reproductive material.

More generally on research and innovation, the new Horizon Europe programme will follow a food systems approach in order to deliver on the objectives of the Farm to Fork Strategy.

One key area of research will relate to increasing the availability and source of alternative proteins such as plant-, microbial-, marine- and insect-based proteins and meat substitutes. In particular, DG SANTE will contribute to the mission in the area of soil, health and food, which aims to develop solutions to restore soil health and soil functions.

"The Farm to Fork Strategy aims to rethink production systems by reducing their environmental impact and intensive farming practices. Innovation is key to achieve these objectives."

Commissioner Kyriakides, May 2020

#### Improving the regulatory framework on Food Contact Materials

Food packaging plays a key role in food systems' sustainability. DG SANTE will propose a revision of the Food Contact Materials legislation to improve food safety and protect citizens' health, in particular by reducing the use of hazardous chemicals and exposure to endocrine disruptors. It will also support the use of innovative and sustainable packaging solutions, using environmentally friendly, re-usable and recyclable materials, and contribute to food waste reduction. We will assess the impact of new measures necessary to counter the risks of exposing consumers to heavy metals in ceramics and vitreous materials.

#### Specific Objective 1.3: International promotion of EU food safety standards

DG SANTE will enhance its work with international partners to promote the European policy model and its agenda for international safety and quality standards. DG SANTE helps steer the Commission's position and coordinates Member States input to ensure policy coherence between our internal policy actions and external engagement on the global stage.

#### Improving multilateral relations

The EU is the largest exporter and importer of agri-food products and the largest seafood market in the world, with a well-recognised and respected framework of food safety legislation. As such, it must ensure that its food safety standards both comply with the obligations under commitments of the WTO-SPS and are – to the extent possible – aligned with the relevant international standards and relevant texts of the internationally recognised standard setting organisations, i.e. the Codex Alimentarius Commission, the World Organisation for Animal Health (OIE), the International Plant Protection Convention (IPPC) as well as the Cartagena Protocol to the Convention on Biodiversity (CBD).

DG SANTE will increase resources devoted to promote adoption of international standards that are closely aligned with the EU's high level of protection for human, animal and plant health and the Farm to Fork objectives. We will ensure the EU is well represented with "one voice" and increase cooperation and capacity building activities to increase support for EU positions - particularly in developing countries.

The EU approach is, at times, challenged within the WTO when measures are thought to limit trade from other countries. Equally, the EU may take a case to the WTO when non-EU countries impose unsubstantiated import bans on EU products. Therefore, efforts to increase the sustainability requirements of the EU food system under the Farm to Fork

Strategy will be mirrored in external policies, bilaterally and multilaterally, helping to progressively raise standards globally.

DG SANTE will help to build green alliances with non-EU countries and aim to ensure ambitious provisions for

"Through Farm to Fork, we embark on promoting a global transition to sustainable food systems through partnerships and green alliances."

Commissioner Kyriakides, May 2020

sustainable food are included in all relevant EU bilateral agreements. These alliances will support the work on global sustainable food systems in the various multilateral fora.

#### Improving bilateral trade relations

DG SANTE aims to negotiate safe, secure and harmonised export conditions for EU products with non-EU countries and to manage, monitor and ensure implementation of the existing agreements. Focusing on the priority list of non-EU countries and issues in the Sanitary and Phytosanitary (SPS) field as agreed with and working together with DG TRADE and DG AGRI, DG SANTE will improve market access for EU agri-food exporters.

DG SANTE leads on the negotiations on SPS chapters in the Free Trade Agreement negotiations underway or planned, e.g. Australia, Eastern and Southern Africa, Indonesia, New Zealand, and Chile. DG SANTE also manages the Agreements already in force and is preparing the ratification or entry into force of four more Agreements.

DG SANTE will also aim for successful negotiations of enlargement related dossiers.

An important component of trade facilitation is the verification by DG SANTE of third countries' capability and capacity to export animals, and goods to the EU and in particular, the capability of third country competent authorities to verify through their official controls that the conditions for accessing the EU market are satisfied. Where DG SANTE audits identify shortcomings in such controls, recommendations are made, which if implemented correctly, should increase confidence in the performance of our trade partners.

Our success in doing so will be measured against *Result indicator 1.3.A* the percentage of DG SANTE's audit recommendations that third countries have satisfactorily addressed with corrective action.

#### Trade standards

DG SANTE's ultimate goal is to ensure that our food safety standards are not compromised on imports and, at the same time, contribute to the achievement of better conditions for trade through greater market access for EU exports. DG SANTE aims to increase its leadership role in the international standard setting bodies when establishing high food safety, animal and plant health standards.

DG SANTE will reinforce the outreach campaign on promoting its high SPS standards, sustainable food systems and policies (i.e. fighting AMR, fraud and e-commerce) through training activities (BTSF and Partnership instruments).

DG SANTE seeks recognition of the EU as a "single entity" to enable consistent application of export rules across all Member States and prevent unfair competition within the Single Market.

#### **General Objective 2: PROMOTING OUR EUROPEAN WAY OF LIFE**

For many citizens, health and healthcare are a fundamental part of how they understand their social fabric and the European Way of Life. This is reflected in the European Pillar of Social Rights which stresses the right to timely access to affordable, preventive and curative health care of good quality (Principle 16).

Guaranteeing access to high-quality health care, including protection against cross-border health threats, is a key objective of social protection systems in EU countries. The COVID-19 pandemic has now shown an asymmetry between public expectations and actual EU intervention powers and lessons should be drawn from this crisis.

From an economic perspective, the EU health sector accounts for 10% of GDP, 15% of public expenditure and 11% of the EU's workforce and has a high potential for innovation and growth. However, it also faces important challenges with potentially huge economic consequences. Specifically, health care systems are facing ageing populations, increasing needs (including those stemming from COVID-19), and the emergence of new (often expensive) treatments. In terms of funding, the cost of healthcare is expected to double by 2050 if nothing is done to tackle key challenges, notably preventable chronic diseases. Currently, only 3% of health budgets is spent on health promotion and disease prevention. This is despite the clear advantage of preventive work, as work hours lost to ill-health currently cost 2.5% of GDP every year and impact all levels of the economy. Finally, in spite of near-universal coverage of health insurance or national health systems, there are still major health inequalities across countries and regions, as well as across socio-economic groups. In short, reforms are needed to improve the resilience of health systems.

The EU must play a critical role in this process. Even with the limited scope it has for health policy, it can – and must – play an important supporting role, helping Member States to reform and prepare their health systems while at the same time

The new **EU4Health Programme** is a vision for a healthier European Union. It is an opportunity to invest in health systems, support innovation and stimulate change.

respecting the rules on subsidiarity and proportionality. The new EU4Health programme will not only provide a significant budget for addressing health challenges across the EU, but it is a genuinely new opportunity to invest greatly in health systems and to stimulate change which can have a lasting impact on populations' health. Synergies with other MFF programmes, in particular Horizon Europe Pillar 2 Health cluster, will provide an opportunity to ensure that policies are evidence-based and research results smoothly implemented in the health systems. Such reforms will also need to take due account of climate change, which is already adversely affecting the health of Europeans and which could have a bigger impact over time.

The EU can channel a more efficient use of resources, including from the new EU4Health Programme, and reduce pressures on public finances by: offering better coordination and cooperation between EU countries, especially during emergencies; improving the evidence base for decisions on health systems and the allocation of resources; promoting digitalisation, cost-effective health technologies and better use of data; and promoting EU-wide exchanges of successful health promotion initiatives. Such actions will make an important contribution to economic stability as well as productivity, mobility and adaptability within the workforce.

More broadly, health policy is about keeping people living, working and ageing in good health, actively engaged in society and actively contributing to the economy. As a consequence, health is now an integral part of most major EU initiatives and the Treaty on

the Functioning of the EU requires the EU to follow a "Health in all Policies" approach. The functioning of the internal market where medicines and medical devices meet the requirements relating to safety, quality and efficacy remain among our top priorities in this area of work. Our overall success in achieving this General Objective will be measured against the *Impact indicator 1: Healthy life years at birth*.

#### **Specific Objective 2.1: Diminishing the impact of cancer in Europe**

Cancer – a term covering over 200 diseases – can affect anyone. Without further action to reverse current trends, it could become the leading cause of death in the EU<sup>7</sup>. Although cancer is caused by a combination of multiple factors including genetic predisposition, environmental influences, lifestyle and infectious agents, people can greatly lower the risk of getting cancer by

"Over the coming months, we will all have an opportunity to rewrite the story of the game as far as cancer is concerned. Today is the first step on that journey."

Commissioner Kyriakides, 4 February 2020
– Launch of the EU Beating Cancer Plan

avoiding known risks, reducing environmental pollution, and adopting healthy lifestyles. For example, tobacco use is the leading preventable cause of cancer mortality: 27% of all cancer deaths – more than one out of four deaths – were attributable to tobacco use in 2018. Prevention, therefore, is the easiest and most (cost-) effective way of reducing the incidence of cancer in the EU, while scientists continue to improve diagnosis and cures for cancer, offering hope to those who are already affected.

EU action can make a difference. The EU has been actively working to reduce the incidence of cancer for decades, and its work has paid off. The first 'Europe against Cancer Plan', dating back to the late 1980s, resulted in important EU legislation on tobacco and occupational health. Since then, EU Member States have taken a number of actions and have committed, in line with the United Nations Sustainable Development Goals, to reduce premature mortality from chronic diseases, including cancer, by one third by 2030. They have also committed to meeting the WHO targets on non-communicable diseases by reducing mortality from cancer by 25% by 2025, as well as to achieve a 30% reduction of current tobacco use rates.

Against this backdrop, President von der Leyen has committed to "a European plan to fight cancer, to support Member States and stakeholders in improving cancer control and care [...] to reduce the suffering caused by this disease" and for Europe to take the lead in the fight against cancer. With the support of Member States, stakeholders and the European Parliament, the European Cancer Plan will complement Member States' existing national cancer plans – including with financing from the EU4Health Programme. The development of the EU Cancer Plan will be closely linked to the Mission on Cancer, a novel initiative of the Horizon Europe Framework Programme for Research and Innovation by reinforcing research and innovation and providing evidence-based knowledge to devise specific actions, ranging from cancer prevention to social integration. In response to the COVID-19 crisis,

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<sup>&</sup>lt;sup>7</sup> https://ec.europa.eu/health/non\_communicable\_diseases/cancer\_en

stakeholders are being consulted on priority needs in the area of cancer, identifying serious challenges such as interruptions of elective procedures and delays in cancer diagnosis and screening, as well as monitoring the supply of medicines and radioisotopes. Lessons learned will inform the development of the plan with a view to stress-proof cancer care in future pandemics.

The overall objective of the EU Cancer Plan is to improve the prevention, detection, treatment and management of cancer in the EU while reducing health inequalities between and within Member States and between socio-economic population groups. It will set out actions that support, coordinate or supplement Member States' efforts as well as potential legislative actions developed in line with Better Regulation requirements.

The EU Cancer Plan will include a combination of measures with tangible and citizen- and patient-centred actions designed to make a real difference to people across the EU. Its primary focus will be on initiatives within the EU and areas for action will encompass:

- Prevention
- Early detection and diagnosis
- Treatment and care
- Quality of life for cancer patients, survivors and carers
- Knowledge, data and scientific evidence

Our success on seeking to diminish the impact of cancer will be measured against *Result Indicator 2.1.A Age-standardised five-year net survival of cervical, breast and colorectal cancer* and *Result Indicator 2.1.B. Ratio of Cancer Registries (CRs) and number of Member States reporting information on cervical, breast, and colorectal cancer stage at diagnosis.* 

DG SANTE will also continue to implement and potentially strengthen EU legislation and global initiatives aimed at reducing the consumption of tobacco and related products, which is the main risk factor in cancer. The current aim is to make full use of the existing tobacco products framework through its proper implementation and enforcement and to report on its application in 2021 (as legally obliged) with a view to identifying next steps. Thereafter, an evaluation of the current policy framework (covering tobacco and related products, tobacco advertising, promotion and sponsorship, smoke-free environments) is planned to assess its fitness for purpose and to prepare for possible initiatives aimed at improving it.

DG SANTE will cooperate closely with DG TAXUD to strengthen tobacco taxation. DG SANTE will also continue to lead the international efforts towards full implementation of the Framework Convention on Tobacco Control and its Protocol on Illicit Trade in Tobacco Products. DG SANTE also supports Member States in achieving their tobacco control goals through Joint Actions. Our success on seeking to reduce tobacco consumption will be measured against *Result Indicator 2.1.C: Smoking prevalence*.

DG SANTE will also continue its current work on the development of cancer guidelines and cooperate with national and regional authorities through the European Network of Cancer Registries (ENCR).

# Specific Objective 2.2: Patients' access to safe, innovative and affordable medicines and medical devices

A vibrant EU health technology sector and an EU legal framework for medicinal products are essential to achieve a high level of public health protection. In addition to nationally authorised medicinal products, DG SANTE issues central authorisation based on the opinion of the European Medicines Agency (EMA). It supports improving patients' access to safe medicinal products and competitiveness in the pharmaceutical industry, ensuring earlier market access for products.

#### A new Pharmaceutical Strategy

The unprecedented coronavirus pandemic clearly demonstrates the need to modernise the way the EU ensures access to medicines for its population. It shows the scale of the necessary and coordinated public health responses that are required to tackle such kind of pandemics. It demonstrates the need to have a future-proof and crisis-proof

"The EU Pharmaceutical Strategy aims to put patients at the centre of our policy and ensure the competitiveness of our pharmaceutical industry."

Commissioner Kyriakides, July 2020

system to ensure timely access to safe, quality and affordable medicines under all circumstances.

The pharmaceutical sector is a major contributor to the EU economy as a knowledge-intensive sector with 715,000 direct jobs and an €91 billion trade surplus in 2018. Scientific developments in fields such as gene therapy and other technological developments such as artificial intelligence (AI) as well as access and analysis of data collected from clinical experience (real world data) are changing the way products are developed and have the potential to transform therapeutic approaches and business models. They are a driver for innovation.

At the same time, the EU has an ageing population and a rising burden of diseases. This increasing demand, coupled with increasingly high prices of innovative pharmaceuticals, results in larger overall spending. To make the best use of available resources and to ensure the sustainability of Member States' health systems, it is important for new therapies to be cost-effective, based on sound evidence.

Against this backdrop, there has been a recurrent debate about access, availability (including shortages) and affordability of medicines. The Council conclusions of 2016<sup>8</sup> focused on how to reconcile innovation with the need to ensure wide access to innovative products for unmet needs and the sustainability of health systems. The European Parliament adopted a resolution in 2017 on possible EU options for improving access to medicines<sup>9</sup>. Finally, in her Mission Letter to Commissioner Kyriakides<sup>10</sup>, President von der

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<sup>8</sup> https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1581347403221&uri=CELEX:52016XG0723(03)

https://eur-lex.europa.eu/legal-content/EN/TXT/?gid=1581347576921&uri=CELEX:52017IP0061

<sup>10</sup> https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides en.pdf

Leyen invited her to help ensure Europe has the supply of affordable medicines to meet its needs, while supporting the European pharmaceutical industry to ensure that it remains an innovator and world leader.

Therefore, over the five years of this Commission mandate, DG SANTE will build and implement a holistic, patient-centred, forward-looking Pharmaceutical Strategy which covers the whole life-cycle of pharmaceutical products and creates synergies with general health policy, for example regarding medical devices, chemicals, environment, the sound functioning of the internal market and the rationalisation of public expenditure.

The strategy will build on an evidence-based assessment and review of the existing regulatory framework and policy, aiming towards a system that is future-proof and that consistently addresses all levels of the value chain, from R&D to post-approval and access of patients to medicines. It will take into account scientific and technological advances and the necessity to ensure environmental sustainability. Furthermore, it will support the EU to maintain its leading role at global level and enhance the outreach and impact of EU policies and approaches worldwide.

The strategy will also seek to address market failures (e.g. lack of new antimicrobials) and build on initiatives to support the financial and fiscal sustainability of health systems. Being linked to the new Industrial Strategy<sup>11</sup>, this initiative aims to boost the global competitiveness of the EU pharmaceutical manufacturing value chain and to secure the EU's strategic autonomy. This autonomy is especially important in a crisis situation where the EU's dependency on pharmaceutical imports from a small number of third countries can lead to serious supply and production challenges. It will create synergies with other policies and key Commission priorities (e.g. the Green Deal<sup>12</sup>, Europe's beating cancer plan<sup>13</sup>, research and innovation, competition, intellectual property rights).

The pharmaceutical strategy will examine the issues outlined above and set the way forward, examining the need for legislative and non-legislative actions in the different areas of work. Legislative actions may encompass follow-up to the initiatives which are already in preparation, such as the legislation on fees<sup>14</sup> for the European Medicines Agency and may include follow-up to the evaluation of the legislation on medicines for rare diseases and children (Orphan<sup>15</sup> and Paediatric<sup>16</sup> Regulations). It could also include a targeted ex-post evaluation of the current legislative framework to prepare the assessment of possible options for changes to the basic pharmaceutical legislation<sup>17</sup> and, to the extent necessary, other legislative acts. DG SANTE will also launch actions to ensure the full implementation of the Clinical Trials Regulation (EU) 536/2014 and make Europe attractive for clinical trials by increased harmonisation between the national regulatory bodies,

<sup>11</sup> https://eur-lex.europa.eu/legal-content/EN/TXT/?gid=1584383364795&uri=CELEX:52020DC0102

<sup>&</sup>lt;sup>12</sup> https://ec.europa.eu/info/publications/communication-european-green-deal en

<sup>&</sup>lt;sup>13</sup> https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2020-693786\_en

<sup>&</sup>lt;sup>14</sup> Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014

<sup>15</sup> https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02000R0141-20190726

<sup>&</sup>lt;sup>16</sup> https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32006R1901

<sup>&</sup>lt;sup>17</sup> Directive 2001/83/EC and Regulation (EC) No 726/2004

introducing the highest standards for participants' safety and sufficient transparency for public scrutiny. Legislative initiatives will be complemented by non-legislative actions. The Commission is also required to submit reports to the European Parliament and Council on the Falsified Medicines Directive 2011/62/EU and the Clinical Trials Regulation (EU) 536/2014 in 2024 and 2026 respectively.

Our success in ensuring European patients have access to medicines will be measured through *Result indicator 2.2.A:* Access to centrally authorised medicines for unmet needs. Meanwhile, *Result indicator 2.2.B:* Number of audits conducted in the EU and in third countries to ensure good manufacturing practices and good clinical practices (Union control) will show to what extent the EU ensures high quality medicines and proper implementation of the clinical trial regulation and supports the implementation of the legislation. Finally, to ensure transparency with regard to shortages, *Result indicator 2.2.C:* Number of shortages of medicines in the single point of contact network will track outcomes in this regard.

DG SANTE's priorities for pharmaceutical regulation and innovation for 2020-2024 will also include efforts at a global level to promote a stable and efficient regulatory framework and advocate the EU model for pharmaceuticals in relevant multilateral fora and in bilateral relations with key strategic partners. Harmonisation of technical requirements, notably through the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), as well as information sharing and promotion of convergence-based approaches in existing multilateral fora of regulatory authorities would contribute to a greater outreach and impact for EU actions and policies.

#### Effective EU assessment of medical products and other treatment

DG SANTE has long supported European health systems achieve the best possible outcomes in terms of available care for patients with available resources. Over the last decade, the EU has supported coordination among Member States. The current scientific-technical cooperation started in 2006. The Third Joint Action EUnetHTA is a widely recognised network and community developing common assessment methodologies, information tools and starting to produce joint reports.

To establish a sustainable framework for this cooperation, in 2018, the Commission adopted a proposal for a Regulation on Health Technology Assessment, building on the 20 years of experience working together with Member States. The proposal would allow Member States to pool their resources and expertise, resulting in quality and efficiency gains. Member States would be better equipped to assess the value of different technologies.

High quality joint clinical assessment reports would also support Member States in taking timely, evidence-based decisions related to pricing and reimbursement of new health technologies, facilitating patient access to truly innovative health technologies while contributing to the sustainability of healthcare systems.

DG SANTE will work towards the adoption of this proposal, and seek out additional avenues for meaningful HTA cooperation and take-up of assessment results, during the upcoming Commission mandate.

#### Medical devices

There are over 500,000 types of medical devices and in-vitro diagnostic medical devices (IVDs) on the EU market. Examples of medical devices are sticking plasters, contact lenses, x-ray machines, pacemakers, breast implants, and hip replacements. IVDs are used to perform tests on samples, and examples include HIV blood tests, pregnancy tests and blood sugar monitoring systems for diabetics. The medical device market accounts for more than €115 billion in Europe (second world-wide market after the United States).

Two regulations (Regulation (EU) 745/2017 and 746/2017) were adopted by the European Parliament and the Council in April 2017 to reflect the scientific progress of the last years and modernise the regulatory framework. They provide a comprehensive review of the existing system and are intended to significantly improve the safety of medical devices for EU citizens, while creating the conditions to modernise the sector and to consolidate the EU's role as a global leader in the field.

The implementation of the new legislative framework is an important challenge for national competent authorities, stakeholders and the Commission. The Commission and Member States have been collaborating closely and a lot of progress has been achieved. In light of the COVID-19 outbreak, the date of application of the Medical Devices Regulation was postponed until May 2021. This postponement takes the pressure off national authorities, notified bodies, manufacturers and other actors so they can focus fully on urgent priorities related to the coronavirus crisis. The In Vitro Diagnostic Medical Devices Regulation's (IVDR, Regulation (EU) 2017/746) corresponding date of application remains the same (May 2022).

Having recently been given the policy lead for this issue, DG SANTE collaborates closely with all parties involved and will work over the coming five years to ensure that the new regulatory framework is correctly implemented. The new Regulations empower the Commission to adopt more than 80 delegated and implementing acts. While the implementation challenge for the overall system remains significant, the Commission is determined to put the new system to work and DG SANTE will play its full role to that effect in close collaboration with Member States.

# Specific Objective 2.3: Effective response coordination of serious cross-border health threats

As we have seen in the case of COVID-19, epidemics and infections represent a serious health and security risk, with a devastating impact on human health, many lives lost, and significant direct economic cost through the interruption of economic activity. They must be contained and well-

"COVID19 has put us under unprecedented pressure. It has also shown the value of solidarity, resilience and togetherness."

Commissioner Kyriakides, June 2020

managed. On the basis that "prevention is better than cure" (and more cost-effective), crisis preparedness, prevention and response capacity will remain a top priority during this Commission mandate.

While the EU already has a well-developed and substantial framework for managing crises and disease outbreaks, it must continually evolve to remain robust in the face of new challenges such as the COVID 19 pandemic. The current tools have shown some limits, and need to be reviewed., DG SANTE will ensure that we draw the right lessons and strive to improve preparedness and response in the EU for future outbreaks, working in close concertation with ECDC.

Member States increasingly turn to DG SANTE for leadership in crisis management situations, even when the legal framework provides limited scope for intervention. It is well recognised that the EU has an important role to play in helping Member States coordinate their preparation and response capacity. A coordinated approach for availability and timely access to safe medicinal products in such a situation is essential.

In this context, DG SANTE will continue to implement the Joint Procurement Agreement, which enables participating Member States to jointly purchase medical countermeasures for serious cross-border health threats. It aims to improve Member States' preparedness, ensure more equitable access to specific medical countermeasures; and ensure more balanced prices. In the course of the current COVID 19 pandemic, it has enabled multiple joint procurement procedures to respond to Member State needs.

This specific objective is also essential to ensure full implementation of Decision 1082/2013/EU outlined above and to help Member States strengthen their International Health Regulation (IHR) core capacities, improve inter-sectoral collaboration and business continuity planning, outreach to other zones including accession countries and neighbourhood countries, and to align strategies on communicable disease and other health threats with the "all hazards" approach of the World Health Organisation.

Our success in ensuring the EU is better prepared to coordinate effectively against cross-border health threats will be measured against *Result indicator 2.3.A: Number of Member States with improved preparedness and response planning.* 

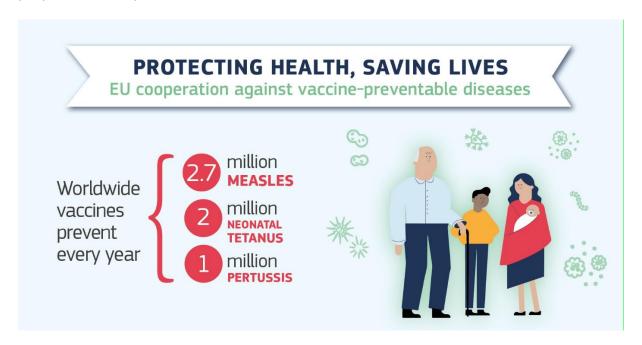
As with all areas of health policy, preparedness, response planning and implementation is the responsibility of Member States and the degree to which EU intervention can be successful is largely dependent on Member States providing adequate resources for the relevant activities.

#### <u>Vaccination</u>

As invited in the Mission Letter of Commissioner Kyriakides, DG SANTE will improve communication on vaccination to explain the benefits and combat the myths, misconceptions and scepticism that surround the issue.

Vaccination is one of the most powerful and cost-effective public health measures. Vaccination has eradicated smallpox and is close to eliminating polio. Vaccines against human papilloma virus are preventing cervical cancer. However, the EU is the region in the world with the lowest confidence in the safety and effectiveness of vaccines.

Vaccination coverage is decreasing, diseases are increasing, and this is a risk for the health security of the EU. In 2018, more than 12,000 cases of measles and 35 deaths by this disease occurred in the EU. Vaccines are not only used during childhood; vaccination is a life-long issue as diseases may occur at any time during one 's lifetime. Seasonal influenza causes around 40,000 deaths per year in the EU and has impacts on the health systems and productivity. Yet, only one Member State has reached the 75% coverage target for people above 65 years.



Vaccination programmes in Europe have become increasingly weakened due to low vaccine uptake, increasing cost of new vaccines and shortages in production and supply. One of the strongest drivers for low and sometimes even decreasing vaccination coverage rates are misunderstandings about the benefits and risks of vaccines, the severity of vaccine-preventable infectious diseases and the fear of potential side effects from vaccination.

Recent Eurobarometer findings showed that 48% of Europeans believe – incorrectly – that vaccines can often produce severe side effects and 38% think vaccines can cause the diseases against which they protect<sup>18</sup>. At global level, the World Health Organisation declared vaccine disinformation as one of the top 10 public health threats in 2019. Access to vaccines and the organisation and delivery of vaccination services also play a role in vaccination coverage.

The Commission stepped up action on vaccination with the adoption of a Communication and Council Recommendation on strengthened cooperation against vaccine-preventable diseases. EU action aims to (1) help tackle vaccine hesitancy and improve vaccination coverage (2) promote sustainable vaccination policies (3) contribute to global health. The Commission works with Member States, stakeholders and the global community in close

<sup>&</sup>lt;sup>18</sup>https://ec.europa.eu/health/sites/health/files/vaccination/docs/20190426\_special-eurobarometer-sp488\_en.pdf

collaboration with the European Centre for Disease Prevention and Control and the European Medicines Agency.

The key actions in the Communication and Council Recommendation include: establishing a European Vaccination Information System to provide reliable and evidence based data; developing guidelines for a core EU vaccination schedule; a virtual warehouse on vaccine needs and stocks; reaching vulnerable groups and addressing knowledge gaps, specifically through research (behavioural, social). An ongoing Joint Action (project) with Member States, co-funded by the EU Health Programme, is strengthening national responses to vaccination challenges in Europe. It will establish an EU Vaccine Network of national programme managers and policy makers to improve vaccine forecasting and stakeholder dialogue.

Data-gathering to develop options and recommendations for an EU citizen's vaccination card, and for physical stockpiling possibilities and intra-EU exchange of supplies is underway with reports expected to be published in 2022.

A Coalition for Vaccination at EU level, established in March 2019, brings together and strengthens the engagement of healthcare professionals with a view to enhancing vaccine acceptance and countering vaccination myths. A high-level Global Vaccination Summit on 12 September 2019 co-organised by the Commission and World Health Organisation created a momentum to raise political attention on vaccination and raise awareness beyond health authorities. In the coming five years, DG SANTE will continue to build on this momentum to implement the remaining key actions and fulfil the mandate set out in Commissioner Kyriakides' Mission Letter.

In response to COVID-19, DG SANTE will contribute to Commission efforts on the implementation of the EU Vaccines Strategy to accelerate the development and availability of safe and effective vaccines. This includes securing the production of vaccines in the EU

and sufficient supplies for its Member States via the use of advanced purchase agreements through the funding of Emergency Support Instrument, as well as adapting the regulatory framework and making existing regulatory use of flexibility.

"Joint action at EU level will increase the chance of finding a vaccine and secure necessary volumes at a good price in the EU and beyond."

Commission President Von der Leyen, 17 June 2020 Launch of the EU Vaccines Strategy

#### Antimicrobial resistance (AMR)

AMR is a global challenge with significant consequences for the economy and human health unless tough action is taken to address it. Currently, around 700,000 deaths in the world each year are linked to antimicrobial resistance; the associated economic cost is estimated to be EUR 1.5 billion in loss of productivity and healthcare costs. By 2050, recent projections suggest that lives lost to AMR will rise to 10 million and the cumulative economic cost will be around 1.5 times the world's GDP today.

Tackling AMR requires action at all levels. Excessive and inappropriate use of antimicrobials in the health sector is the fundamental cause of AMR and the health sector needs to adopt a new and up-to-date approach that limits abuse of antimicrobials and increases awareness of the need to use them correctly.

The 'European One Health Action Plan against Antimicrobial Resistance' was adopted in June 2017. It is built on three pillars: (i) making the EU a best practice region; (ii) boosting research, development and innovation; and (iii) shaping the global agenda. The action plan is delivering tangible results, and DG SANTE produces regular progress reports on implementation.

Over the coming five years, DG SANTE will continue to implement the Action Plan and maintain the EU's global leadership role in the fight against AMR, promoting cooperation across Member States and actively engaging at international level. Specifically, as invited in the Mission Letter of Commissioner Kyriakides, DG SANTE will work with our international partners to advocate for a global agreement on the use of and access to antimicrobials.

Another factor that threatens global efforts to contain drug resistant infections is lack of new antimicrobials or their alternatives. Within its Pharmaceutical strategy (Specific Objective 2.2), DG SANTE will seek to address the market failure and boost antibiotics development. We will work with Member States and all stakeholders in order to find innovative and sustainable solutions to the challenge of AMR. DG SANTE will deploy an outreach campaign on AMR through its available training tools aimed at promoting cooperation at worldwide level. It takes active part in the AMR-related work conducted by the World Organisation for Animal Health, the Food and Agriculture Organisation, and the World Health Organisation.



#### Specific Objective 2.4: More effective, accessible and resilient health systems

To face the dual challenge of rising healthcare costs and public spending constraints, healthcare systems need to become more cost-effective, accessible and robust to remain sustainable. In part, this requires adapting to and facing specific challenges, in particular preventable chronic disease and the rise of AMR. In part, it means embracing and making full use of innovative new technologies that can support more cost-effective and flexible healthcare solutions.

Though health policy is a national responsibility, experience shows that an effective way to promote health and prevent disease is to share best practices and support Member States in the design and implementation of targeted initiatives, involving stakeholders where relevant and appropriate.

EU public health activities – which focus principally on facilitating and supporting effective public health policy by Member States – are explicitly oriented to delivering EU policy objectives that not only improve health in its own right, but also contribute to policy objectives in employment and social exclusion. These activities support the modernisation of health systems in Member States, in particular to reduce levels of "treatable" and "preventable" mortality without increasing the level of public spending on healthcare i.e. those deaths influenced by public health interventions and prevention strategies and those influenced by health care. Doing so makes an important contribution to the economic structure of Member States as well as rates of labour force participation. Our success in this regard will be measured against *Result indicator 2.4.A: Implementation of best practices by EU Member States*.

#### Innovation and technology in healthcare

eHealth – including telemedicine and mHealth – play an essential role in modernising healthcare. It offers important opportunities both in respect of treatment and care and the economy and growth. It is a key element of the Digital Market Strategy and has the potential to bring about significant cost reductions and better patient outcomes within a modern, open care framework.

The deployment of eHealth solutions across Member States' health systems can play an important role in increasing more efficient use of scarce resources and providing possibilities for an integrated approach through better flow of information in healthcare. Furthermore, eHealth could increase the quality of healthcare by preventing duplication and mistakes. Telemedicine improves access to healthcare for people living in remote areas or those who are less mobile.



Ultimately, health digitalisation has the potential to deliver better disease prevention, diagnosis and treatment, but needs to take account of important issues related to data protection, privacy and security. The Commission works to ensure a digital transformation of health and to address these concerns. The 2018 Commission Communication on enabling the digital transformation of health outlines the need to improve citizen access to their health data, to strengthen citizen empowerment through digital and, importantly, to ensure sensitive personal health data is well protected. Making sure that every citizen has secure access to their Electronic Health Record (EHR) and can ensure the portability of his/her data – within and across borders – will improve access to and quality of care, cost effectiveness of care delivery and contribute to the modernisation of health systems.

As invited in Commissioner Kyriakides' Mission Letter, DG SANTE will work during this Commission mandate on the creation of a European Health Data Space. In doing so, DG SANTE will pay particular attention to the governance of data security to ensure citizens

have control over their own personal Specifically, DG SANTE data. evaluate the achievements of the e-Health policy interventions and conduct a comprehensive analysis of existing gaps and potential for EU added value, in line with the Better Regulation requirements. This work will inform a number of initiatives (legislative and non-legislative) in view of the creation of the European Health Data Space to complement the horizontal framework of the common data space.

"We need to make the most of the potential of e-health to provide high quality healthcare and reduce inequalities. I want you to work on the creation of a **European Health Data Space** to promote health data exchange and support research on new preventive strategies, as well as on treatments, medicines, medical devices and outcomes."

Commission President Von der Leyen's mission letter to Commissioner Kyriakides, 2019

The European Health Data Space Initiative could address the need to further facilitate and scale up the cross border exchange of health data (including electronic health records, medical images, laboratory results and discharge reports) within the EU and the use and reuse of that data for public health and research purposes.

DG SANTE will also build on and potentially amend the current framework established by Directive 2011/24/EU, and provide for the necessary infrastructure, governance and tools to support big data projects promoted by Member States' health regulators. DG SANTE will also continue to support and encourage increased interoperability of digital health solutions between Member States, notably via the EU's eHealth network and cross-border exchanges of health data through the MyHealth@EU (also known as the eHealth Digital Service Infrastructure) and a European electronic health record exchange format, enabling the exchange of electronic patient summaries and ePrescriptions between 22 Member States by 2022.

DG SANTE will also continue to promote greater access to medical expertise and information for medical conditions, notably via the European Reference Networks (ERN), including by enhancing the virtual consultation model and associated registries. The ERN bring together highly specialised healthcare providers from different EU Member States in areas where expertise is rare, giving patients with specific conditions better access to high quality, affordable healthcare and providing a focal point for medical training and research, information exchange and healthcare evaluation. The ERN provide important economies of scale and allow a more efficient use of increasingly stretched EU healthcare resources. Their implementation is currently one of the most important and innovative pan-European cooperation initiatives in health care.

#### Country knowledge

In order to identify tools and methodologies that will contribute to better and more accessible healthcare and more efficient and more resilient healthcare systems, DG SANTE will continue to develop a broad country knowledge through the State of Health in the EU. This is a two-year information gathering cycle, undertaken with the OECD and the European Observatory on Health Systems and Policies. It contributes to more cost-effective health promotion and disease prevention by providing the necessary evidence base for such policies. The country knowledge on the performance of health systems goes beyond the work of the European Semester to inform policies at national and European level.

In even years, the joint EU-OECD report Health at a Glance: Europe will be published, readjusted to the Commission's priorities of effective, accessible and resilient health systems. In odd years, individual country health profiles will be published, along with a Commission Staff Working Document that distils a cross-country, EU level narrative, focussing on best practices, concrete tools and processes and further EU added value. The country health profiles will be prepared in a tripartite collaboration with the OECD and the European Observatory on Health Systems and Policies.

These deliverables will support Member States' capacity to improve the effectiveness, accessibility and resilience of their health systems and will help identify potential areas of EU added value in which the Commission could support Member States through EU action. The Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases will be a key platform to operationalise the knowledge provided by the State of Health Process. The group allows countries to work together in priority areas though transfer of best practices with the support from relevant EU funding mechanisms.

#### Cross-Border Healthcare

DG SANTE will carry out a comprehensive evaluation of the Directive 2011/24/EU on the application of patient rights in healthcare to review the Directive's impact with regard to patient rights, reimbursement of healthcare costs, e-health, European Reference Networks for rare, low prevalence and complex diseases and to propose areas for improvement.

#### Substances of human origin (SoHO)

SANTE will launch an impact assessment to identify best options to address the shortcomings identified by the ex-post evaluation. The overall objectives are to ensure safety, access and innovation, and specifically to ensure a high level of health protection for EU citizens and equal access of patients to high quality, effective blood tissue and cells treatments.

#### D. Key performance indicators

DG SANTE has selected the following two Key performance indicators from the result indicators corresponding to objectives from Part 1 and Part 2 of this strategic plan:

#### PART 1

Specific objective 2.1: Diminishing the impact of cancer in	Related to spending
Europe	programme(s): European Social
	Fund Plus

## Result indicator 2.1.A: Age-standardised five-year net survival of cervical, breast and colorectal cancer

**Explanation:** Cervical, breast and colorectal cancer survival is one of the key measures of the effectiveness of health care systems in cancer care, reflecting both efficiency in early detection and the effectiveness of treatment.

**Source of data:** EUROCARE (Joint Research Centre) and CONCORD Programme, London School of Hygiene and Tropical Medicine

Baseline (2014)	Interim milestone (2022)	<b>Target</b> (2024)
<b>Cervical cancer:</b> 63% (EU average)	Increase	Increase, with at least 2/3 of Member States above baseline
<b>Breast cancer:</b> 83% (EU average)	Increase	
<b>Colorectal cancer:</b> 59% (EU average)	Increase	

#### PART 2

**Objective:** The authorising officer by delegation has reasonable assurance that resources have been used in accordance with the principles of sound financial management, and that cost-effective controls are in place which give the necessary guarantees concerning the legality and regularity of underlying transactions

Indicator:	<b>Estimated</b>	risk at c	losure

Source of data: Internal follow-up Excel tables

Baseline	Target
(2018)	(2024, on annual basis)
1% (M€4.4/M€441.3)	< 2% of relevant expenditure

#### **PART 2. Modernising the administration**

DG SANTE is committed to fostering a modern and effective administration and work environment. Ahead of the start of the new Commission, DG SANTE undertook a strategic reflection for the future and review of internal working methods towards more transparency and collaboration. This work has resulted in a development plan and an action plan on internal working methods. Actions taken have already resulted in, *inter alia*, more guidance and political steer on SANTE policies; well-being actions in the DG; increased knowledge-sharing; greater interaction between colleagues; improved internal communication; cross-Unit cooperation; and increased leadership guidance from senior management. In the course of this mandate, DG SANTE will further develop these themes with a view to modernise and improve work life and collaboration within the DG.

As a modern public administration, the Commission implements an internal control framework inspired by the highest international standards. The Commission's system covers all the principles of internal control identified in the Committee of Sponsoring Organisations of the Treadway Commission 2013 Internal Control framework, including financial control, risk management, human resource management, communication and the safeguarding and protection of information. Within this framework DG SANTE has established an internal control system tailored to its particular characteristics and circumstances and regularly assesses its implementation and overall functioning. This assessment is based on indicators, the most strategic of which are listed in this section of the strategic plan.

#### A. Human resource management

**Objective:** DG SANTE employs a competent and engaged workforce and contributes to gender equality at all levels of management to deliver effectively on the Commission's priorities and core business.

In order to ensure the effective management of human resources and to optimise the capacity to deliver on priorities in this strategic plan, DG SANTE will develop a local HR strategy with a medium to long-term outlook (3–5 years) consistent with the overall corporate HR strategy.

DG SANTE will face important challenges to continue to ensure it has sufficient qualified and experienced staff to carry out its critical mission to ensure food is safe and the health of the European citizens is safeguarded. The new Commission shifted the focus towards building a Europe for its Citizens, which has led to an important increase of new initiatives in SANTE's areas of competence. Several which were deprioritised previously. Moreover the Covid-19 pandemic will have major consequences for SANTE as an organisation and for individual Staff Members. The crisis mode will still last during a long period and many new demands are expected to emerge in the aftermath.

Additional complexity exists due to DG SANTE being located in three different countries with their own specific problems. In Luxembourg we face the issue of the attractiveness for Staff and in Grange (IRL) we are faced with the effect of isolation and a rapid ageing population. The latter was confirmed in the IAS' last audit report on SANTE's audit Directorate located in Grange.

HR activity will focus on actions to counterbalance the above potential negative stress factors on DG SANTE<sup>.</sup>

- Revision of its organisational structure to face the new realities;
- Organise competitions and selections for specialised SANTE profiles to avoid staff shortages;
- Invest in building resilient teams by means of team coaching, fostering social connections, and assist managers in developing as resilient leaders
- Continue to focus on actions to develop management potential in particular of female staff to ensure the availability of sufficient female candidates for management positions allowing the reaching of the target of at least 4 female first appointments to middle management positions;
- Increase staff participation and internal collaboration by consequent internal communication and the implementation of more cross unit task forced based working arrangements;
- Improve Senior Management connecting with Staff.

Objective: [The service] employs a competent and engaged workforce and contributes to gender equality at all levels of management to effectively deliver on the Commission's priorities and core business

Indicator 1: Number and percentage of first female appointments to middle management positions

**Source of data**: SEC(2020) 146 – Measures to reach gender equality at all levels of management by the end of 2024

Baseline (female representation in management)	<b>Target</b> 2022 <sup>19</sup>
2019	
39% - 14 females out of 36	4 first female middle management appointments

Indicator 2: DG SANTE staff engagement index

**Source of data:** Commission staff survey [data to be provided by DG HR]

Baseline	Target
2018	(2024)
69% (SANTE and Comm. average)	≥70%

<sup>&</sup>lt;sup>19</sup> The target will be revised and extended for the period 2023-2024 by January 2023.

### **B.** Sound financial management

**Objective:** The authorising officer by delegation has reasonable assurance that resources have been used in accordance with the principles of sound financial management, and that cost-effective controls are in place which give the necessary guarantees concerning the legality and regularity of underlying transactions.

DG SANTE uses the organisational structure and the internal control systems suited to achieving both its policy and internal control objectives in accordance with the internal control principles set by the Commission<sup>20</sup>. To achieve the objective, DG SANTE has established a comprehensive control strategy including all control and anti-fraud measures for all types of expenditure directly managed by the DG in the two policy areas. The control measures encompass risk assessment and risk management integrated into the planning process and control activities including ex-ante and ex-post verifications. Furthermore, DG SANTE co-operates with OLAF and implements fraud prevention and detection measures.

Management receives reports on a regular basis on budget implementation and control results as well as communications on the progress of the implementation of action plans. In addition, DG SANTE receives feedback from external audits of the Commission's Internal Audit Service and the European Court of Auditors and systematically compiles, implements and monitors the corresponding action plans. In its internal control system, DG SANTE embedded continuous monitoring measures to ensure that its management and internal control framework is effective. Annual management assessments of the effectiveness of key internal control systems are carried out to ascertain whether the components of internal control are present and functioning and whether deficiencies are remedied in a timely manner. DG SANTE follows the methodology proposed in the "implementation guide of the internal control framework of the Commission".

**Objective:** The authorising officer by delegation has reasonable assurance that resources have been used in accordance with the principles of sound financial management, and that cost-effective controls are in place which give the necessary guarantees concerning the legality and regularity of underlying transactions

Indicator: Estimated risk at closure

**Source of data:** Internal follow-up Excel tables

 Baseline
 Target

 (2018)
 (2024, on annual basis)

 1% (M€4.4/M€441.3)
 < 2% of relevant expenditure</td>

Commission Communication (2017) 2373 on the revision of the Internal Control Framework

### C. Fraud risk management

**Objective:** The risk of fraud is minimised through the application of effective anti-fraud measures and the implementation of the Commission Anti-Fraud Strategy (CASF) aimed at the prevention, detection and correction of fraud.

Fraud risks are addressed by specific controls designed and implemented to mitigate the risks. To this end, DG SANTE has developed and implemented its own anti-fraud strategy and action plan on the basis of a specific fraud risk assessment and a methodology provided by OLAF. The controls to prevent and detect fraud are basically the same as those intended to ensure the legality and regularity of the transactions.

Once the Multi-annual Financial Framework (2021-2027) is adopted, DG SANTE will update its anti-fraud strategy and action plan for 2021-2024 based on a fraud risk assessment, lessons learned from the previous strategy and the Commission Anti-Fraud Strategy (CAFS) and action plan of April 2019<sup>21</sup>.

Especially important to DG SANTE are the following tasks already well embedded in existing procedures:

- Continued awareness raising in DG SANTE's decentralised financial cell network and through promoting ethics training, in particular on how to deal with lobbyists;
- Actions linked to handling "conflict of interest" in agencies, scientific committees and expert groups;
- Active participation in the network "Fraud Prevention and Detection" (FPD) chaired by OLAF;
- Regular updates of the Standing Operating Procedures for the handling of allegations of fraud, other irregularities and OLAF cases;
- Arrangements for an appropriate cooperation with OLAF according to the new CAFS of April 2019.

The internal control officer monitors the implementation of the action plan associated to the anti-fraud strategy and reports the results to DG SANTE management twice a year, at mid-term and at year-end.

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Latest update of April 2019: Communication from the Commission 'Commission Anti-Fraud Strategy: enhanced action to protect the EU budget', COM(2019) 176 of 29 April 2019 – 'the CAFS Communication' – and the accompanying action plan

Objective: The risk of fraud is minimised through the application of effective anti-fraud measures and the implementation of the Commission Anti-Fraud Strategy<sup>22</sup> aimed at the prevention, detection and correction<sup>23</sup> of fraud Indicator 1: Update of DG SANTE's anti-fraud strategy and action plan according to the CAFS of April 2019 and covering the period 2021-2024 Source of data: DG SANTE Intranet, ARES **Baseline Target** (2017)(2021)DG SANTE's anti-fraud strategy (2017-2020) DG SANTE's anti-fraud strategy (2021-2024) adopted adopted by the Management Board in July 2017 by the Management Board in Q1 2021 Indicator 2: Implementation of the actions included in DG SANTE's anti-fraud strategy over the whole strategic plan lifecycle (2020-2024) Source of data: Internal follow-up Excel tables, OLAF reporting Target (2018)(2024)90% 100% of action points implemented in time

### D. Digital transformation and information management

**Objective:** DG SANTE is using innovative, trusted digital solutions for better policy-shaping, information management and administrative processes to forge a truly digitally transformed, user-focused and data-driven Commission.

The College adopted a new European Commission Digital Strategy<sup>24</sup> (ECDS) in November 2018 to steer the digital transformation of the Commission. DG SANTE maintains a significant digital solutions portfolio, which enables fast, effective and transparent policy implementation and monitoring, encompassing a large user base including EU-citizens, business operators and national authorities.

This portfolio includes solutions at the highest eGovernment maturity level, implementing user centric interaction through interoperable services through full electronic case handling, eSubmissions, eSignatures and electronic certificates, and exchanges in the health and food safety domain fully in line with the 2018 ECDS orientations.

**DG SANTE's digital strategy** will aim towards a digital native organisation working with and offering trusted and personalised digital solutions, across all activities and processes in its policy domains and daily operations by 2024. The digital strategy will include three

Communication from the Commission 'Commission Anti-Fraud Strategy: enhanced action to protect the EU budget', COM(2019) 176 of 29 April 2019 – 'the CAFS Communication' – and the accompanying action plan, SWD(2019) 170 – 'the CAFS Action Plan'.

<sup>&</sup>lt;sup>23</sup> Correction of fraud is an umbrella term, which notably refers to the recovery of amounts unduly spent and to administrative sanctions.

https://ec.europa.eu/info/sites/info/files/file import/digitally-transformed user-focused datadriven commission en.pdf.

different perspectives: the inner perspective looking at electronic collaboration, modernisation and improvements towards a more 'open, inclusive and cooperative way of working' within SANTE; the *near perspective*, with initiatives to co-create, co-innovate and co-deliver with the SANTE policy agencies<sup>25</sup> delivering cost-effective, efficient digital solutions; and the *outward perspective*, towards secure, interoperable digital solutions based on reusable corporate building blocks and services towards modern transformed eGoverment services towards Member States, business and citizens alike.

The SANTE digital strategy and IT modernisation plans will be established in 2020 and will be the key drivers for the transformation work for all SANTE digital solutions in full adherence to the ECDS. Progress in these plans will be captured through appropriate indicators fixed in the management plans in an annual basis.

#### Data, information and knowledge management including document management:

DG SANTE is fully committed to participate in the transition to a knowledge-and data-driven Commission. Our aim is to maintain DG SANTE policies solidly founded on data, information and knowledge while enabling a work culture change in line with the Commission strategy on data, information and knowledge management, adopted in 2016<sup>26</sup>, and its subsequent work programmes<sup>27</sup>, as well as its document management and archiving policy.

The priorities for the next five years are: (i) to embed knowledge and document management in the policy-making and administrative processes, (ii) to enhance staff awareness and data literacy and (iii) to promote a behavioural and culture change towards a knowledge- and data-driven DG.

SANTE already shares with other DGs a large amount of the information produced<sup>28</sup>, and publishes online documents made available to stakeholders through access to documents procedure<sup>29</sup>. The DG uses the KOEL<sup>30</sup> database to manage and share information on its vast acquis, and proactively makes publicly available draft Decisions sent to Regulatory Committees for vote. DG SANTE has started the process of integrating in Hermes-ARES-NomCom relevant IT systems managing records to be preserved.

Building on these achievements SANTE will develop its Data Strategy and annual work plans to implement it. By mobilising indispensable support and leadership drive from senior and middle managers across the DG, the Data Strategy will aim to create in SANTE a policymaking environment where existing knowledge is fully accessible, accessed and used, shared, and where new knowledge is created and preserved for optimal usability. It will look at how the DG's working methods can be improved through the establishment of dedicated data processes and roles (e.g. on foresight and forward-looking), and through an enhanced

29 Procedure under Regulation (EC) No 1049/2001

DG SANTE has launched the Health Policy Agencies Collaboration (HPAC) initiative to create a cluster of DGs and Agencies on the Health policy to pursue synergies and collaborations in the Digital Strategy goals and ambitions for the delivery of user focused, secure borderless interoperable digital services implementing EU-wide policies.

Data, information and knowledge management at the European Commission (C(2016) 6626).

<sup>2020-2021</sup> work programme: ARES(2019)6848885

<sup>28</sup> [Include here a reference to % of files shared in ARES]

<sup>[</sup>SANTE uses Knowledge Online for European Legislation (KOEL) tool to manage its secondary and tertiary legislation]

use of the SANTE Collaboration platform (and its relevant features), modern document management and evolving digital tools and solutions. Staff upskilling and reskilling will be part of the strategy to increase progressively the collective knowledge management capacity of the DG.

Specific actions will focus, amongst others, on developing and continuously updating the SANTE local data catalogue, on increasing the in-house data-searching capabilities for available information and staff's general awareness and ability to retrieve evidence. To the extent possible future actions will automate the acquisition and preservation of relevant records in corporate document management tools. Dedicated trainings will improve data analysis skills (including through the use of AI). To retain valuable knowledge from departing staff, specific measures will be proposed and the work on the preservation and accessibility of records managed through IT applications will continue.

**Data protection:** SANTE pays particular attention to the protection of personal data, and successfully adapted to the regime of the new legal framework. In the following five years, SANTE will focus on maintaining full compliance with data protection rules and constant implementation of therein-embodied principles.

In particular, it will ensure that all actions, digital solutions and systems, including legislative, which might lead to potential processing of personal data respect the principle of data protection by design and by default. The necessary awareness will be achieved by a variety of trainings, ranging from general to dedicated ones, developed for particular categories of SANTE staff. While making full use of tools provided at a corporate level, when needed SANTE will create its own templates, guidelines, models, etc., that will reflect its needs and provide its staff with solutions that will be at the same time easy to implement and will respect data protection rules.

**Objective:** DG SANTE is using innovative, trusted digital solutions for better policy-shaping, information management and administrative processes to forge a truly digitally transformed, user-focused and datadriven Commission

Indicator 1: Degree of implementation of the digital strategy principles by the most important IT solutions<sup>31</sup>

Source of data: DG SANTE

Baseline	Interim milestone	Target
(2018)	(2021 <sup>32</sup> )	(2024)
N/A	20%	100% (all digital solutions)

Indicator 2: Percentage of DG SANTE's key data assets<sup>33</sup> for which corporate principles for data

The European Commission Digital Strategy (C(2018)7118) calls on Commission services to digitally transform their business processes by developing new innovative digital solutions or make evolve the existing ones in line with the principles of the strategy. At the beginning of the year N+1, the Solution Owner and IT Investments Team will assess the progress made on the basis of the proposed modernisation plan. For each of the 3 solutions, a table will reflect per principle - the progress achieved during the last year.

<sup>32</sup> As this is a new indicator, there is no baseline in 2018, and in the DSF of 04/03/2020 SG instructed the DGs to provide the value as from 2021.

governance <sup>34</sup> have been implemented					
Source of data: [each service]					
Baseline	Interim milestone	Target			
(2019)	(2022)	(2024)			
20% 50% 80%					
Indicator 3: Percentage of staff attending awareness raising activities on data protection					

### Indicator 3: Percentage of staff attending awareness raising activities on data protection compliance

Source of data: DG SANTE

Baseline	Interim milestone	Target
(2019)	(2022)	(2024)
98% newcomers	50%	100% of staff
17% rest of the staff		

### E. Sound environmental management

**Objective:** DG SANTE takes full account of its environmental impact in all its actions and actively promotes measures to reduce the related day-to-day impact of the administration and its work

DG SANTE has sites in three different Member States, Belgium, Luxembourg and Ireland. SANTE's buildings in Brussels and Luxembourg fall under the responsibility of OIB and OIL respectively. Nonetheless, SANTE and its staff in all three sites are committed to participating in the sound environmental management of the Commission's building and of reducing our negative impact on the environment.

SANTE will promote the EMAS (Commission's Eco-Management and Audit scheme) corporate campaigns at local level and identify local environmental actions in order to support the Commission's commitment to implement the objectives of the Green Deal for its own administration, including becoming climate neutral by 2030.

A key data asset is defined as any entity that comprises a source of data based on projects or administrative processes, structured or semi-structured in an information system, a database or a repository of data or corpora of text. A data asset can include multiple datasets or files somehow linked, e.g. by common codes or metadata. Commission key data assets have been documented in the data inventory Ares(2019)2586155.

This indicator follows up on the progress of services in implementing corporate data governance and data policies for their key data assets included in the EC data inventory. See <a href="mailto:Ares(2019)4441343">Ares(2019)4441343</a> in the context of the <a href="mailto:DataStrategy@EC">DataStrategy@EC</a> action plan. In summary, this means that for each key data asset, services should assess if the following principles have been respected:

Identify and designate the data owner and the data steward(s).

Instruct their data stewards to share the metadata of their data assets in the Commission's data catalogue and to keep them up to date.

Design and document processes for data collection/creation, acquisition, access, sharing, use, processing
preservation, deletion, quality, protection and security. Information concerning these processes should be made
available to anyone interested, as long as any confidentiality restrictions are respected.

Make any necessary changes and updates to the IT systems used for storing, managing and disseminating these data assets to implement the aforementioned requirements and processes.

A data governance hub will shortly offer a single point of access on the intranet for related guidance and information. It will be complemented by further practical guidance in the course of 2020.

The DG SANTE building and site in Grange, Ireland is managed by SANTE itself and is fully integrated into EMAS. SANTE aims to maintain the EMAS registration and continuously improve the environmental performance of the site. To do that, we will take measures to ensure that the targets set at corporate level will be achieved over the implementation period, with a reduction in consumption of both utilities and resources, a move to renewable energy sources, and a reduction in emissions and waste.

In addition, the site will take advantage of its unique location to further enhance biodiversity in its landscape planning by following a strategy to return as much of the site as possible to a natural pastoral woodland. Over the next five years, a bio-diversity project will be rolled out on the 9 hectare site, to conserve and restore indigenous flora and fauna in the area. On top of the net biodiversity gain, an increased carbon offset is expected as the landscape scheme establishes and matures.

As noted above, the DG SANTE sites in Brussels and Luxembourg are managed by OIL and OIB. As such, in these latter locations, SANTE will support, promote and implement at the local level those environmental policies and initiatives which are agreed centrally by EMAS.

#### **ANNEX: Performance tables**

### General Objective 1: A European Green Deal

#### **IMPACT INDICATOR**

#### General objective 1: A European Green Deal

Impact indicator 1: Pesticide risk35

**Explanation:** This indicator shows changes in the potential risks from pesticide use for human health and the environment. The indicator is calculated by multiplying the quantities of active substances placed on the market in plant protection products by their hazard weighting. Index: 2015-2017 = 100

**Origin of the indicator**: <u>Directive (EU) 2019/782</u> amending <u>Directive 2009/128/EC;</u> EU Sustainable Development Goal indicator

Source of the data: Member States annually report data to Eurostat under Regulation (EC) No 1185/2009

Methodology for calculating the indicator: Directive (EU) 2019/782 Annex I

Baseline	Interim milestone	Target
(2015-2017)	(2022)	(2024)
100	80	70

#### **RESULT INDICATORS**

Specific objective 1.1: Ensuring food and feed safety

Related to spending programme(s): Single Market
Programme

Result Indicator 1.1.A (Animal health): Increase of the officially free areas from certain zoonoses (Bovine Brucellosis, Bovine Tuberculosis, Sheep and Goat Brucellosis)

**Explanation:** Member States implement EU co-financed programmes aiming to reduce and eventually eliminate certain zoonoses from their territories (Bovine Brucellosis, Bovine Tuberculosis, Sheep and Goat Brucellosis). As control progresses more countries or parts thereof are declared officially free from these diseases. Increase of the overall officially – free areas reflects the progress achieved in the control of these diseases.

**Source of data:** Grant Commission Decisions designating MS or regions thereof officially free from the above mentioned diseases

Baseline (2019)	Interim milestone (2022)	<b>Target</b> (2024)
EU countries (or parts thereof) free from the above diseases	+15%	+25%

<sup>&</sup>lt;sup>35</sup> The indicator will be published in Eurobase with code sdg\_02\_51 once the 2020 edition of the EU SDG monitoring report is released

Specific objective 1.1: Ensuring food and feed safety	Related to programme(s):	sper Food	nding and
	feed	expend	liture
	Regulation	(EU)	No.
	652/2014		

Result Indicator 1.1.B (Plant health): Number of phytosanitary programmes successfully implemented / total number of phytosanitary programmes approved

**Explanation:** Following the submission of technical and financial final reports by the Member States, the Commission carries out the evaluation and decides on the final payment of the eligible costs incurred for each previously approved programme (survey, eradication and containment). Programmes whose implementation is in line with the EU legislation and the terms agreed with the Commission are considered successful.

**Source of data:** Data can be procured using the Survey programs submitted by MS

Baseline (2020)	Interim milestone	Target (2024)
	(2022)	
N/A <sup>36</sup>	80%	90%

Specific objective 1.1: Ensuring food and feed safety	Related	to	spending
	programme		Single
	Market Prog	gramr	ne

Result indicator 1.1.C (Official controls): Percentage of DG SANTE's recommendations following its audits that Member States (MS) have satisfactorily addressed with corrective action

**Explanation:** This is a dynamic rolling indicator and the objective is to demonstrate the impact of DG SANTE audits based on verified corrective actions taken by Member States in response to DG SANTE audit recommendations. The basis for the indicator is not static and therefore the objective is to increase the result level over the five year period through intensified systematic follow-up actions.

The indicator for Year N is calculated based on the verified actions taken in respect of the sum of recommendations resulting from audits conducted in years N-4, N-3 and N-2.

All recommendations remaining open at the end of Year N continue to be subject to monitoring by the Commission services to assess progress.

**Source of data:** Commission internal (DG SANTE)

Baseline
(2019)

Target
(2022)

70%: Based on sum of audits carried out in years 2015+2016+2017

Target
(2024)

80%: Based on sum of audits carried out in years 2018+2019+2020

80%: Based on sum of audits carried out in years 2020+2021+2022

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<sup>&</sup>lt;sup>36</sup> This is a new Result Indicator and no Baseline is available at the time of drafting. As such, measurements will start in and a baseline will be established for 2020 (n) and included in the Management Plan for each following year (as of n+1). The Annual Activity Report for each following year (as of n+1) will report the trend based on data from the year before (n-1).

#### Specific objective 1.1: Ensuring food and feed safety

Related to spending programme(s): Single Market Programme

## Result indicator 1.1.D (Burden reduction): Proportion of proposed legislative revisions that include burden reduction measures

**Explanation:** The indicator measures how the Commission upholds its commitment to ensure that proposals for legislative revisions incorporate burden reduction measures, in the broader context of REFIT programme and One-In, One-Out approach. The indicator shows how many proposed legislative revisions out of the total, for each relevant specific objective, include measures that concretely reduce burden.

**Source of data:** DG SANTE

Baseline	1	Interim milestone	Target
(2020)		(2022)	(2024)
N/A		Positive trend	Positive trend

# Specific objective 1.2: Ensuring sustainable food systems — the 'Farm to Fork' strategy

Related to spending programme(s): Single Market Programme

#### Result indicator 1.2.A: Use of more hazardous pesticides

**Explanation:** This indicator shows changes in the quantities of pesticides, containing active substances categorised as candidates for substitution, as defined by Article 24 of Regulation (EC) No 1107/2009, which are sold each year. Member States are obliged to perform a comparative assessment when evaluating an application for authorisation for a pesticide containing an active substance approved as a candidate for substitution, and shall not authorize, or shall restrict the use of, the pesticide if certain criteria are satisfied.

**Source of data:** Member States report data on pesticide sales annually to <u>Eurostat</u> under <u>Regulation (EC) No</u> 1185/2009.

Baseline	Interim milestone	Target
(2020)	(2022)	(2024)
100	85 (15% decrease)	70 (30% decrease)

# Specific objective 1.2: Ensuring sustainable food systems — the 'Farm to Fork' strategy

Related to spending programme(s): Single Market Programme

#### Result indicator 1.2.B: Sales of antimicrobials in farmed animals and aquaculture

**Explanation:** This indicator measures the average volume of overall sales of antimicrobials in Europe, expressed in milligrammes of antimicrobial sold per animal population correction unit (mg/PCU). A population correction unit ('PCU') is applied as a proxy for the size of the animal population.

**Source of data:** European Medicines Agency [European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) Report]. Please note that the baseline is set based on data from 2017 (latest available ESVAC report) and that the interim milestone in 2022 and the target in 2024 will reflect data from 2020 and 2022, respectively.

Baseline	Interim milestone	Target
(2020)	(2022)	(2024)
110 mg/PCU	95 mg/PCU	85 mg/PCU

# Specific objective 1.2: Ensuring sustainable food systems — the 'Farm to Fork' strategy

Related to spending programme(s): Single Market Programme

# Result indicator 1.2.C : Number of Member States that have put in place national food waste prevention strategies

**Explanation:** The number of Member States that have put in place integrated food waste prevention strategies and roadmap/action plan to prevent food loss and waste, based on the "Target, Measure, Act" approach<sup>37</sup> and involving all key players. The development of such strategies by Member States is one of the key recommendations of the EU Platform on Food Losses and Food Waste (adopted in Dec 2019).

**Source of data:** DG SANTE will carry out a data collection exercise to assess implementation of national food loss and waste prevention programmes by Member States. Such an exercise could also support a possible initiative of the DE PcY to update EU/Member States developments/progress on the Council conclusions on food losses and waste (2016).

Baseline (2020)	Interim milestone (2022)	<b>Target</b> (2024)
N/A <sup>38</sup>	20	27

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<sup>&</sup>lt;sup>37</sup> https://champions123.org/

<sup>&</sup>lt;sup>38</sup> This is a new Result Indicator and no baseline is available at the time of drafting. A data collection exercise to be carried out by the DE PcY in the second half of 2020. As such, a baseline will be established for 2020 (n) and included in the Management Plan and Annual Activity Report for each following year (as of n+1).

# Specific objective 1.2: Ensuring sustainable food systems — the 'Farm to Fork' strategy

Related to spending programme(s): Single Market Programme

Result indicator 1.2.D : Percentage of DG SANTE's recommendations following its audits on Animal Welfare that Member States have satisfactorily addressed with corrective action

**Explanation:** The objective of this indicator is to evaluate the compliance of Member States with animal welfare legislation based on verified corrective actions taken by Member States in response to DG SANTE audit recommendations in the area of animal welfare. The indicator is based on all recommendations made to Member States in audit reports on animal welfare since 2010. The indicator represents the percentage of recommendations closed following verification of corrective actions taken by the Member States in response to these recommendations.

**Source of data:** Commission internal (DG SANTE)

Baseline	Interim milestone	Target
(2020)	(2022)	(2024)
81% (based on recommendations 2010-2019)	83% (based on recommendations 2010-2021)	85% (based on recommendations 2010-2023)

Specific objective 1.2: Ensuring sustainable food systems — the 'Farm to Fork' strategy

Related to spending programme(s): Single Market Programme

Result indicator 1.2.E (Burden reduction): Proportion of proposed legislative revisions that include burden reduction measures

**Explanation:** The indicator measures how the Commission upholds its commitment to ensure that proposals for legislative revisions incorporate burden reduction measures, in the broader context of REFIT programme and One-In, One-Out approach. The indicator shows how many proposed legislative revisions out of the total, for each relevant specific objective, include measures that concretely reduce burden.

Source of data: DG SANTE

Baseline (2020)	Interim milestone (2022)	<b>Target</b> (2024)
N/A	Positive trend	Positive trend

#### Specific objective 1.3: International promotion of EU food safety standards

Related to spending programme(s): Single Market Programme

# Result indicator 1.3.A: Percentage of DG SANTE's audit recommendations that third countries have satisfactorily addressed with corrective action

**Explanation:** This is a dynamic rolling indicator and the objective is to demonstrate the impact of DG SANTE audits based on verified corrective actions taken by third countries in response to DG SANTE audit recommendations. The basis for the indicator is not static and therefore the objective is to increase the percentage over the five year period through administrative and audit follow-up.

The indicator for Year N is calculated based on the verified actions taken in respect of the sum of recommendations resulting from audits conducted in years N-4, N-3 and N-2. All recommendations remaining open at the end of Year N continue to be subject to monitoring by the Commission services to assess progress

Baseline (2019)	Interim milestone (2022)	<b>Target</b> (2024)
67%: Based on sum of audits carried out in years 2015+2016+2017	sum of audits carried out in years	75%: Based on sum of audits carried out in years 2020+2021+2022

### General Objective 2: Promoting our European way of life

#### **IMPACT INDICATOR**

#### General objective 2: Promoting our European Way of Life

Impact indicator 1: Healthy life years at birth

**Explanation:** Number of years in absolute value that a person is expected to continue to live in a healthy condition

Source of the data: Eurostat (Eurostat data code: [hlth hlye])

Baseline	Interim milestone	Target
(2018)	(2022)	(2024)
Males:	Increase	Increase
63.7 years		
Females:	Increase	Increase
64.2 years		
Total:		
64.0 years		

#### **RESULT INDICATORS**

Specific objective 2.1: Diminishing the impact of cancer in Europe

Related to spending programme(s): European Social Fund Plus

## Result indicator 2.1.A: Age-standardised five-year net survival of cervical, breast and colorectal cancer

**Explanation:** Cervical, breast and colorectal cancer survival is one of the key measures of the effectiveness of health care systems in cancer care, reflecting both efficiency in early detection and the effectiveness of treatment.

**Source of data:** EUROCARE (Joint Research Centre) and CONCORD Programme, London School of Hygiene and Tropical Medicine

Baseline (2014)	Interim milestone (2022)	<b>Target</b> (2024)
Cervical cancer: 63% (EU average)	Increase	Increase, with at least 2/3 of Member States above baseline
Breast cancer: 83% (EU average) Colorectal cancer: 59% (EU average)	Increase	

Specific objective 2.1: Diminishing the impact of cancer in Europe

Related to spending programme(s): European Social Fund Plus

# Result indicator 2.1.B: Ratio of Cancer Registries (CRs) and number of Member States (MSs) reporting information on cervical, breast, and colorectal cancer stage at diagnosis

**Explanation:** Information on cervical, breast and colorectal cancer stage at diagnosis is an essential information item collected by Cancer Registries (CRs) to estimate stage-specific survival, and to evaluate population based screening performance. It has been recognized that cancer stage at diagnosis is an essential information to be collected by all European Cancer Registries.

**Source of data:** European Cancer Information System (ECIS - Joint Research Centre) and EUROCARE

Baseline (2015)	Interim milestone (2022)	<b>Target</b> (2024)
CRs reporting cervical cancer stage at diagnosis: 51%	Increase	Increase, at least 2/3 of Cancer Registries above baseline.
CRs reporting breast cancer stage at diagnosis: 53%	Increase	
CRs reporting colorectal cancer stage at diagnosis: 52%	Increase	
Number of MS reporting cervical cancer stage at diagnosis: 20	Increase	
Number of MS reporting breast cancer stage at diagnosis: 20	Increase	All Member States reporting the information on cancer stage
Number of MS reporting colorectal cancer stage at diagnosis: 20	Increase	

# Specific objective 2.1: Diminishing the impact of cancer in Europe

Related to spending programme(s): N/A

#### Result indicator 2.1.C: Smoking prevalence

**Explanation:** This indicator is part of the EU Sustainable Development Goal Indicator set and measures the percentage of the population aged 15 years and over who report that they currently smoke boxed cigarettes, cigars, cigarillos or a pipe. It does not include the use of other tobacco products such as electronic cigarettes and snuff.

**Source of data:** Collected through a Eurobarometer survey and are based on self-reported use during face-to-face interviews in people's homes. <a href="https://ec.europa.eu/health/tobacco/eurobarometers\_en">https://ec.europa.eu/health/tobacco/eurobarometers\_en</a>

Baseline	Interim milestone	Target
(2010)	(2021)	(2024)
29%	25% <sup>39</sup>	21% <sup>40</sup>

## Specific objective 2.2: Patients' access to safe, innovative and affordable medicines and medical devices

Related to spending programme(s): N/A

#### Result indicator 2.2.A: Access to centrally authorised medicines for unmet needs

**Explanation:** This indicator measures the number of new marketing authorisations granted by the Commission for the EU market for the following medicinal products: (a) those including at least one of the following – orphan authorisations, Advanced Therapy Medicinal Products, Paediatric Use Medicinal Products and (b) vaccines. The data is corrected for the number of medicines which belong to more than one of those groups and concerns only medicines for humans. The measurement is the average annual number of marketing authorisations granted for this basket of medicinal products for each reference period.

Source of data: European Commission European Medicinal Products database

Baseline	Interim milestone	Target
(2019)	(2022)	(2024)
	Average number per calendar year for the period 2020-2021	Average number per calendar year for the period 2022-2023
7	Increase	Increase

 $^{40}$  This target is based on the international processes, most notably the SGD goals and the WHO (and FCTC) global targets for NCDs. This corresponds to a 30% reduction in smoking prevalence by 2025 against a baseline in 2010. The 2024 target has been calculated on that basis.

<sup>&</sup>lt;sup>39</sup> Estimated prevalence reduction as a result of the Tobacco Products Directive.

Specific objective 2.2: Patients' access to safe, innovative and affordable medicines and medical devices

Related to spending programme(s): N/A

Result indicator 2.2.B: Number of audits conducted in the EU and in third countries to ensure good manufacturing practices and good clinical practices (Union control)

**Explanation:** This indicator shows to what extent the EU ensures high quality medicines and proper implementation of the clinical trial regulation and supports the implementation of the legislation. The EU has been supporting Member States in conducting audits of the national system on GMP for many years in the context of EU-US MRA and to ensure high quality API. This ensures increased control of GMP in the pharma industry and ascertains full implementation of the EU-US MRA. For clinical trials, the law will require to implement audits of the clinical trials system (Union control) as of 2022.

**Source of data:** European Commission

Baseline	Interim milestone	Target
(2020)	(2022)	(2024)
10	20	40

Specific objective 2.2: Patients' access to safe, innovative and affordable medicines and medical devices

Related to spending programme(s): N/A

#### Result indicator 2.2.C: Number of shortages of medicines in the single point of contact network

**Explanation:** This indicator measures the level of transparency on shortages of human and veterinary medicines by measuring the number of shortages of medicines that were either critical or had an impact on human/animal health reported by the SPOC (single point of contact) at EMA. This indicator will increase in the short term as Member States should improve their reporting practices and should decrease over the long term (where short term is 2020-2024 and long term is post-2024) once legislative measures and the actions of the pharmaceutical strategy are put into place.

**Source of data:** European Medicines Agency

Baseline	Interim milestone	Target
(2019)	(2022)	(2024)
9141	300	450

<sup>&</sup>lt;sup>41</sup> From April to December 2019

### Specific objective 2.2: Patients' access to safe, innovative and affordable medicines and medical devices

Related to spending programme(s):

## Result indicator 2.2.D (Burden reduction): Proportion of proposed legislative revisions that include burden reduction measures

**Explanation:** The indicator measures how the Commission upholds its commitment to ensure that proposals for legislative revisions incorporate burden reduction measures, in the broader context of REFIT programme and One-In, One-Out approach. The indicator shows how many proposed legislative revisions out of the total, for each relevant specific objective, include measures that concretely reduce burden.

**Source of data:** DG SANTE

<b>Base</b> (202	eline 20)	Interim milestone (2022)	<b>Target</b> (2024)
N/A		Positive trend	Positive trend

Specific objective 2.3: Effective response coordination of serious cross-border health threats

Related to spending programme(s): European Social Fund Plus

## Result indicator 2.3.A: Number of Member States with improved preparedness and response planning

**Explanation:** This indicator shows the number of Member States who have completed the implementation of International Health Regulations (IHR) core capacities in accordance with Article 4 of Decision 1082/2013/EU on serious cross border health threats.

**Source of data:** Member State reporting under Article 4 of Decision 1082/013/EU and the relevant implementing act

Baseline	Interim milestone	Target
(2019)	(2022)	(2024)
24	26	27

# Specific objective 2.4: More effective, accessible and resilient health systems

Related to spending programme(s): European Social Fund Plus

#### Result indicator 2.4.A: Implementation of best practices by EU Member States

**Explanation:** This indicator measures the number of Member States implementing best practices, demonstrating how the health challenges identified by the Steering Group on Promotion and Prevention are addressed through best practices at the national level with the support of the EU funding. The unit of measurement is the number of best practices over the number of Member States.

Source of data: DG SANTE (Unit C1) and CHAFEA and/or its follow-on entity.

Baseline (2020)	Interim milestone (2022)	<b>Target</b> (2024)
At least 1/3 of Member States implement at least one best practice selected by the SGPP	At least 1/2 of Member States implement at least one best practice selected by the SGPP	At least 2/3 of Member States implement at least one best practice selected by the SGPP