λληνική Οδοντιατρική Ομοσπονδία

Από: Γραμματεία Δ.Σ. της Ε.Ο.Ο.
Αποστολή: Τρίτη, 9 Ιουλίου 2024 8:39 πμ
Προς: Ελληνική Οδοντιατρική Ομοσπονδία
Θέμα: FW: Ένταξη στην ημερήσια διάταξη της 12.7.2024 εισήγησης από Β. Σταθόπουλο

Φ47 ΔΣ

Με εκτίμηση,
Γραμματεία ΔΣ

Be green. Keep it on the screen

ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ
ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ
ΕΛΛΗΝΙΚΗ ΟΔΟΝΤΙΑΤΡΙΚΗ ΟΜΟΣΠΟΝΔΙΑ
Θεμιστοκλέους 38, 106 78 ΑΘΗΝΑ
Τηλ. 210-38.13.380, 210-33.03.721,Fax: 210-38.34.385 (εσωτ. 201), e-mail: ds@eoo.gr

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From: stathvas@otenet.gr <stathvas@otenet.gr>
Sent: Δευτέρα, 8 Ιουλίου 2024 3:49 μμ
To: Γραμματεία Δ.Σ. της Ε.Ο.Ο. <ds@eoo.gr>; Δημήτρης Κήττας / Γενικός Γραμματέας Ε.Ο.Ο. <g.gram@eoo.gr>
Subject: RE: Ένταξη στην ημερήσια διάταξη της 12.7.2024 εισήγησης από Β. Σταθόπουλο

Κα Οικονομίδου,
Εκ παραδρομής παρέλειψα να ζητήσω αρ. πρωτοκόλλου.
Βασίθλης Σταθόπουλος

From: stathvas@otenet.gr <stathvas@otenet.gr>
Sent: Monday, July 8, 2024 10:45 AM
To: Οικονομίδου Πολυτίμη (ds@eoo.gr) <ds@eoo.gr>; Δεβλιώτης Αθανάσιος (devliotisath@gmail.com) <devliotisath@gmail.com>
Cc: Βάρδας Εμμανουήλ (mbardas@gmail.com) <mbardas@gmail.com>; Δέδες Νίκος (nidedes@gmail.com) <nidedes@gmail.com>; Διακογεωργίου Νικόλαος (nikosdent@yahoo.gr) <nikosdent@yahoo.gr>; 'ΚΑΛΛΙΦΑΤΙΔΗΣ ΑΝΤΩΝΗΣ' <akallif@gmail.com>; Κατσούλας Βασίλειος (vasileios.katsoulas@gmail.com) <vasileios.katsoulas@gmail.com>; Κήττας Δημήτριος (g.gram@eoo.gr) <g.gram@eoo.gr>; Μαρουφίδης Νικόλαος (nikmaroufidis@yahoo.gr) <nikmaroufidis@yahoo.gr>; Μενενάκου Μαρία (drmmenenakou@gmail.com) <drmmenenakou@gmail.com>; Μωραΐτης Πάνος (pmwraitis@gmail.com) <pmwraitis@gmail.com>; Πάλλης Δημήτρης (pallisdimitris@gmail.com) <pallisdimitris@gmail.com>; Τράπαλης Ιωάννης (trapalis1924@gmail.com) <trapalis1924@gmail.com>; Τσανίδης Βασίλειος (btsanidi@otenet.gr) <btsanidi@otenet.gr>; Υφαντής Αθανάσιος (yfadent.a@gmail.com) <yfadent.a@gmail.com>
Subject: Ένταξη στην ημερήσια διάταξη της 12.7.2024 εισήγησης από Β. Σταθόπουλο

Ψηφίστηκε στην αρμόδια Επιτροπή EPSCO στις 21.6.2024 Council conclusions "on the future of the European Health Union: A Europe that cares, prepares and protects" όπου στην σκέψη 16 αναφέρεται στην έλλειψη ιατρικών συσκευών στην ΕΕ, αναφορά έμμεση στη χαλάρωση δυνητικά των προθεσμιών του Κανονισμού MDR. Αυτό έρχεται σε συνέχεια της κατάθεσης τροποποιήσεων στον Κανονισμό MDR που έχουν προτείνει οι Ευρωβουλευτές Peter Liese & Angelika Niebler οι οποίοι αμφότεροι επανεξελέγησαν με την EPP Ομάδα του

Κοινοβουλίου. Σας επισυνάπτω τις τροπολογίες που εισηγήθηκαν στην προηγούμενη θητεία τόσο στα Γερμανικά όσο και σε μετάφραση προκειμένου σε συζητήσεις με αρμόδια υπουργεία να μην τίθενται μόνον κατά περίπτωση θέματα αλλά σε κάθε ευκαιρία να υπάρχει φάκελος έτοιμος και να τίθεται και ένα θεσμικό θέμα όπως αυτό. Τυχόν επιφυλάξεις για την ετοιμότητα ή κατά νόηση των ΕΕ θεμάτων από τις υπηρεσίες του Υπ. Υγείας ή άλλων συμμερίζομαι αλλά σταδιακά θα πρέπει να θέτουμε ατζέντα με πολιτικά θέματα διαφύλαξης του Κλάδου και όχι μόνο να ακολουθούμε διαμαρτυρόμενοι εξελίξεις.

Παρακαλώ όπως εισαχθεί στην ημερήσια διάταξη της προσεχούς συνεδρίασης του ΔΣ ώστε να συζητηθεί ως θέμα: «Υποβολή τροποποιήσεων στον Κανονισμό MDR» μέσω παρεμβάσεων της ΕΟΟ.

Με εκτίμηση,

Βασίλειος Σταθόπουλος
Ορθοδοντικός
Κυβέλης 1 - Αθήνα 10682
Τηλ: 210- 8253176
Κιν.: 6972 282237

6ον. 1

Βρυξέλλες, 10 Ιανουαρίου 2024

10 αιτήματα για αλλαγές στον κανονισμό για τα ιατροτεχνολογικά προϊόντα

1. **Διατήρηση προτύπων ασφάλειας και ποιότητας**: Οι τρέχουσες απαιτήσεις ασφάλειας και ποιότητας του MDR θα πρέπει να παραμείνουν αμετάβλητες για να διασφαλιστεί η ασφάλεια των ασθενών και η ποιότητα της θεραπείας.
2. **Εισαγωγή ειδικών κανόνων για ιατροτεχνολογικά προϊόντα με μικρή αγορά** το συντομότερο δυνατό: Πρέπει να θεσπιστούν ειδικοί κανόνες για ιατροτεχνολογικά προϊόντα που εξυπηρετούν μια σχετικά μικρή αγορά, όπως προϊόντα για τη θεραπεία παιδιών ή σπάνιων ασθενειών. Παράδειγμα: Ρύθμιση ορφανής συσκευής ανάλογη με αυτή στις Ηνωμένες Πολιτείες. Η αναστολή της πιστοποίησης των ορφανών συσκευών, όπως οι συσκευές για την παιδοκαρδιολογία, είναι απαραίτητη τουλάχιστον για τη μεταβατική περίοδο. Θα πρέπει να καθιερωθεί ένα μητρώο για την κατοχύρωση της ασφάλειας.
3. **Εισαγωγή μιας διαδικασίας ιεράρχησης προτεραιοτήτων για καινοτόμες ιατροτεχνολογικές συσκευές**: Μια ταχεία διαδικασία έγκρισης για πρωτοποριακές ιατροτεχνολογικές συσκευές. Παράδειγμα: Μια ειδική διαδικασία «fast track» για την έγκριση ιατρικών συσκευών που μπορούν να σώσουν ζωές.
4. **Συστηματική αναθεώρηση των κανονισμών MDR και IVDR**: Διαγραφή όλων των κανόνων που δεν επιβεβαιώνονται αλλά αποτελούν μόνο γραφειοκρατική προσπάθεια.
5. **Κατάργηση της 5ετούς επαναπιστοποίησης για προϊόντα χαμηλότερου κινδύνου**: Για προϊόντα χαμηλότερου κινδύνου θα πρέπει να αρθεί η υποχρέωση επαναπιστοποίησης ανά πενταετία, καθώς τα προϊόντα αυτά ελέγχονται συνεχώς από τους κοινοποιημένους φορείς.
6. **Έγκαιρη αξιολόγηση του MDR**: Νέα αξιολόγηση του MDR το 2025 προκειμένου να εντοπιστεί η ανάγκη προσαρμογής σε πρώιμο στάδιο και να αντιδράσει ανάλογα.
7. **Αναθεώρηση των κριτηρίων προσόντων για το Υπεύθυνο Πρόσωπο**: Τα κριτήρια προσόντων για το Υπεύθυνο Πρόσωπο θα πρέπει να αναθεωρηθούν ώστε να λαμβάνεται υπόψη η εμπειρία και η κατάρτιση και όχι ένα αμιγώς ακαδημαϊκό προσόν.
8. **Ενίσχυση των ικανοτήτων των κοινοποιημένων οργανισμών και επιτάχυνση των διαδικασιών**: Η αύξηση της αποτελεσματικότητας και η επέκταση της ικανότητας των κοινοποιημένων οργανισμών είναι απαραίτητη για την επιτάχυνση της πιστοποίησης των ιατροτεχνολογικών προϊόντων.

9. **Προώθηση ενός αποτελεσματικού συστήματος διακυβέρνησης**: Η δημιουργία μιας υπόλογης δομής διακυβέρνησης για την επίβλεψη και τη διαχείριση του ρυθμιστικού συστήματος είναι απαραίτητη.

10. **Οριστική αναβολή της μεταβατικής περιόδου**: Χρειαζόμαστε μια θεμελιώδη λύση, αλλά αυτή η θεμελιώδης λύση θα πάρει φυσικά κάποιο χρόνο λόγω της διαδικασίας συναπόφασης. Ως εκ τούτου, είναι απαραίτητο να αποφασιστεί εκ των προτέρων η αναβολή των προθεσμιών για τελευταία φορά κατά τη μεταβατική περίοδο.

6 UV. 2

Brüssel, 10. Januar 2024

10 Forderungen für die Änderung der Medizinprodukteverordnung

1. **Beibehaltung der Sicherheits- und Qualitätsstandards:** Die aktuellen Sicherheits- und Qualitätsanforderungen der MDR sollten unverändert bleiben, um Patientensicherheit und Behandlungsqualität zu gewährleisten.
2. **Schnellstmögliche Einführung von besonderen Regeln für Medizinprodukte mit kleinem Markt:** Besondere Regelungen sollten für Medizinprodukte eingeführt werden, die einen relativ kleinen Markt bedienen, wie z.B. Produkte zur Behandlung von Kindern oder seltenen Erkrankungen. Beispiel: Eine Orphan-Device-Regulierung analog zu der in den Vereinigten Staaten. Mindestens für die Übergangszeit ist eine Aussetzung der Zertifizierung von Orphan-Devices, wie Geräten für die Kinderkardiologie, erforderlich. Ein Register sollte zur Sicherheitsgewährleistung eingeführt werden.
3. **Einführung eines Priorisierungsverfahrens für innovative Medizinprodukte:** Ein beschleunigtes Zulassungsverfahren für bahnbrechende Medizinprodukte. Beispiel: Ein spezieller „Fast-Track"-Prozess für die Genehmigung von Medizinprodukten, die lebensrettend sein können.
4. **Systematische Überarbeitung der MDR und IVDR-Regulierung:** Streichen aller Regeln, die keine Sicherheit, sondern nur bürokratischen Aufwand bringen.
5. **Abschaffung der 5-jährigen Rezertifizierung für Produkte mit geringerem Risiko:** Für Produkte mit geringerem Risiko sollte die Pflicht zur Rezertifizierung alle fünf Jahre aufgehoben werden, da diese Produkte ständig von den Benannten Stellen kontrolliert werden.
6. **Vorzeitige Evaluierung der MDR:** Eine frühere Überprüfung der MDR im Jahr 2025, um Anpassungsbedarf frühzeitig zu erkennen und entsprechend zu reagieren.
7. **Überarbeitung der Qualifikationskriterien für die Verantwortliche Person:** Die Qualifikationskriterien für die Verantwortliche Person sollten überarbeitet werden, um Erfahrung und Ausbildung anstelle eines ausschließlich akademischen Abschlusses zu berücksichtigen.
8. **Stärkung der Kapazitäten der Benannten Stellen und Beschleunigung der Verfahren:** Effizienzsteigerung und Kapazitätserweiterung der Benannten Stellen sind erforderlich, um die Zertifizierung von Medizinprodukten zu beschleunigen.
9. **Förderung eines effektiven Governance-Systems:** Die Schaffung einer verantwortlichen Governance-Struktur zur Überwachung und Verwaltung des Regulierungssystems ist erforderlich.
10. **Letztmalige Verschiebung der Übergangsfrist:** Wir brauchen eine grundsätzliche Lösung, aber diese grundsätzliche Lösung wird naturgemäß durch das Mitentscheidungsverfahren einige Zeit in Anspruch nehmen. Daher ist es für die Übergangszeit erforderlich, eine letztmalige Verschiebung der Fristen vorab zu beschließen.

6CV.3

Council of the European Union

Brussels, 29 May 2024
(OR. en)

9900/24

LIMITE

SAN 282
PHARM 68
MI 502
COMPET 546
RECH 229
SOC 362
ENV 518

NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Draft Council conclusions on the Future of the European Health Union: A Europe that cares, prepares and protects - *Approval*

1. On 27 March 2024, the Presidency submitted to the Working Party on Public Health a set of draft Council conclusions on the Future of the European Health Union: A Europe that cares, prepares and protects[1].

2. Among several events on these topics, the High-level Conference on the Future EU Health Union on 26-27 March 2024, the High-Level Conference on Health needs as drivers for healthcare policy and innovation on 17-18 April, the informal meeting of Ministers of Health on 23-24 April 2024 and the High-Level Conference on Antimicrobial resistance (AMR) on 6-8 May 2024 provided input for the draft Council conclusions.

3. The Working Party on Public Health examined the draft Council conclusions at its meetings on 15 April, 30 April and 17 May 2024. Following further consultations, the Working Party reached an agreement on 24 May 2024 on the text.

[1] 7893/24

4. The Permanent Representatives Committee is invited:
   - to confirm the agreement reached in the Working Party on the draft Council conclusions as set out in the Annex to this Note;
   - to submit them to Council (EPSCO) for approval at its session on 21 June 2024.

ANNEX

The Future of the European Health Union: a Europe that cares, prepares and protects

Draft Council Conclusions

RECALLING THAT

1. Access to health care and prevention is a fundamental right[1] and Article 168 TFEU provides that a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.

2. The European Parliament, the Council of the European Union and the Commission have made a shared political commitment to ensure within their competencies that everyone has the right to "timely access to affordable, preventive and curative health care of good quality"[2].

3. Solidarity is a fundamental principle of the European Union and a pillar on which the Health Union should be built. In this regard, Member States should promote solidarity in the field of health.

4. The COVID-19 pandemic demonstrated that the EU is a crucial actor when dealing with cross-border health threats, and that European citizens expect the EU to have a more active and effective role in protecting their health and wellbeing, beyond crisis management.[3]

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[1] Article 35 of the Charter of fundamental rights of the European Union, OJ C 326, 26.10.2012, p. 391–407, ELI: http://data.europa.eu/eli/treaty/char_2012/oj

[2] Principle 16 of the European Pillar of Social Rights (2017/C 428/09), (EUR-Lex 32017C1213(01) - EN - EUR-Lex (europa.eu)

[3] European Parliament, Directorate-General for Communication, Zalc, J., Maillard, R., Uncertainty/EU/hope – Public opinion in times of Covid-19 – Second round, European Parliament, 2020. https://data.europa.eu/doi/10.2861/784439

5. The Commission Communication on 'Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats'[4] recognises that a strong European Health Union will protect our way of living, our economies and societies. It establishes health as a precondition for the well-functioning of our society and economy and the wellbeing of the European citizens. The European Commission adopted the Communication "The European Health Union: acting together for people´s health", which summarises the Union´s response to the COVID-19 pandemic and subsequent components of a comprehensive European Health Union, ensuring Member States are better prepared for and respond to future health crises, putting equity in access to healthcare and protecting EU citizens at its centre.

6. The combined challenges of an aging population, technological and innovation challenges, existing and emerging new health threats, climate change and CBRN threats/bioterrorism, socio-economic disparities, migration, shortages of medicinal products and medical devices, and a context of growing budgetary pressure increasingly put the sustainability of our health systems at risk. These challenges are of a systemic nature and require cross-border cooperation between the EU and its Member States, as well as with international partners.

7. Health workforce shortages are a challenge in all Member States (especially nurses and primary care professionals), exacerbated by demographic challenges and an aging health workforce, skill mismatches and uneven health workforce distribution between countries and within them.[5] This leads to significant pressure on the health workforce. In OECD countries, the share of medical doctors over 55 years of age increased from 20% in 2000 to 35% in 2019. These shortages are compounded by geographic disparities across the EU, with data showing a 5.6-fold difference between the regions with the lowest and the highest density of physicians.[6] Mismatches in skills of health workers and the skills required in a modern health system need to be addressed to reflect emerging needs and boost new care models.

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[4] Communication (COM) 2020/724 final from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0724

[5] European Commission, Directorate-General for Health and Food Safety, The State of Health in the EU: Synthesis Report 2023, Publications Office of the European Union, Doi:10.2875/458883

[6] European Commission, Directorate-General for Health and Food Safety, State of health in the EU – Companion report 2021, Publications Office of the European Union, 2022, https://data.europa.eu/doi/10.2875/835293

8. The rapid evolution of digital technologies impacts healthcare systems. The acceleration of digital tools in healthcare, including telemedicine, medical devices software and remote patient monitoring, as well as digital self-diagnosis, have the potential to improve patient outcomes and enhance healthcare accessibility. At the same time, technological advancements, such as Artificial Intelligence, provide opportunities for research, policy making, gathering and using real world data, the development of new medicinal products and medical devices, and innovation for public health, but also introduce complex ethical and societal challenges that requires coordinated action at national, European and international levels.

9. Health data play a pivotal role in enhancing individual patient care, advancing medical research, and shaping public health policies. It is fundamental that citizens have the transparency over the use of their personal health information, ensuring protection and security, as well as raising awareness to foster trust and encourage data sharing for the greater good. The benefits of utilising health data in line with European values and patients' data protection rules for society are immense, including the potential for early disease detection, personalized medicine and improved healthcare outcomes.

10. Evidence-based disease prevention and the promotion of health are key elements to reduce the burden of non-communicable diseases in a cost-effective manner. Non-communicable diseases cause almost 90% of all deaths and account for 77% of the disease burden in the EU, and their prevalence is increasing, thereby negatively affecting the health and wellbeing of the population, especially of vulnerable groups, the workload of the health workforce and the resilience of our health systems. Additionally, the burden of some diseases, for example neurodegenerative diseases, including dementia, is expected to increase greatly over the coming decades, with significant social impact not only on individuals, but also on their, families, communities, societies and the workforce.

11. Non-communicable diseases should be addressed in a cross-sectoral and a holistic manner, taking into account areas with a high burden of disease or a high mortality, through evidence-based, affordable and cost-effective health promotion, preventive interventions and disease management strategies. Mental health is a key aspect of wellbeing and impacts a variety of sectors both socially and financially. Health promotion and disease prevention, early development of psychosocial skills, in addition to national, also at European level, as laid down in the Healthier Together initiative, can reduce the prevalence of non-communicable diseases by as much as 70%.[7] For this reason, investments in health promotion and disease prevention, as well as in treatment and rehabilitation, can lead to a healthier population, a healthier and increased workforce potential and economic gain for the Union in the long run.

12. Evidence-based disease prevention and management are key elements to reduce the burden of communicable diseases in a cost-effective manner. Communicable diseases in the EU account for an increasing disease burden. These include emerging and re-emerging infectious diseases and outbreaks, as well as sustained increases. Further, some infectious disease experiencing declining incidence still do not reach elimination targets. The sustained increase of sexually transmitted infections is of particular concern as it affects the sexual and reproductive health, especially of the younger populations.

13. Health-related unmet patient and societal needs encompass both unmet needs arising from the direct impact of a health condition on patients' lives (patient needs) and unmet needs arising from social externalities induced by a health condition (societal needs). Patient and societal needs can relate to the health, healthcare and social impact of a condition. A holistic approach requires that besides treatment development, also prevention, diagnosis, coordination and organisation of care, and availability of information to patients, among others, is considered to meet health-related unmet patient and societal needs.

[7] European Commission, Directorate-General for Health and Food Safety, Healthier together – EU non-communicable disease initiative, Publications Office of the European Union, 2022, https://data.europa.eu/doi/10.2875/195572

14. In a patient-centred healthcare system, research and development (R&D) focus on addressing high-priority health-related unmet patient and societal needs. Needs may relate e.g. to increased life expectancy, quality of life, healthcare-related costs and accessibility to healthcare services or preventive measures. While important efforts are being done to orient R&D towards rapidly changing needs, current frameworks for innovation and supply of health interventions partially fail to stimulate solutions for priority health-related needs both from the patients' and the societal point of view. This is due to a lack of evidence on what the highest unmet needs are, a lack of evidence on relevant expected outcomes or a lack of commercial or public interest in unheeded needs. Structured scientific evidence on what the highest unmet needs are, is thus necessary. This should make it possible to direct private and public R&D investments to the highest unmet needs.

15. An independent needs-evidence database can help to support addressing priority needs in healthcare and innovation policies. This database should gather disease-specific, disease-overarching, and systems-level scientific evidence, collected in a standardised way, based on a framework with transparent needs criteria. This framework should be developed by independent researchers, taking into account input from stakeholders, including citizens, patients, healthcare providers, policy makers and developers. Data from existing national and international databases, including from Eurostat, can, whenever relevant, be used to feed into the needs-evidence database. Other initiatives, e.g. the 1+ Million Genomes Initiative can contribute to realise the full potential of data sharing for wider health benefits, including developing possible solutions for identified unmet health-related needs, along with supporting research and health policy making.

16. Targeted legislative initiatives and non-legislative measures have been taken to reduce the risk of shortages of medical devices and in-vitro diagnostic medical devices. The Regulations on medical devices and in-vitro diagnostic medical devices are necessary to ensure a high level of safety and health for European citizens, whilst supporting innovation and ensuring a smooth functioning internal market by establishing a robust, transparent, predictable and sustainable regulatory framework. Nonetheless, there are remaining challenges related to the implementation of the Regulations on medical devices and in-vitro diagnostic medical devices, including increased costs and length of conformity assessment procedures, notably for orphan devices, increasing risks of supply disruptions and withdrawal of some medical devices and in-vitro diagnostic medical devices from the EU market needed for appropriate patient care. This also affects the competitiveness and innovation capacity of the European medical device industry, in particular small and medium sized enterprises.

17. The European Centre for Disease Prevention and Control (ECDC) estimates that 35,000 people die each year in the EU from antimicrobial-resistant infections. Meanwhile, the total consumption of antibacterials for systemic use has decreased by only 2.5% since the baseline year of 2019, indicating slow progress towards the EU target reduction of 20% by 2030.[8] Therefore, more efforts to promote the prudent use of antibiotics are needed.

18. Climate change health-related hazards, exposures, vulnerabilities, and risks from climate change are showing clear, accelerating trends in Europe.[9] Climate change leads to increased risks of both communicable and non-communicable diseases, creating new vulnerabilities and exacerbating existing inequalities by disproportionally affecting vulnerable population groups. Climate and public health policies can have important synergies. This should be seen in line with the One Health approach recognising the strong interlink between the health of humans, animals, and the environment. Efforts to decarbonize the European Union, and in particulier efforts to decarbonize European healthcare systems must, while taking into account the impact on availability and affordability, continue in order to limit these effects.

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[8] European Centre for Disease Prevention and Control, Merk, H. Diaz Högberg, L. Pachouras, D. et al., Assessing the health burden of infections with antibiotic-resistant bacteria in the EU/EEA, 2016-2020. ECDC; 2022. https://data.europa.eu/doi/10.2900/73460

[9] European Environment Agency, Is Europe on track towards climate resilience? - Status of reported national adaptation actions in 2023, Publications Office of the European Union, 2023, https://data.europa.eu./doi/10.2800/112091

19. The EU's capacity to conduct public, large scale multinational clinical trials is essential for the generation of reliable evidence on safety and effectiveness of interventions, and to strengthen Europe as a hub for development and manufacturing. During the pandemic, an unprecedented number of academic clinical trials were launched in the EU to accelerate COVID-19 treatment and prevention. Strengthening future initiatives through more efficient coordination across Member States and among national ethic committees is key, since the lack thereof resulted in numerous underpowered trials that could not provide meaningful results and a duplication of research activities. Moreover, the lack of clarity about the interface with related legislation such as Regulations on medical devices and in-vitro diagnostic medical devices is an obstacle to the efficient conduct of clinical trials. The creation of the MedEthics EU group is supported by the Commission to promote cooperation between national ethics committees involved in clinical trials and to promote progress in the coordination for the implementation of the Clinical Trials Regulation as developed in the Clinical Trials Coordination and Advisory Group (CTAG). It is also important to continue to pursue the efforts with a view to enabling a smooth operation of the coordinated assessment procedure relating to clinical investigations and performances studies.

20. A coherent, transparent and effective EU institutional framework is key to strengthening preparedness and crisis response at EU level in an all-hazards and whole-of-society approach in line with the European Council conclusions of 21 and 22 March 2024. Health emergency prevention, preparedness and response is indispensable to prepare for future crises. EU preparedness contributes to global health security and EU's role in global health. The European Union adopted numerous reforms in the emergency governance structure which remain yet to be fully implemented and tested, including the implementation of the serious cross-border threats to health Regulation, extension of the ECDC and European Medicines Agency (EMA) mandates and the establishment of the EC service Health Emergency Preparedness and Response Authority (HERA). The 2023 State of Health Preparedness Report outlines the level of implementation already achieved and where further action and efforts are needed to ensure its proper implementation.

21. Shortages of medicinal products put the health and wellbeing of citizens at risk. The delocalisation of the manufacturing of medicinal products and Active Pharmaceutical Ingredients (API) to a limited number of locations outside the EU has accentuated concerns about security of supply inside the EU. Addressing vulnerabilities in the supply chain of critical medicinal products is a key action for the resilience of EU healthcare systems. The need to address vulnerabilities was recognised by the European Council Conclusions of June 2023, the Leaders' Declaration in Granada in October 2023 and the Commission Communication on 'Addressing medicine shortages in the EU' of that same month, which puts forward a set of short-term and longer-term actions to address shortages of critical medicinal products and enhance their security of supply in the EU.

22. To improve access to medicinal products, medical devices and in-vitro diagnostic medical devices under the current legal framework, and as the European Council indicated in its conclusions of 17 and 18 April 2024, it is important to ensure the cross-border movement of goods, including of strategic goods such as medicinal products, while addressing transparency in supply chain.

23. Strategic investments in health are crucial to reinforce the sustainability and resilience of European health systems. The EU provides multiple funding streams at the disposal of Member States and stakeholders. However, Member States face challenges finding and accessing existing EU funds to support impactful investment in national health system transformations. It is of great importance that the work programmes of the EU existing funding instruments promoting research & innovation and those supporting implementation of policy initiatives are in synergy with national priorities in the health area and the nexus between research, innovation, policy and funding instruments is upheld.

STRESSES the urgent need to continue to build upon and improve the European Health Union in light of the systemic challenges our health systems are facing today,

INVITES the MEMBER STATES and the EUROPEAN COMMISSION in close cooperation and in accordance with their respective competences to:

I. address the health workforce crisis

INVITES the MEMBER STATES and the EUROPEAN COMMISSION to:

24. CONSIDER PRIORITISATION of investments in the health workforce through national investments and the use of existing EU funds and technical support, in order to facilitate targeted investments in the health workforce.

25. SUPPORT the development and uptake of innovative digital tools that can assist health professionals in their everyday clinical practice, as well as the integration of digital competences in training and further education, and the development of digital health literacy.

26. ENHANCE EU-level collaboration in order to support knowledge sharing between Member States on national health workforce strategies, in line with and complementing the new Action plan to tackle labour and skills shortages presented in March 2024[10].

27. IDENTIFY an appropriate forum composed of Member States, the Commission and stakeholders, including the EU social partners of the healthcare sector where appropriate, to discuss appropriate actions at EU-level in coordination with actions at national level.

[10] Communication from the Commission COM(2024) 131 final to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Labour and skills shortages in the EU: an action plan https://ec.europa.eu/social/BlobServlet?docId=27473&langId=en

INVITES the EUROPEAN COMMISSION to:

28. DEVELOP a comprehensive approach on health workforce at EU level that supports Member States and their strategies, in line with the Framework for action on the health and care workforce in the WHO European Region 2023–2030 and WHO Global Code of Practice on the International Recruitment of Health Personnel, taking into account all relevant dimensions such as planning and forecasting, national and international recruitment and training, continuous professional development, retaining staff, sustaining mental and physical health of healthcare workers, working conditions, the challenges of skill mix, life-long training and retraining, including on digital competences and leadership skills, and surge capacity to cope with crisis situations.

29. IDENTIFY elements, instruments and good practices to support national strategies, such as the development of common goals, exchanging good practices and information, setting up joint actions taking into account the lessons learned and outcomes of the current and previous actions, including joint actions, on health workforce and enhanced access to existing EU funding mechanisms to enable the proposed actions.

30. ASSESS the effects of the legal frameworks at EU level regarding the regulation of the qualifications of health professions, to address the health workforce crisis, whilst preserving the mobility of health professionals and in respect of Member States' and Union competences. This assessment should be based on a consultation of Member States health authorities, social partners and civil society actors as well as take into account the ageing population and a correspondingly ageing health workforce.

31. CONSIDER, where appropriate and necessary, and based on the above-mentioned assessment, actions to ensure that these legal frameworks can enhance national health system goals and national health workforce strategies, in line with Single Market principles.

II. address priority needs in healthcare and innovation policies

INVITES the MEMBER STATES and the EUROPEAN COMMISSION to:

32. STRENGTHEN synergies between existing and upcoming infrastructures and programmes in Member States and at EU level to set up an independent needs-evidence database, which identifies health-related unmet patient and societal needs using a scientific approach.

33. CONSIDER to set up a voluntary Member State driven mechanism for the appraisal and prioritisation of the highest disease-specific, disease-overarching, and systems-level, health-related unmet patient and societal needs, based on the scientific evidence about the disease-specific needs and using transparent assessment criteria.

INVITES the EUROPEAN COMMISSION to:

34. EXAMINE the need for an EU initiative to coordinate and direct public support, within Union competence, to adequately and effectively address the most pressing health-related unmet patient and societal needs. This initiative should consider that different types of (health)interventions, including treatments optimisation, may provide a solution to the identified health-related unmet patient and societal needs, taking into account the potential of the EU cooperation on health technologies.

35. CONSIDER the identified most pressing health-related needs in priority setting for the EU framework programmes in the field of research, innovation and health, and the EU health programme once the database contains sufficient information.

INVITES the MEMBER STATES to:

36. ENHANCE the voluntary exchange of information and best practices on national approaches on reimbursement policies in existing fora with the aim to provide predictability to healthcare developers as to how health-related unmet patient and societal needs are considered in decisions about including cost-effective health interventions in the national benefit package.

37. CONSIDER the identified most pressing unmet health-related patient and societal needs when deciding on national research funding and incentives.

III. take action in the field of prevention of non-communicable diseases

INVITES the MEMBER STATES and the EUROPEAN COMMISSION to:

38. STRENGTHEN EU policies on health promotion, including mental health and the prevention of non-communicable diseases, thereby addressing the disease groups responsible for more than 80% of the disease burden in the EU countries and the leading causes of avoidable premature deaths[11] in line with the health in all policies approach.

39. PROMOTE healthy environments and communities that encourage and enable healthy lifestyle choices, addressing tobacco and related products and alcohol, unhealthy diets, physical inactivity, psychosocial and environmental factors including climate change.

40. CONTINUE and STRENGTHEN the work of the Healthier together - EU Non-Communicable Diseases Initiative by implementing and completing in a stepwise manner an overarching, integrative, comprehensive and multi-sectoral EU-level approach, to support the implementation of effective policies in the area of NCDs, including as strands, action plans on health determinants, cancer, cardiovascular diseases, chronic respiratory diseases, diabetes, mental health and neurological disorders, and rare diseases.

[11] The EU 'Healthier Together'Non-Communicable Diseases Initiative. https://health.ec.europa.eu/document/download/18238342-e8a8-493a-8afe-ed44da987800_en?filename=ncd_initiative_factsheet.pdf

INVITES the EUROPEAN COMMISSION to:

41. ADOPT the legislative proposals and continue to work on non-legislative measures announced under Europe's Beating Cancer plan, with a special focus on the initiatives related to determinants of health including socioeconomic and commercial determinants such as legislative and non-legislative measures announced for achieving a tobacco-free Europe, reducing harmful alcohol consumption and improving health promotion through access to healthy diets and physical activity.

42. CONTINUE to work on the measures of the Healthier together – EU NCD Initiative.

43. CONSIDER additional action to ensure a better protection of health of European citizens from environmental risk factors.

44. ADDRESS the issue of the marketing of addictive substances towards children on social media and develop a framework that puts greater responsibility on social media providers for advertising of addictive substances aimed at children and that are illegal in Member States.

45. CONSIDER how the negative mental and physical health effects on children of extended use of social media and screen based technologies can be addressed in order to improve the well-being of children in Europe.

IV. effectively combat antimicrobial resistance

INVITES the MEMBER STATES and the EUROPEAN COMMISSION to:

46. IMPLEMENT the Council recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach.[12]

47. WORK towards a more integrated one-health approach in the monitoring and the surveillance of antimicrobial resistance in organisms associated with humans, animals, plants and the environment as well as consumption of antibiotics by humans and animals.

[12] Council recommendation (2023/C 220/01) on stepping up EU actions to combat antimicrobial resistance in a One Health approach OJ C 220, 22.6.2023, p.1-20. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32023H0622(01)

48. STRENGHTEN coordinated cooperation of the EU and its Member States with third countries to exchange and disseminate best practice, in line with the One Health approach, related to infection prevention and control, diagnostics, surveillance, access to effective antibiotics, as well as use and stewardship of antimicrobials, including antibiotic medicinal products and veterinary medicinal products.

INVITES the EUROPEAN COMMISSION to:

49. DEVELOP guidelines, in close collaboration with Member States and relevant agencies, to support evidence-based cost-effective policies to reduce inadequate and inappropriate consumption of antimicrobials as well as guidelines for addressing environmental aspects in AMR National Action Plans within the framework of the One Health approach and guidelines for infection prevention policies, especially for healthcare, veterinary and environment workforce.

50. FURTHER EXPLORE and IMPLEMENT an EU funded Union pull incentive from existing EU funds in order to improve innovation, the development of new antimicrobials and access to existing and new antimicrobials in line with the Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach.

INVITES the MEMBER STATES to:

51. ENHANCE and REINFORCE more performance-based antimicrobial stewardship and infection prevention and control in all related sectors.

V. strengthen the EU ecosystem for clinical trials

INVITES the MEMBER STATES and the EUROPEAN COMMISSION to:

52. ESTABLISH a coordination mechanism to prioritise and streamline the funding of clinical trials by the EU and the national funders to be implemented in the EU for an optimal preparedness and response to public health infectious diseases emergencies.

53. IMPROVE EU-level public clinical trial databases, notably by connecting the Clinical trials in the European Union portal with the future EUDAMED and additional databases, where appropriate, and, with the common goal of improving visibility of ongoing and future clinical trials, streamlining the functional programming interface of national clinical trial databases, where appropriate and in line with European values and data protection regulations.

54. ESTABLISH an EU collaborative effort for enhanced public-private partnerships around the recruitment into clinical trials.

55. COORDINATE trial funding processes between the EU and national funders in terms of scope, review process and accelerated approvals when justified, where appropriate.

56. STRENGTHENS research and clinical trial governance across Member States through enhanced coordination of regulatory and ethical review across Member States.

57. ESTABLISH a European partnership on pandemic preparedness to better coordinate pandemic preparedness research and innovation along the whole research continuum including the consolidation of an EU-wide network of ever-warm clinical trial sites.

58. SUPPORT collaboration at national level and between Member States to facilitate the conduct of clinical trials of medicinal products combined with performance studies of in-vitro diagnostic medical devices or clinical investigations of medical devices. Additionally, continue providing support to initiatives intended to improve the synergies between the IVDR/MDR/CTR, such as the Combine project.

INVITES the MEMBER STATES to:

59. STREAMLINE data collection principles to enhance access, linkage and sample sharing between different clinical research databases and data from clinical trials, nationally, at European level and internationally in line with European values and data protection standards.

VI. take actions in the fields of preparedness and communicable diseases

INVITES the EUROPEAN COMMISSION to:

60. ENSURE to keep preparedness and response to cross border-health threats high on the agenda.

61. ORGANISE sectorial exercises followed by a large scale simulation exercise on health crisis management in the EU between all relevant actors at national and European level, taking into account an all-hazard and whole-of-society approach.

62. CONDUCT a thorough evaluation of the post-pandemic EU health emergency governance framework and, where necessary, subsequently clarify the relations between relevant entities involved in crisis preparedness and management. The evaluation should take into account the results of the evaluation of the Regulation on serious cross-border threats to health and of the review of the operations of HERA, the role of the EMA and the ECDC in crisis preparedness and management, as well as taking into account the results of the sectorial exercises. This evaluation should also consider new crisis scenarios impacting public health such as climate change-related, hybrid, cyber or security threats.

INVITES the MEMBER STATES and the EUROPEAN COMMISSION to:

63. STRENGTHEN and PRIORITISE EU and national policies on health promotion and the prevention and management of communicable diseases as well as those strengthening the continuum of preparedness including prevention and societal resilience.

64. PROMOTE healthy and stigma-free environments and engaged communities that encourage healthy lifestyle choices, addressing the promotion of vaccination, as well as other primary prevention measures to prevent communicable diseases, such as sexually transmitted infections, the impact of environmental factors, migration and climate change.

65. STRENGTHEN the fight against mis- and disinformation on health, by implementing, when available, models for evidence-based awareness-raising campaigns, by supporting research on this topic, and by promoting transparency on targeted campaigns against vaccination, including on social media.

VII. improve the security of supply for and access to medicinal products, and the security of supply for medical devices and in-vitro diagnostic medical devices

INVITES the EUROPEAN COMMISSION and the MEMBER STATES to:

66. CONTINUE the work on addressing vulnerabilities in the supply chains of critical medicinal products, including in the Critical Medicines Alliance and, where appropriate, make suggestions to improve their security of supply with a focus on strengthening EU-wide manufacturing of critical medicinal products, while ensuring better access to medicinal products in all Member States and an innovative and competitive pharmaceutical sector.

67. CONTINUE the work on mitigating critical medicine shortages in the context of crisis preparedness and management, and addressing supply chain vulnerabilities of critical medicinal products in the MSSG provided for in Regulation (EU) 2022/123 and beyond.

68. CONTINUE monitoring closely the implementation of the Regulations on medical devices and in-vitro diagnostic medical devices, to ensure they achieve their stated objectives in practice which include ensuring a high level of safety and health for European citizens, whilst supporting innovation. All necessary measures should be taken to maximise the availability of data on the supply and demand of medical devices throughout the EU, in line with European values and data protection rules, and on this basis to secure the availability of devices needed for maintaining a high level of patient safety and care, to allocate the resources necessary for an effective management of the regulatory system and to call on all actors, in particular manufacturers and notified bodies, to make full use of the extended transitional periods provided for in the Regulations and non-legislative measures to ensure timely transition to the Regulations.

69. STRENGTHEN collaboration and early involvement of competent authorities responsible for medical devices and in-vitro diagnostic medical devices and other stakeholders in developing and meeting environmental requirements applicable to those devices.

70. PROMOTE the voluntary exchange of data, in line with European values and data protection rules, in order to get an overview, on the supply and demand of critical medicinal products on the EU market, the manufacturing site of critical medicinal products and their active substances and the vulnerabilities and strategic dependencies of medicinal products. Duplication of data exchange for the national authorities and the pharmaceutical industry should be avoided.

71. DEVELOP a common strategic approach on a voluntary basis to stockpiling for preparedness for cross-border health emergencies and impactful supply disruptions, giving due consideration to sensitive aspects such as national defence stocks, in line with the Commission Communication introducing HERA and the Commission Communication on Addressing medicine shortages, while taking into account solidarity between Member States and their experiences.

72. ENCOURAGE a worldwide level playing field in environmental rules applying to the manufacturing of medicinal products, excipients and active substances, while respecting WTO law (GPA) and other binding international commitments.

73. MAKE USE of existing tools within the current legal framework in order to improve access to medicinal products and medical devices in Member States facing challenges, in particular where there are low volumes, such as in the case of orphan medicines, with voluntary participation of Member States in such initiatives.

INVITES the EUROPEAN COMMISSION to:

74. CONSIDER to propose a Critical Medicines Act, taking into account, amongst others, the findings of the Critical Medicines Alliance, to provide a legal framework to address supply chain vulnerabilities of critical medicinal products, with the aim to strengthen EU production and diversify vulnerable supply chains of critical medicinal products which could include state aid and public procurement measures, while respecting Member State competences and WTO law (GPA) and other binding international commitments (e.g. trade agreements with relevant public procurement chapters.

75. PROPOSE a comprehensive medicinal products roadmap in order to help competent authorities and other relevant stakeholders, including manufacturers, in addressing the environmental risks identified in the manufacturing process, in the upstream supply chain and across the lifecycle of these products to increase sustainability, to reduce greenhouse gas emissions and meeting environmental requirements applicable to those products.

76. EXAMINE remaining challenges related to the implementation of the legislation on medical devices and in-vitro diagnostic medical devices with a specific focus on its performance to ensure a high level of safety and health for EU citizens, whilst supporting innovation and also ensure the availability of devices for small patient populations (especially 'orphan devices' or 'pediatric devices') and to fostering the development and availability of innovative and affordable devices in the EU; special attention should be given to the governance system, the additional resource and expertise requirements as well as the costs and administrative burdens stemming from the implementation of the legislation, especially for SMEs; if appropriate, come up with a legislative proposal to address any identified shortcomings with a view to making the EU regulatory system sustainable in the medium- and long-term to ensure it is implemented as originally intended and agreed and to ascertain a high level of patient care and safety in the EU.

INVITES the MEMBER STATES to:

77. CONTINUE the work of the EU voluntary solidarity mechanism within the Medicine Shortages Steering Group (MSSG) while considering national requirements.

78. ASSESS the need for financial aid as well as dedicated instruments to support sustainable production of critical medicinal products in the EU.

79. STRENGTHEN voluntary collaboration and accelerate regional initiatives to enhance access to innovative medicines, taking stock of the experiences achieved, sharing best practices in joint negotiations and increasing transparency and expertise among collaborating Member States.

VIII. address the impact of climate change on health

INVITES the MEMBER STATES and the EUROPEAN COMMISSION to:

80. ESTABLISH in collaboration with Member States an EU agenda on climate and health following the One Health approach on both the adaptation and mitigation side. This agenda should take account of the EU research agenda on climate and health. It should consider the impact of extreme temperatures, synergies between temperature and air pollution, vector borne diseases, extreme weather events such as floods and droughts, water quality and food security. The agenda should address the health benefits of mitigation measures and promote the development and availability of effective medical countermeasures to respond to climate-sensitive infectious diseases.

81. ENCOURAGE cooperation in terms of early-signalling, monitoring and response to climate-related health threats, where EU coordinated action can have a beneficial and complementary role on the work already being done in the Member States.

82. WORK TOWARDS reducing the impacts of healthcare systems on climate and the environment in the EU. Ensure that national strategies, EU legislation, existing tools and funds enable the health and care sector to manage the transition to decarbonised health care systems, taking into account the importance of the sustainability of the healthcare sector, the impact on availability and affordability, and the reduction of its climatic footprint.

IX. improve EU implementation tools

INVITES the MEMBER STATES and the EUROPEAN COMMISSON to:

83. INITIATE an in-depth discussion in the EU4Health Steering Group in order to make the mechanism of joint actions more effective and sustainable in addressing future trends in health and Member States needs to implement priority areas within the EU Health Union.

84. STRENGHTEN the coordination between policy and funding instruments, ensuring that available EU funding continues to be used in a strategic, effective and sustainable manner, in line with health priorities of Member States and taking into account technical support, with a focus on implementing transformations with long-term impact.

85. ASSESS the current landscape of EU funds and its corresponding legislative framework to better align EU funding with Member States national health policy priorities.

INVITES THE EUROPEAN COMMISSION TO:

86. ESTABLISH an EU Health investment Hub in consultation with Member States and taking into consideration the lessons learnt from the Technical Support Instrument project "EU Resources Hub for sustainable investing in health", to provide on-demand, tailored and fit-for-purpose support to Member States in accessing and using existing EU funds delegated to Member States for the planning, financing and implementation of national health projects of high interest and impact and within the context of national health reforms and health care transformation processes, as well as identifying opportunities from different EU programmes for projects with objectives that span across multiple EU funding instruments and their priorities;

87. IMPROVE and update the procedures to facilitate access to existing fundings.

88. CONTINUE to work on the consolidation of the initiatives already launched under Europe's Beating Cancer Plan that have demonstrated their potential, to ensure sustainable progress for the benefit of cancer patients in Europe.

1. EU Interinstitutional

- Article 168 of the Treaty on the Functioning of the European Union

- The European Pillar of Social Rights

2. Council:

- Council conclusions on Common values and principles in European Union Health Systems, approved on 22 June 2006

- Council conclusions on investing in Europe's health workforce of tomorrow: Scope for innovation and collaboration, approved on 7 December 2010

- Council conclusions towards modern, responsive and sustainable health systems approved on 8 July 2011

- Council conclusions on the economy of wellbeing, approved on 24 October 2019

- Council conclusions on strengthening the European Health Union, approved on 20 December 2021

- Council conclusions on Access to medicines and medical devices for a Stronger and Resilient EU, approved on 15 June 2021

- Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach, adopted on 13 June 2023

- Council conclusions on mental health, approved on 30 November 2023

3. European Council

- European Council conclusions of 30 June 2023

- European Council conclusions of 21 and 22 March 2024

- European Council conclusions of 17 and 18 April 2024

4. European Commission

- Commission proposals for a reform of the EU pharmaceutical legislation (COM/2023/193 final and COM/2023/194 final) and Commission Communication on Reforming of the pharmaceutical legislation and measures addressing antimicrobial resistance COM(2023) 190 final

- Commission Communication on Addressing shortages in the EU, published on 24 October 2023, COM(2023) 672 final

- Commission Communication on The European Health Union: acting together for people´s health, published on 22 May 2024, COM(2024) 266 final