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The EU Health Agenda

2019 - 2024

BACKGROUND

On 2 July 2019, Dr Ursula von der Leyen, who is a physician, was proposed by the European Council as the candidate for the office of President of the European Commission. She was elected by the European Parliament on 16 July. At the beginning of September 2019, President von der Leyen presented the political guidelines for the next European agenda 2019 – 2024, headed by the theme ***'A Union that strives for more, my agenda for Europe'***. Furthermore, on 10 September 2019, the President-elect of the European Commission sent mission letters to all Commissioner designates, in which the respective portfolios of the commissioners designate were elaborated. The one sent to the Commissioner-designate for Health Stella Kyriakides, together with the political guidelines provide a glimpse of the Health Agenda of the Commission for the period 2019 – 2024.

The von der Leyen Commission came in office on 1 December 2019, following a positive vote in the European Parliament on 27 November 2019.

The 2014 – 2019 Commission led by President Juncker was guided by the political guidelines[1] headed by the theme '***A New Start for Europe: My Agenda for Jobs, Growth, Fairness and Democratic Change'***. Throughout its mandate the Juncker Commission focused on the following ten priorities:

1. A New Boost for Jobs, Growth and Investment
2. A Connected Digital Single Market
3. A Resilient Energy Union with a Forward-Looking Climate Change Policy
4. A Deeper and Fairer Internal Market with a Strengthened Industrial Base
5. A Deeper and Fairer Economic and Monetary Union
6. A Balanced and Progressive Trade Policy to Harness Globalisation
7. An Area of Justice and Fundamental Rights Based on Mutual Trust
8. A New Policy on Migration
9. A Stronger Global Actor
10. A Union of Democratic Change

All Commission initiatives within this period which were also guided by the principle '***big on big things and small on small things'*** had to be framed within the above 10 points. As voiced in Eurobarometer surveys, health is a big thing for EU citizens; however, unfortunately health policy was sidelined during the Juncker Presidency. In the field of public health, the Commission only adopted one legal proposal for a regulation on Health Technology Assessment[2] and one Recommendation on vaccination.[3] The former relates to the advancement of Europe in the area of permanent cooperation on Health Technology Assessments. The latter addresses vaccine hesitancy, coordination on vaccine procurement, research and innovation, as well as EU cooperation on vaccine-preventable diseases. The recommendation was adopted by the Council in December 2018, whilst negotiations on the regulation on Health Technology Assessment are still ongoing within the Council of Ministers and within the European Parliament.

THE VON DER LEYEN COMMISSION

The Von der Leyen Commission will focus on the following six priorities:

1. A European Green Deal
2. An Economy that Works for People
3. A Europe Fit for the Digital Age
4. Protecting our European Way of Life
5. A Stronger Europe in the World
6. A New Push for European Democracy

The von der Leyen Commission is structured in hierarchical layers. A system of Executive Vice Presidents and Vice Presidents has been introduced. Consequently, the health Sector will fall under the Responsibility of the Executive Vice President Frans Timmermans who will coordinate the work on the *European Green Deal* and of

the Vice President Margaritis Schinas who has been tasked with *Protecting our European Way of Life*. The Executive Vice President Valdis Dombrovskis will lead the Commission's *An economy that works for people*, under which Europe's social pillar falls.

Digital health which was high on the EU agenda under the Juncker Commission, under the Connected Digital Single Market priority, will remain a priority under the van der Leyen Commission under the *Europe fit for the digital age* strategy. This work will be led by Executive Vice-President Margrethe Vestager. The Internal Market and Services Commissioner, Thierry Breton will also promote the Digital Single Market. Digital health is also given prominence in the mandate letter sent to the Health Commissioner Stella Kyriakides,

The health Commissioner's portfolio falls within the first and second priorities listed within the political guidelines, i.e. *European Green Deal* when it comes to the 'Farm to Fork Strategy' and *An Economy that Works for People* in which the implementation of the European Pillar of social rights is being prioritized.

The pillar of social rights[4] includes 20 points, which includes one on health, which is however very broad and practically encompasses the entire spectrum of health services. In fact principle 16 states that *'Everyone has the right to timely access to affordable, preventive and curative health care of good quality'*. It should be borne in mind that the delivery and management of healthcare services are exclusive Member State competences, thus direct EU action in this field is rather limited. Notwithstanding this, the EU may play a significant role as elaborated below.

The political guidelines for the next European agenda 2019 – 2024 make a specific reference to the adoption of a European plan to fight Cancer with the aim to support Member States in improving cancer control and care. This plan should propose actions to strengthen our approach at every key stage of the disease: prevention, diagnosis, treatment, life as a cancer survivor and palliative care. There should be a close link with the research mission on cancer in the future Horizon Europe programme. The Cancer plan will only be adopted in late 2020. On the 'World Cancer Day' that is 4 February 2020, Commissioner Kyriakides will announce the start of a comprehensive consultation process, with stakeholders.

These political guidelines for the next European agenda 2019 – 2024 are further supplemented by the mission letter which was sent to Stella Kyriakides. Through this letter, President designate von der Leyen has requested that the Commissioner Designate for health:

- Finds ways to help **ensure Europe has the supply of affordable medicines** to meet its needs. In doing so, she should **support the European pharmaceutical industry to ensure that it remains an innovator and world leader.**
- Implements effectively the new regulatory framework on **medical devices** to protect patients and ensure it addresses new and emerging challenges.
- Makes the most of the potential of **e-health** to provide high-quality healthcare and reduce inequalities.
- Works 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, whilst ensuring that citizens have control over their own personal data.
- Focuses on the full implementation of the European One Health Action Plan against **Antimicrobial Resistance** and work with the EU's international partners to advocate for a global agreement on the use of **and access to antimicrobials.**
- Prioritizes communication on **vaccination**, explaining the benefits and combating the myths, misconceptions and scepticism that surround the issue.

The European Cancer Plan is also mentioned in the mission letter.

ACCESSIBILITY AND AFFORDABILITY MATTERS

Currently the EU is facing problems related to availability, accessibility and affordability of pharmaceuticals and medical devices. Affordability has been explicitly referred to within the mission letter, yet it should be recalled that both affordability and accessibility are linked to the pricing and reimbursement policies of the respective Member State which is of the Member State competence. In fact, article 168(7) of the Treaty of the European Union explicitly states that "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them." Any EU action in this regard would have to maneuver within the limits of its competence. Having said that, the pharmaceutical market must comply with EU internal market provisions and with EU competition rules amongst others. The placing on the market of pharmaceuticals and medical devices is regulated at EU level. Consequently, EU legislation sets the requirements the industry must comply with to place

and retain products on the EU market. However, there is no obligation of the industry to place products on each Member State market, nor to maintain the products in the respective markets of the Member States. These decisions are taken by the industry and are usually market-driven.

It should be recalled that the EU grants various incentives to pharmaceutical companies. These range from financial incentives at research and development stage to supplementary protection certificates and market exclusivity once a product has been placed on the market. The EU therefore has leverage on the industry and may impose conditions linking these incentives to access at an affordable price.

During the last few years Member States have also grouped together in different regional groups to tackle these common challenges related to access and affordability together. The Valletta Declaration, BENELUXA and the Visigrad groups are the main groups.

Shortages and the excessive pricing of innovative medicines were also on the agenda of the Employment, Social Policy, Health and Consumer Protection Council held on 9 December 2019. Many Member States shared the view that structural cooperation and coordination on pharmaceutical policy at an EU-level is essential to tackle current and future challenges within the pharmaceutical system. In this regard a large group of Member States, in particular those forming part of the Valletta Declaration and BENELUXA, invited the Council to prepare a draft EU working agenda 2020-2024 on pharmaceutical policy, addressing key priorities and concerns, in cooperation with the Commission. The proposed agenda should include priorities, actions, timetables, responsible parties and desired outcomes, while respecting the existing division of competences between the national and EU-level.

There are various reasons for shortages. These include manufacturing problems such as global shortages of an active pharmaceutical ingredient, increasing demand for the specific product, quality problems, uncontrolled market withdrawals, the increasing concentration outside Europe of the manufacturing and logistics chains (with their associated vulnerability, in particular of older medicines) and the fragmentation caused by subcontracting chains. Consequently, there is no one single solution to address these shortages and a multifaceted approach is required. The Commission is in the preparatory phase to propose legislation to incentivize the development of medicinal products which are not financially attractive to develop and to manufacture. This proposal will probably include within the scope the development of antimicrobials, vaccines and also cheap essential drugs of which many EU Member States are facing shortages.

A European Health Data Space was also mentioned in the mission letter of the Health Commissioner. This could speed up the current work on the cross-border exchange of health data and could draw inspiration from the eHealth Digital Service Infrastructure. This includes e-prescriptions and patient summaries, the clinical consultations on rare disease patients under the European Reference Networks, and the emerging collaboration on putting together more than 1 million sequenced genomes, as well as other research infrastructures which showcase benefits of health-data sharing. The European Health Data Space could be backed up by European and national legislation or other instruments that implement the data protection rules, data security and related ethical principles, in particular on the secondary use of health and social data.

On another note, on 11 October 2019, the Commission published its Evaluation of the Union legislation on blood, tissues and cells.[5] The evaluation concluded that many of the EU requirements within the legislation in force no longer reflect the best practice and guidance issued by authoritative expert bodies in the field, including the Council of Europe or the European Centre for Disease Prevention and Control. Amongst others, the report concluded that the current framework is inefficient, when it comes to technical updates and that that there is a lack of a robust oversight of the blood tissues and cells sectors. The report also concluded that there are shortcomings related to vigilance, inspections and authorizations and insufficient measures in place to protect blood tissue and cells donors. In response to this report it is highly likely that the Commission adopts legislative proposals to amend the current legislative framework, in order to address the deficiencies highlighted within the report.

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