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NOTE TO MEMBERS OF THE COMMISSION

Subject: **European Parliament. Hearing by the Committee on the Environment, Public Health and Food Safety (ENVI) of Stella Kyriakides, Commissioner-designate for Health. Brussels, 1 October 2019**

Summary record

Generally positive atmosphere for the hearing. Some pressure from MEPs on pesticides, GMOs, and access to medicines, but MEPs seemed satisfied with the responses of the Commissioner-designate (which were based very much on the mission letter). Support from MEPs on planned actions on cancer, anti-microbial resistance, digital health and food labelling. MEPs also welcomed the Commissioner-designate's declaration that she would be a voice for mental health in the Commission.

In his opening statement, Pascal Canfin (RE) noted that, whilst he believed his Committee members were largely satisfied with the Commissioner-designate's written responses on health, they wanted more clarity on some of her views on food safety.

In the Commissioner-designate's opening speech she emphasised the high expectations of EU citizens with regard to healthcare, and standards of animal and plant health. She stressed the opportunities offered by the Green deal to address health and food challenges holistically. She also highlighted a number of other points: taking forward the Farm to Fork strategy; clamping down on food fraud; ensuring the supply of affordable medicines; implementing the legislation on medical devices; the use of digital and AI technology in health; action on anti-microbial resistance; the Beating Cancer Plan.

On **pesticides**, MEPs put the Commissioner-designate under pressure to commit to a target for the reduction of their usage. They also asked her to commit to taking their side on issues relating to the protection of bees. The Commissioner replied by stressing that there would be no lowering of the bar on the protection of bees and other pollinators. She declined to commit to a target, but instead gave a general commitment to decreasing the dependence on pesticides and encouraging the use of low-risk alternatives. She also committed to working on ensuring proper implementation of the legislation on the basis of the scientific evidence (giving a very similar reply to a question asking her to commit to taking the Parliament's side in the argument on **GMOs**).

There were questions on **medicines policy**, particularly concerning unequal access to medicines across Member States. The Commissioner-designate stressed the need to look at a range of issues including pricing and reimbursement, and referred to the need for an early-warning system for medicines shortages. She referred to the legal obligation on the pharmaceutical industry to ensure patient access to affordable medicines, but also noted the need for Europe to remain a global leader and promote innovation. On **health technology assessment,** she noted that no country should be left behind, and stated her intention to work to build consensus in order to move the Commission's proposal forward.

The **Cancer Plan** was welcomed by a number of MEPs. When asked for more detail about what it would cover, the Commissioner-designate noted the need for screening services to be accredited, and to follow European guidelines. She highlighted the need to tackle the determinants of cancer as much as possible, and stressed the importance of measures to help cancer survivors.

The Commissioner-designated stressed the importance of implementing the One Health Agenda to tackle **anti-microbial resistance**.

On **digital health**, the Commissioner-designate highlighted how much progress had been made in recent years e.g. on ePrescriptions and European Reference Networks. She stressed the incoming Commission's commitment to digitalisation, and the importance of creating a European Health Data Space. At the same time, she underlined the importance of ensuring data protection.

In response to other questions, the Commissioner-designate said that she would be a voice for **mental health** in the Commission; stated her wish to have a five-year plan to tackle **food waste** and to find a common approach to **consumer information on food**; stressed the need to tackle health misinformation (particularly concerning **vaccines**); and defended the EU's current **crisis management** framework for animal and plant health.

signed

Personal data Head of Unit

Further information: , *SG D.3,* ; , *SG E.2,*

The Chair, Pascal Canfin (RE, FR) opened the hearing by recording his feeling of shared commitment in relation to health from the written answers of the Commissioner-designate. Whilst the replies on health included some specific answers and commitments, further elucidation was needed on some of the responses around food safety.

Commissioner-designate Kyriakides spoke as per annexed speaking note.

First Round of Questions: Political group Coordinators or their representatives

1. **Dolors Montserrat (EPP, ES)** welcomed the Commissioner-designate's words on the fight against cancer which is fast becoming the number one cause of death in Europe. Despite progress in recent years, there is still inequity across the EU: patients in Eastern Europe are 30% less likely to be cured than those in the west. Would the cancer plan include measures to ensure fair access to treatment?
   The Commissioner-designate responded that the plan must cover all aspects of cancer, and must leave no one behind. It needed to encompass all aspects from prevention to palliative care. It is unacceptable that, despite clear evidence of the link between lifestyle and cancer, we are not investing to change habits. Whilst many Member States have screening programmes in place, these must be accredited and follow EU guidelines. She recalled recent Parliament resolutions regarding access to medicines and agreed it must be part of the plan. There is also a link with AMR: many patients recovering from cancer lose their lives because of untreatable infections. So cancer must be looked at horizontally, across all policies. The Commissioner-designate mentioned that she was involved in the first EP Resolution on breast cancer in 2003.

The MEP followed up by agreeing with the need to look at all aspects of the disease, including social support to families and asked which measures to promote access to treatment would be taken.

The Commissioner-designate replied that the plan must cover everything. The Cross-border Healthcare Directive and the European reference Networks demonstrated how action at EU level could change the lives of patients. She concluded that, whilst there are no quick fixes to address shortages of medicines, she would have some proposals to make in due course.

2. **Jytte Guteland (S&D, SE)** raised the issue of endocrine disruptors (EDs), which she said were to be found everywhere. Exposure to even low doses of EDs is linked to many diseases and small children are particularly sensitive. There are also high costs to health systems associated with them. The MEP asked if the Commissioner-designate would propose, without delay, horizontal criteria to cover EDs in all sectors, rather than hiding behind the "weak Commission strategy" or the need for more evaluations. .
The Commissioner-designate responded by reminding the Committee of the reference to EDs in the mission letter. She also referred to the EP resolution of 2019 noting the call for legislation before 2020. Progress had been made, but more needed to be done. The definition of horizontal criteria must be a priority, as must examination of 'cocktail effects', on which we needed to expand the scientific knowledge base. Member States should be supported in their actions, and we should also await the outcome of the fitness check.

By way of follow-up, the MEP asked if the Commissioner-designate agreed that EDs are just as dangerous as cancer and other toxic substances and suggested a need to have a distinction between suspected EDs and other toxic substances.

The Commissioner-designate replied that whilst such comparisons are not helpful, all concerns needed be taken into account. EDs clearly affect human health and so must be addressed.

3. **Pascal Canfin (RE, FR),** referring to the reply to written questions, asked if, as part of the farm-to-fork strategy, the Commissioner-designate would support targets for pesticide reduction and associated risk?
The Commissioner-designate acknowledged that the strong EU framework for pesticides is not being implemented fully. She recognised the work of the parliament in this field, notably the important recommendations of the PEST Committee and called for greater efforts by Member States. The REFIT evaluation is ongoing and the outcome would have to be examined. Changes to the General Food Law would improve transparency in the assessment process. The Commissioner-designate concluded by committing herself to efforts to decrease dependency on pesticides and to encouraging low-risk alternatives.

The MEP raised the EFSA Bee Guidance Document and asked if the Commissioner-designate would join the Parliament in pressuring Member States to adopt it.

The Commissioner-designate committed to no lowering of the bar on protection of bees and pollinators. EFSA is currently reviewing effects of chronic toxicity for bees.

Shewould work with Member States and the Parliament through consensus to find a way forward so that we can protect our environment – the One Health approach.

4. **Michele Rivasi (Greens, FR)** expressed unhappiness at the reply to the previous question. The Parliament has been unhappy with the Commission on pesticides for some time. Pesticides should only be approved if there are no chronic effects on bees. However, some Member States oppose the bee guidance document and the Commission is not acting. MEP asked if the Commissioner-designate would adopt guidelines on chronic toxicity.
   Commissioner-designate reminded the Committee of the President-elect's programme and the mission letter to demonstrate the importance of pesticides in the Farm to Fork strategy and the Green Deal. There is a recognition that implementation is less than satisfactory and she would work to build consensus on its improvement. The new Commission must address the findings of the PEST Committee.

   The MEP expressed dissatisfaction with the reply and repeated her view that chronic effects must be taken into account. This must be tackled politically by the Commission.

   The Commissioner-designate committed to taking this issue up and pursuing it politically.

5. **Sylvia Limmer (ID, DE)** raised the issue of organ donation, and the different rules on becoming an organ donor that operate in different Member States. She asked if the Commissioner-designate would address this at EU level. She also asked about plans on antimicrobial resistance (AMR), expressing concerns at the high cost of development of new antimicrobials.
   The Commissioner-designate underlined the importance of safety in organ donation and noted that the opt-out system is not universally successful. Consideration of possible action at EU level should wait until after the publication of the evaluation on the blood, tissues and cells legislation at the end of this year before addressing the EU Organs legislation. She echoed concerns on AMR, and the need to encourage industry to come up with new and innovative solutions. The EU should lead on this.

6. **Joanna Kopcinska (ECR, PL)** asked about Commission efforts to reach the UN Sustainable Development Goals and whether improved coordination on health issues is needed with the agencies and Commission services involved.
   The Commissioner-designate replied that coordination can always be improved. The architecture of the new College had been set out. She would work with other Commissioner and VPs involved with the Green Deal and farm to fork.

   As follow-up, the MEP asked if the Commission could encourage the pharmaceutical sector to return to the EU, thus ensuring greater safety and less dependence on imports.

   The Commissioner-designate expressed awareness of this issue. The EU should and encourage innovation and remain a leader in pharma. Products entering the EU must be safe. A holistic strategy is needed : all factors contributing to shortage of medicines and affordability must be examined, including pricing, reimbursement. Health Technology Assessment at EU level can help keep Europe in the lead on this issue.

7. **Katerina Konecna (GUE, CZ)** took up the theme of Health Technology Assessment (HTA), asking about the Commissioner-designate's intentions on the file and how it might be unblocked in Council. She also reminded the Commissioner-designate that Eurobarometer surveys show that citizens want more EU-level action on health.
   The Commissioner-designate agreed with the importance of the HTA proposal. She noted the reluctance of a number of Member States but said it was important that no Member State is left behind. She wanted to see the proposal moving forward and would try to build consensus to do this.

The MEP followed-up by asking about expanding the role of patients in other areas of health.

The Commissioner-designate referred to her history as a patient advocate in Cyprus and committed to working with patients and other stakeholders to move forward.

Second Round of Questions: Other Members

8. **Cristian-Silviu Busoi (EPP, RO) asked about efforts to support digitalisation of health at EU level and how to harness support of Member States and citizens.**
   The Commissioner-designate emphasised the importance of digitalisation in health. Progress is being made: – cross-border health, European Reference Networks, e-prescriptions, sharing of patient summaries all show that we can work across borders. Digitalisation can also promote research and innovation. She stressed the need to ensure data protection for patients. Part of the problem is that some Member States are less advanced than others: it is important to help all Member States to move forward together.

9. **Rory Palmer (S&D, UK)** asked how the Commissioner-designate would stand up to powerful industries (pharma, food, tobacco, alcohol) in the context of the cancer plan. He also asked about equal access to treatment and revision of the paediatrics and orphan drugs legislation.
   The Commissioner-designate underlined the importance of prevention of cancer. Lots can be done, for example in tobacco and alcohol. And she would have no hesitation to call out those who are not on board. She would await the outcome of the evaluation of the paediatrics and orphan legislation in order to assess if further action was needed. She noted the 2016 resolution of the Parliament and suggested that more cross-border clinical trials are needed.

10. **Martin Hojsik (RE, SK)** asked about improving transparency in comitology procedures involving Member State positions. Will the Commissioner-designate follow the Ombudsman's recommendations? Will she call on Member States to make their decisions public?
    The Commissioner-designate agreed on the importance of transparency and expressed the belief that the amendment of the General Food Law would improve this situation and improve the trust of citizens. She would work with stakeholders to rebuild trust in the EU system. She would also try to convince Member States of the need for transparency.

11. **Ewa Kopacz (EPP, PL)** asked about efforts to deal with shortages of drugs, including inexpensive products and if there would be any activity on industry fees to the European Medicines Agency (EMA).

The Commissioner-designate referred to the EMA and member State task force on shortages and looks forward to its findings Parallel trade is also an issue here where Member States can take measures. Industry has an obligation to ensure continuous supply of medicines and patients have a right to affordable and effective treatment. Work is in progress on EMA fees and this should support innovation. She saw shortages and access as part of the same challenge.

12. **Maria Arena (S&D, BE)** noted that despite clear links between pesticides and health, sales of products are constant in the EU. She asked about intended actions to decrease dependence on pesticides and to encourage use of non-chemical alternatives. How would highly toxic chemicals be addressed? If we continue to renew authorisations, there is no incentive for industry to replace them.
    The Commissioner-designate assured the Committee that she would work to lower dependence on pesticides and to find alternatives, and reiterated the need to implement the current rules. If there are ongoing problems in Member States, these must be identified and addressed as necessary. Work on pesticides is integral to the Green Deal and the farm to fork strategy. Risk reduction targets should be considered as part of the Green Deal.

13. **Tilly Metz (Greens, LU)** noted the last Parliament's history of objecting to GMO approvals. Would this Commission stop approving the products in the absence of a Qualified Majority of Member States? The Commission has taken no meaningful action to protect citizens from 'new GMOs'. Would the Commissioner-designate ensure the ECJ ruling is upheld, including for labelling? EFSA must develop new detection methods to ensure traceability.
    The Commissioner-designate recognized the divisive nature of the GMO debate. Decisions must be based on science and the General Food Law review should improve transparency and trust. The Court judgement must be respected and implemented and the Commission would work with Member States on this. New Breeding Techniques should be discussed based on science. If a new legislative framework is needed, she wouldn't hesitate to propose this. Citizens' trust is key.

14. **Oscar Lancini (ID, IT)** underlined the damage caused by food fraud. The Official Control Rules are the basis for Commission action but there is lots of overlap in responsibilities across services. How would prevention and enforcement be improved at EU level? He also asked about the possibility for harmonised measures for food contact materials at EU level.
    The Commissioner-designate agreed with the seriousness of food fraud. Referring to the Parliament resolution of 2013, she noted that there is still no real legal definition of food fraud. Europol and OLAF must be involved and consideration should be given to the introduction of new legislation. The food contact materials legislation is currently being evaluated and would include the lack of coverage of all materials, such as those 13 highlighted in the Parliament resolution. More information is also needed on the 'cocktail effect' in relation to food contact materials.

15. **Hermann Tertsch (ECR, ES)** asked how the Commissioner-designate would increase the role of science in the legislative process and how she would gain the support of her colleagues for this. Disproportionate use of the precautionary principle has had a negative effect on research and development in the EU and we have seen clinical trials moving to

other parts of the world. Will the Commissioner-designate revisit this principle and push for innovation in the EU?

The Commissioner-designate emphasised the importance of legislation being based on science and gave the example of vaccine hesitancy as an example of the negative impacts of m. Whilst the changes to the Clinical Trials Directive have helped, many trials still take place outside of the EU. Horizon Europe demonstrates the commitment of the EU to innovation and moving forward. The Green Deal must be supported by innovation.

16. **Bartosz Arlukowicz (EPP, PL)** raised the cancer plan. As a former Minister for Health and a doctor, he emphasised the need for action at EU level. He asked about standards for early diagnosis and treatment of all patients across Europe. He also asked how the Commissioner-designate would ensure that there would be no shortages of essential treatments.

    The Commissioner-designate agreed with the need to follow protocols for treatment. Member States screening programmes must be accredited. Survivorship must also be addressed: survivors are facing big issues regarding employment, insurance etc. She also noted that economic situations in Member States have an impact on the care that can be provided.

17. **Caroline Voaden (RE, UK)** asked what the Commissioner-designate would do to put mental health back on the agenda.

    The Commissioner-designate highlighted that in her opinion health as such refers to physical and mental health but she agreed that mental health has not been high enough on the agenda recently for a number of possible reasons. In some Member States there is still a stigma attached to mental health issues. There is ever more pressure on people, and adolescents in particular. She said that she would work with Member States and other Commissioners to be a voice for mental health.

18. **Athanasios Konstantinou (NI, EL)** noted that are different cultural norms as to what is considered mental illness in different Member States.

    The Commissioner-designate agreed that there are inconsistencies across Member States, and noted that consistency in general was not always easy (citing the revisions of the Diagnostic and Statistical Manual of Mental Disorders) Protection and promotion of human rights are the key to dealing with patients in psychiatry.

19. **Sara Cerdas (&SD, PT)** returned to antimicrobial resistance. Misuse of antibiotics and return of preventable diseases due to vaccine hesitancy are among the causes. What was the strategy to increase health literacy and health information? What was the Commissioner-designate's opinion of the shutting down of the HIV think tanks and civil society forum?

    The Commissioner-designate agreed that misinformation is rife nowadays. Citizens must have access to sound scientific information. The EU should lead by example on antimicrobial resistance under the one health umbrella. Accurate health information is needed to fight misinformation. More can be done on diseases including TB, HIV and hepatitis. The EU remains committed to efforts to fight them. She reminded the Committee of the EU's commitment of EUR 550 million to fight these diseases via the Global Fund which was announced at the Biarritz G7 summit.

20. **Daniel Buda (EPP, RO),** for the AGRI Committee asked about the Commissioner-designate's vision and strategy for African swine fever (ASF) in the short and medium term. Could a mechanism like that used for civil protection be employed for animal health crises?

    The Commissioner-designate stressed the level of threat to farming and trade that is posed by ASF, a truly global threat. The EU has a robust legal framework and strategy that has helped to contain the disease. Whilst it has been eradicated in Czechia, it is still very much a problem in some areas. Effective controls and improved biosecurity are needed, as is increased public awareness and research. Overall, the EU's crisis management frameworks has proved capable of dealing with animal health crises: countries outside the EU have much greater problems in controlling ASF. She concluded by noting that the same applied to plant heath crises, for example *xylella.*

21. **Joao Ferreira (GUE, PT)** asked about the influence of industry. There were still many questions around transparency and the rigour of our authorisation processes. What would the Commissioner-designate do about this? The MEP also asked about chronic effects of pesticides and how they can be taken into account, as well as ensuring that Free Trade Agreements do not provide a backdoor to the EU regarding illegal products.

    The Commissioner-designate emphasised the independence of EFSA, its rules on conflicts of interest and the new transparency measures to be brought about under the review of the General Food Law. EU scientific bodies operate under very strict rules and should be trusted. Data from industry must be independently assessed. She reiterated her commitment to take measures on pesticides, and noted the forthcoming report from EFSA on chronic toxicity.

22. **Alessandra Moretti (S&D, IT)** spoke of the importance of food information to consumers in ensuring a balanced diet and fighting childhood obesity. She asked whether there should be a single label at EU level and how to prevent spurious claims on food. She also asked about labelling regarding the environmental impact on foods as well as GMO presence.

    The Commissioner-designate remarked on the paradox of food waste and rising obesity rates, whilst one in four EU citizens cannot afford a quality meal every day. Citizens want nutrition labelling and nutrition profiles. There is evidence that foods labelled as healthy have high levels of salt and sugar. A common approach across Member States would be desirable and she was awaiting the report on front of pack labelling that would be published later this year. There is also a demand for origin labelling among citizens and seven Member States have introduced measures on this. A common approach is desirable: we could not renationalise food in the Single Market.

23. **Margrete Auken (Greens, DK)** said that none of the Parliament demands in the 2017 report on access to medicines have been addressed. High drug prices and weak Member State negotiating positions are a problem. In the WHO, Italy, supported by several other EU Member States supported a Resolution on price transparency but the resulting resolution was eventually watered-down by other EU MS. How would the Commissioner-designate tackle this? Would she ensure transparency on pricing?

    The Commissioner-designate replied that she would work closely with industry and Member States to tackle the availability and affordability of medicines, including by looking at pricing and reimbursement issues. She recalled the legal obligation on industry

to provide information on pricing. She thought the EMA task force would provide valuable information on this issue, and stressed the need for transparency at all levels.

24. **Nicolae Stefanuta (RE, RO)** again brought up the issue of scarcity of medicines, which has been a big issue in several Member States this summer. Would the Commissioner-designate commit to the development of an EU essential medicines list? Would she consider legislation for early notification of shortages?
The Commissioner-designate referred to the EMA and Member State task force. Its findings should be assessed before consideration is given to the creation of a list of essential medicines. There should be a system for early detection of shortages. Shortages of medicines is also an issue in the Brexit debate, where it is a concern for smaller Member States in particular. Minimal disruption could be assured through ratification of the Withdrawal Agreement.

25. **Peter Liese (EPP, DE)** congratulated the Commissioner-designate on her performance in the hearing and asked what action would be taken to motivate development of new antibiotics by industry. He also asked whether the Commissioner-designate was prepared to draw up a list of antibiotics reserved for human use.
The Commissioner-designate mentioned the recently adopted legislation on veterinary medicines and medicated feed as the cornerstone in EU efforts to combat AMR, including the possibility to reserve certain antimicrobials for human use. She reiterated that the EU must lead on AMR, and stressed the importance of implementing the actions under the One Health Agenda.

The Commissioner-designate concluded by welcoming this first policy debate with the European Parliament. In expressing her enthusiasm for the portfolio, she noted that the topics are close to the hearts of citizens, who expect action. She looked forward to working closely with the Parliament, underlined the importance of a scientific approach and encouraged all to strive for more.

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