Madam Chair,

Ladies and gentlemen, Members of the European Parliament,

Thank you for your interest in the health priorities of the Bulgarian Presidency of the Council of the European Union. It is an honour to present our programme to the members of the ENVI Committee of the European Parliament.

Bulgaria takes over the Presidency of the Council at a critical juncture for the EU. The future development of the European Union depends on the discussions in the coming months. In order to find the right way forward, now is the time to work together to analyse the achievements, challenges and mistakes of the past.

The motto for our Presidency of the Council - "United we stand strong" - demonstrates the importance we place on maintaining the unity of the European Union, keeping Europe united and strong. Our approach is one of consensus, compromise and cooperation. We advocate a European Union where economic growth is a tool for achieving social equality and prosperity for the citizens of all Member States. We will work towards a Europe of security, stability and solidarity, guaranteeing peace for its people and its neighbours.
I am here today to present our priorities in the health sector, and to answer your questions.

In the coming months there will be discussions on the future financing of EU policies and the future of key areas of cooperation. We believe that a united Europe is impossible without core values such as health, education, and culture. Regardless of the differences between the systems of the Member States, cooperation in these fields at European level - with no need for harmonisation - brings tangible benefits for EU citizens on a daily basis.

Let us first consider the areas of health policy where the European Union has already contributed active political messages, initiatives and legislation.

At European level, a legal framework for the free movement of patients across Europe (Directive 2011/24/EU on the application of patients' rights in cross-border healthcare) has been established, including the use of electronic solutions. With the active support of the Commission, a network of highly specialised treatment centres (European Reference Networks) has been established. The expertise of all national drug agencies, coordinated by the European Medicines Agency, is being harnessed to launch innovative medicines of proven quality, safety and efficacy and to ensure pharmacovigilance (Regulation No 726/2004, and the entire body of legislation relating to medicinal products, including paediatric medicines, orphan medicines, etc.).

We have extensive, detailed regulations on the marketing authorisation for pharmaceutical products, on clinical trials (Regulation No 536/2014), on medical devices and devices for in-vitro diagnostics (Regulations 2017/745 and 2017/746). There is a regulatory framework for tissues, organs and cells, organ donation and transplantation.
Within the internal market, there are opportunities for the free movement of medical professionals and patients, and for the exchange of experience. A mechanism for a joint coordinated response by all Member States to control the transmission of communicable diseases and cross-border health threats has been established.

These mechanisms rely and will continue to rely on expertise at national level. That is why it is essential to promote and develop support for that expertise in all Member States, and to communicate and cooperate at European level. This is crucial to ensuring the proper functioning of the healthcare systems.

A number of political documents - Council conclusions and European Parliament resolutions - highlight the significance of the policies on communicable and non-communicable chronic diseases and activities to prevent widespread diseases such as cardiovascular disease and diabetes. Coordinated efforts at European level are needed to address risk factors such as alcohol, smoking, and an unhealthy diet.

EU legislation in the area of health, together with the political messages articulated in Council conclusions and recommendations and European Parliament resolutions, give a strong impetus to initiatives at European and national level.

The discussions at European level are very important, as is the opportunity to exchange experiences and best practices and learn from each other by uniting the expertise and experience of the EU Member States in relation to the different health systems. The multiannual health programme contributes significantly to this cooperation; it has proven to be a useful tool for supporting initiatives in the area of health.
The implementation of each and every initiative and legal act, including at EU level, requires those involved in the process of implementation to be in the driving seat.

Healthcare is one of the areas where the EU's contribution to the daily lives of its citizens is most tangible. At the same time, Europe is aspiring towards more innovation and competitiveness. **Healthcare initiatives at EU level should be guided not only by the drive to support industry and innovation, but above all by the need to protect human health.** Whenever a product is launched on the market, for example a medicine, a foodstuff, etc., we need to be conscious of its impact on human health. Otherwise we risk losing the most valuable asset of all: people’s trust in the system.

Let me recall that the obligation to ensure a high level of health protection when undertaking initiatives within the internal market is explicitly mentioned in the Treaty (even in Article 114 of the Treaty on the Functioning of the European Union). This obligation is imposed on all of us: Commission, Parliament, and Council.

This is precisely the context in which we have considered and planned our priorities in the healthcare field as a Presidency. Our discussions in the next six months will be anchored in a clear awareness of this context.

During the Bulgarian Presidency we will prioritise two politically important topics: **healthy nutrition for children** and the need for **effective pharmaceutical products at affordable prices**.

**Healthy nutrition for children** is a topic of utmost importance and a topic related to the debate about the future of Europe. **The future of a competitive Europe is inconceivable without a healthy and well-educated young generation.**
Our healthcare focus is on children's nutrition. It is proven that one of the main health determinants is nutrition – an unhealthy diet is a major factor in the spread of chronic diseases. We plan to hold discussions on the impact of nutritional habits and foods on children's health and their physical and mental development. We will talk about the need for foods which are not only safe but healthy too, the marketing of foods to children, traditional diets in Europe, and the need to maintain dietary diversity.

Children’s health is an investment in a healthy population and workforce. I believe that this discussion will strengthen the health perspective in discussions on foods and diets, including in the context of the future Common Agricultural Policy, which is currently being revised. The success of prevention policies depends on market availability and the supply of healthy and affordable foods. Healthcare and agriculture should collaborate within this priority.

We have planned an expert level conference which will take place in Sofia on 6 February, and discussions on Council conclusions at the EPSCO meeting on 22 June.

Our second priority focuses on the increasingly topical subject of pharmaceutical products. We will concentrate on the two aspects of effectiveness in this area: **effectiveness of therapy and effectiveness of public spending**.

Europe has proven that the current regulatory framework supports innovation while guaranteeing patient safety. Sustaining this balance is essential in order to maintain patients’ confidence: that is why the health perspective should be central to all pharmaceuticals-related discussions. It is unacceptable that the market - and especially the EU internal market - should be used as an excuse for issues and critical situations with pharmaceuticals.
We will host discussions concerning the provision of quality treatment based on effective therapies and on the affordability of medicinal products at an expert level conference on 6 March in Sofia, and a further discussion at the Informal Council of Health Ministers on 22-23 April.

I believe these are topics that concern not only health ministers, but also the European Parliament.

As co-legislator, the European Parliament is obviously interested in the Council's legislative priorities. We will prioritise work on the sole legislative file currently active in the health sector: the amendments to the EMA Regulation (Regulation No 726/2004). The first dates for trilogues with the European Parliament have also been scheduled.

This dossier is part of the so-called "veterinary package". I hope that we will be able to make significant progress and find a compromise with the European Parliament.

The Commission has announced that there will probably be a new legislative proposal in the field of HTA and an initiative on vaccines. If so, Bulgaria will present the proposals to the Council and start discussions on them.

However, I would like to point out that for us, the quality of European legislation is what matters most. I therefore appeal to you, as participants in the legislative process, to contribute to a constructive discussion of the concrete provisions proposed, based on what is actually written in the final text. Conducting a general discussion based on common assumptions is not an acceptable approach. We all need to take into account the discussions at national level, the opinions of the experts from the Member States and the assessment of the impact on national health systems.
In conclusion: in all discussions, our starting point will be a strong focus on health. These discussions are important for the future of the EU. I believe that we can count on your support in the forthcoming six months.

Thank you for your attention!