AMENDMENT
1 - 98

Draft opinion
Shortage of medicines - how to address an emerging problem
(PE650.657v01-00)

Shortage of medicines - how to address an emerging problem
(2020/2071(INI))
Amendment 1
Elżbieta Katarzyna Łukacijewska

Draft opinion
Recital A

A. whereas the problem of medicine shortages in the Member States is getting ever more severe on account of the lack of production capacity in the EU and the relocation of our industries in the sector to other markets in third countries;

Amendment
A. whereas the problem of the shortage of medicines in the Member States is constantly growing due to multifactorial reasons, such as economic causes, increasing regulatory and administrative burden, unforeseen surges in demand, supply chain interdependencies, transportation-related bottlenecks and manufacturing and quality challenges;

Or. en

Amendment 2
Clare Daly, Mick Wallace

Draft opinion
Recital A

A. whereas the problem of medicine shortages in the Member States is getting ever more severe on account of the lack of production capacity in the EU and the relocation of our industries in the sector to other markets in third countries;

Amendment
A. whereas the problem of medicine shortages in the Member States is getting ever more severe on account of the lack of production capacity in the EU and the relocation of our industries in the sector to other markets in third countries and the artificial shortage created by pharmaceutical companies which choose to focus on profitability;

Or. en

Amendment 3
Henna Virkkunen, Sara Skyttedal, Pernille Weiss

Draft opinion
Recital A

A. whereas the problem of medicine shortages in the Member States is getting ever more severe on account of the lack of production capacity in the EU and the relocation of our industries in the sector to other markets in third countries;

Amendment

A. whereas the problem of medicine shortages in the Member States is getting ever more severe on account of the lack of production capacity in the EU and the relocation of our industries in the sector to other markets in third countries; whereas fostering medical innovation and research in the EU is required to benefit patients and to ensure the EU pharmaceutical industry remains globally competitive;

Or. en

Amendment 4
Tilly Metz

Draft opinion
Recital A

A. whereas the problem of medicine shortages in the Member States is getting ever more severe on account of the lack of production capacity in the EU and the relocation of our industries in the sector to other markets in third countries;

Amendment

A. whereas the problem of medicine shortages in the Member States was highlighted during the COVID-19 crisis, demonstrating that the problem is getting ever more severe on account of the lack of production capacity in the EU and during epidemics considering our dependency on production in third countries;

Or. en

Amendment 5
Sara Cerdas, Maria Grapini, Isabel García Muñoz, Inma Rodríguez-Piñero, István Ujhelyi, Andris Ameriks

Draft opinion
Recital A

A. whereas the problem of medicine shortages in the Member States is getting ever more severe on account of the lack of production capacity in the EU;
A. whereas the problem of medicine shortages in the Member States is **getting ever more severe on account of** the lack of production capacity in the EU and the relocation of our industries in the sector to other markets in third countries;

A. whereas the problem of medicine shortages in the Member States is **growing due** the lack of production capacity in the EU and the relocation of our industries in the sector to other markets in third countries;

**Amendment 6**
Tilly Metz

**Draft opinion**
**Recital A a (new)**

**Draft opinion**

**Amendment**

A a. whereas climate change is one of the factors behind the multiplication of epidemics, both in terms of geographic spread and severity, that are linked to globalisation and the intensification of travel, and whereas the destruction of biodiverse habitats and industrial farming creates favourable conditions for the spread of 'zoonoses' by allowing pathogens and animal origin to reach humans and spread rapidly;

**Amendment 7**
Marian-Jean Marinescu

**Draft opinion**
**Recital A a (new)**

**Draft opinion**

**Amendment**

A a. Whereas access to medicines is a growing problem within the Union, usually associated with the high price of medicines and hindering European citizens' right to access to health care, and whereas it is expected for
the socio-economic situation to decline as a consequence of coronavirus pandemic and to worsen the living conditions for vulnerable citizens;

Amendment 8
Elissavet Vozemberg-Vrionidi
Draft opinion
Recital A a (new)

Draft opinion

Amendment

A a. whereas the problem of the shortage of medicines in the Member States is increasingly observed, due to economic and regulatory burdens, unforeseen surges of demand and supply chain bottlenecks in manufacturing and quality insurance.

Amendment 9
Kosma Złotowski
Draft opinion
Recital A a (new)

Draft opinion

Amendment

A a. whereas the European Commission’s response to the COVID-19 pandemic was late and insufficient, and the burden of fighting the coronavirus was mainly on the Member States;

Amendment 10
Sara Cerdas, Maria Grapini, Isabel García Muñoz, Andris Ameriks, Patrizia Toia,
Inma Rodríguez-Piñero, István Ujhelyi

Draft opinion
Recital B

Draft opinion
B. whereas transport and logistics management are of crucial importance for the supply of medicine, pharmaceutical products, medical equipment, personal protective equipment, other medical supplies and raw materials, not least given the increasing degree of complexity of the transport chain;

Amendment
B. whereas transport and logistics management are of crucial importance for the supply of medicine, pharmaceutical products, medical equipment, personal protective equipment, other medical supplies and raw materials, not least given the increasing degree of complexity of the transport chain, and whereas it is important to have efficient crossing green lane borders with fast track lanes in order to ensure the unobstructed flow of medicines;

Or. en

Amendment 11
Elissavet Vozemberg-Vrionidi

Draft opinion
Recital B a (new)

Draft opinion
B a. whereas any EU strategy to address medicine shortages should be a wholesome approach that takes into consideration the root causes of medicines shortages and that addresses concrete actions for their prevention. The Union needs to focus on ways to increase production of medicines in Europe avoiding any future recurrence of shortages during a crisis and avoiding dependency on third countries for pharmaceutical ingredients.

Amendment
Or. en
Amendment 12
Kosma Złotowski

Draft opinion
Recital B a (new)

Draft opinion

Amendment

B a. whereas free competition in the road transport sector, the absence of administrative barriers and easy access to transport services, including cabotage, play a crucial role in ensuring an adequate level of supply of medicines and medical devices and preventing their shortages;

Or. en

Amendment 13
Clare Daly, Mick Wallace

Draft opinion
Recital C

Draft opinion

Amendment

C. whereas high safety standards should be guaranteed and whereas pharmaceutical regulation should ensure the quality, safety and efficiency of the supply of medicines between Member States;

C. whereas high safety standards and preservation of working conditions for transport workers should be guaranteed and whereas pharmaceutical regulation should ensure the quality, safety and efficiency of the supply of medicines between Member States;

Or. en

Amendment 14
Maria Grapini

Draft opinion
Recital C

Draft opinion

Amendment
C. whereas high safety standards should be guaranteed and whereas pharmaceutical regulation should ensure the quality, safety and efficiency of the supply of medicines between Member States;

C. whereas high safety standards should be guaranteed and whereas pharmaceutical regulation should ensure the quality, **quantity**, safety and efficiency of the supply of medicines between Member States;

Amendment 15
Josianne Cutajar

Draft opinion
Recital C a (new)

Draft opinion

Amendment

C a. Whereas the Treaties and the European Charter of Fundamental Rights state that everyone shall have access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices, and whereas this right should be enforced for all citizens, including those living in the most peripheral areas of the Union;

Amendment

C a. whereas ensuring full patient access is one of the core objectives of the Union and the WHO, and one of the Sustainable Development Goals, and whereas patients rely on equitable and efficient access to medicines based on a sustainable, competitive, multi-source
and well-functioning Single Market, including the Single European Transport Area;

Amendment 17
Kosma Złotowski
Draft opinion
Recital C a (new)

Draft opinion

Amendment

C a. whereas ensuring patient access is one of the core objectives of the Union and the WHO, and of the Sustainable Development Goals, and whereas patients rely on equitable and sustainable access to medicines based on a sustainable, competitive, multi-source and well-functioning single market;

Amendment 18
Marco Campomenosi, Roman Haider
Draft opinion
Recital C a (new)

Draft opinion

Amendment

C a. whereas stocks are often not in the right storage location, even if available in the supply chain, and patients are unable to get them at the delivery point due to a lack of information, giving a false sign of a shortage of medicines;

Amendment 19
Elissavet Vozemberg-Vrionidi

Draft opinion
Recital C a (new)

Draft opinion

Amendment

C a. whereas the coronavirus pandemic highlighted the importance of coordinated action between EU institutions, Member States and industry in order to mitigate supply disruptions of medicines.

Or. en

Amendment 20
Elżbieta Katarzyna Łukacijewska

Draft opinion
Recital C b (new)

Draft opinion

Amendment

C b. whereas the COVID-19 pandemic outbreak demonstrated the importance of coordination between EU policies and departments to promptly and efficiently react to emergencies as well as to prevent medicines shortages, and to mitigate them in case they occur;

Or. en

Amendment 21
Kosma Złotowski

Draft opinion
Recital C b (new)

Draft opinion

Amendment

C b. whereas the COVID-19 pandemic demonstrated the importance of coordination between EU policies and department to promptly and efficiently
react to emergencies as well as to prevent medicines shortages, and to mitigate them in case they occur;

Or. en

Amendment 22
Elissavet Vozemberg-Vrionidi

Draft opinion
Recital C b (new)

Draft opinion  Amendment
C b. whereas the COVID-19 exacerbated the existing situation, and highlighted that the pharmaceutical supply chain is interconnected within EU Members States and externally;

Or. en

Amendment 23
Elżbieta Katarzyna Łukacijewska

Draft opinion
Recital C c (new)

Draft opinion  Amendment
C c. whereas the COVID-19 pandemic outbreak stressed that European coordination among EU Institutions, regulators and pharmaceutical supply chain experts is vital to respond in real-time to health crisis and to supply disruption, including shortages of medicines, in all relevant policy areas;

Or. en

Amendment 24
Kosma Zlotowski
Draft opinion
Recital C c (new)

Amendment

C c. whereas the COVID-19 pandemic stressed that European coordination among the EU institutions, the Member States, regulators and pharmaceutical supply chain experts is vital to respond to health crisis and to supply disruption such as shortages of medicines in all policy areas;

Or. en

Amendment 25
Elżbieta Katarzyna Łukacijewska

Draft opinion
Recital C d (new)

Amendment

C d. whereas the COVID-19 pandemic outbreak exacerbated the existing situation, it emerged that the pharmaceutical supply chain is interconnected within EU Members States and externally, and relies heavily on fully and properly functioning Single European Transport Area;

Or. en

Amendment 26
Elżbieta Katarzyna Łukacijewska

Draft opinion
Recital C e (new)

Amendment

C e. whereas the COVID-19 pandemic
outbreak demonstrated the importance of prioritising the circulation of essential goods, such as medicines and medical goods, including their undisrupted flow between Member States;

Or. en

Amendment 27
Tilly Metz

Draft opinion
Paragraph 1

1. Calls on the Member States to enhance their cooperation in order to improve the distribution chain through better visibility and efficient monitoring, particularly on cross-border routes, and to establish corridors where medical supplies have priority of delivery;

Amendment

1. Calls on the Member States to enhance their cooperation at EU level, to put patient's interests at the heart of EU policies, including strong considerations of the security of supply and affordability, and to improve the medicine distribution chains through better visibility and efficient monitoring, particularly on cross-border routes, and to establish dedicated rail or low emission corridors where medical supplies but also raw materials, intermediates, APIs, substances of human origin like plasma, related materials and also packaging have priority of delivery;

Or. en

Amendment 28
José Ramón Bauzá Díaz, Elsi Katainen, Nicola Danti, Ilhan Kyuchyuk, Jan-Christoph Oetjen, Ondřej Kovařík, Caroline Nagtegaal, Clotilde Armand

Draft opinion
Paragraph 1

1. Calls on the Member States to enhance their cooperation in order to improve the distribution chain through

Amendment

1. Calls on the Member States to enhance their cooperation in order to improve the medical supply and
better visibility and efficient monitoring, particularly on cross-border routes, and to establish corridors where medical supplies have priority of delivery;

distribution chain through better visibility and efficient monitoring, especially on "green lane" border crossings, and calls on Member States to implement the Green Lanes under the Guidelines for border management measures to protect health and ensure the availability of goods and essential services without unnecessary restrictions across borders;

Or. en

Amendment 29
Cláudia Monteiro de Aguiar

Draft opinion
Paragraph 1

Draft opinion

1. Calls on the Member States to enhance their cooperation in order to improve the distribution chain through better visibility and efficient monitoring, particularly on cross-border routes, and to establish corridors where medical supplies have priority of delivery;

Amendment

1. Calls on the Member States to enhance their cooperation in order to improve the distribution chain through better visibility and efficient monitoring, particularly on cross-border routes, and to establish corridors where medical supplies have priority of delivery; calls on the Commission to maintain the green lanes to address future unexpected events;

Or. en

Amendment 30
Marco Campomenosi, Roman Haider

Draft opinion
Paragraph 1

Draft opinion

1. Calls on the Member States to enhance their cooperation in order to improve the distribution chain through better visibility and efficient monitoring, particularly on cross-border routes, and to

Amendment

1. Calls on the Member States to enhance their cooperation in order to improve the distribution chain through better visibility and efficient monitoring, particularly on cross-border routes, and to establish corridors where medical supplies have priority of delivery; calls on the Commission to maintain the green lanes to address future unexpected events;

planning and timely exchange
establish corridors where medical supplies have priority of delivery;

information regarding important deliveries, particularly on cross-border routes, and to establish corridors where medical supplies have priority of delivery.

Amendment 31
Sara Cerdas, Isabel García Muñoz, Andris Ameriks, Inma Rodríguez-Piñero, István Ujhelyi

Draft opinion
Paragraph 1

Draft opinion

1. Calls on the Member States to enhance their cooperation in order to improve the distribution chain through better visibility and efficient monitoring, particularly on cross-border routes, and to establish corridors where medical supplies have priority of delivery;

Amendment

1. Calls on the Commission to coordinate with Member States a strategy for a cooperation in order to improve the distribution chain through better visibility and efficient monitoring, particularly on cross-border routes, and to establish corridors where medical supplies have priority of delivery;

Amendment 32
Maria Grapini

Draft opinion
Paragraph 1

Draft opinion

1. Calls on the Member States to enhance their cooperation in order to improve the distribution chain through better visibility and efficient monitoring, particularly on cross-border routes, and to establish corridors where medical supplies have priority of delivery;

Amendment

1. Calls on the Member States to enhance their cooperation and coordination between them in order to improve the distribution chain through better visibility and efficient monitoring, particularly on cross-border routes, and to establish corridors where medical supplies have priority of delivery;
Amendment 33
Elżbieta Katarzyna Łukacijewska

Draft opinion
Paragraph 1 a (new)

\[\textit{Draft opinion} \quad \textit{Amendment}\]

1 a. Calls on the Commission to coordinate a pan-European response to medicines shortages in order to ensure equitable and sustainable access to medicines; believes that a coordinated EU response is of utmost importance to avoid spill-over effects of individual and uncoordinated national measures addressing local medicines shortages, and to ensure the patients' right to universal, equitable, affordable, effective, safe and timely access to essential medicines, as well as to guarantee the sustainability of the EU public healthcare systems; is of the opinion that this pan-European approach should focus on coordinating Member States' policy measures to address the root causes of medicines shortages;

Or. en

Amendment 34
José Ramón Bauzá Díaz, Elsi Katainen, Nicola Danti, Ilhan Kyuchyuk, Jan-Christoph Oetjen, Ondřej Kovařík, Caroline Nagtegaal, Clotilde Armand

Draft opinion
Paragraph 1 a (new)

\[\textit{Draft opinion} \quad \textit{Amendment}\]

1 a. Highlights that the air freight is a crucial part of the pharmaceutical supply chain; and therefore calls on the Commission and the Member States to create dedicated hubs in the Union to build receiving points of air freight of
medicines, active pharmaceutical ingredients and medical equipment insufficient capacity in order to cover needs of the supply chain as well as creating open routes between the Union and third countries for these essential goods; calls on the Member States to encourage cargo and express airlines to apply reasonable shipping rates for medical and emergency supplies;

Amendment 35
Kosma Złotowski

Draft opinion
Paragraph 1 a (new)

Draft opinion

1 a. Calls on the Commission to coordinate a European response to medicines shortages to ensure equitable and sustainable access to medicines; believes that a coordinated EU response is of utmost importance to avoid spillover effects of individual and uncoordinated national measures to address medicines shortages and ensure the right of patients to universal, equitable, affordable, effective, safe and timely access to essential medicines, as well as to guarantee the sustainability of the EU public healthcare systems;

Amendment 36
Tilly Metz

Draft opinion
Paragraph 1 a (new)
1 a. Notes with concern that climate change being one of the factors behind the multiplication of epidemics, their number will grow in future; underlines that globalisation and the intensification of travel also results in the aggravation of epidemics and their geographical spread;

Amendment 37
Tilly Metz

Draft opinion
Paragraph 1 b (new)

1 b. Notes that in times of epidemics, the few countries responsible for most of the production of active substances for medicines can become unable to meet demand; remarks that long supply chains for medicines can therefore pose a risk to human life;

Amendment 38
Tilly Metz

Draft opinion
Paragraph 1 c (new)

1 c. Notes that the security of supply is central to fight against medicine shortages and that problems with cross border transport and controls make it even more important to uphold the Schengen agreement;
Amendment 39
Tilly Metz

Draft opinion
Paragraph 2

Draft opinion

2. Stresses that boosting the industrial production of the Member States through favourable economic conditions in the context of national fiscal policies would lead to a more efficient and sustainable logistics network, while reducing the length of transport routes, thereby reducing emissions, mitigating the impact on the environment, and improving the functioning of the internal market;

Amendment

2. Calls for the shortening of supply chains and relocation of European pharmaceutical companies production; stresses that boosting the industrial production in the Union through proper regulation and part-mandatory production within the Union would lead to securing supplies; emphasises the need for more efficient and sustainable transport and logistics options and a shift to rail and more sustainable transport modes, while reducing the length of transport routes, that would lead to a reduction of emissions, mitigating the impact on the environment, and improving the functioning of the internal market;

Amendment 40
Maria Grapini

Draft opinion
Paragraph 2

Draft opinion

2. Stresses that boosting the industrial production of the Member States through favourable economic conditions in the context of national fiscal policies would lead to a more efficient and sustainable logistics network, while reducing the length of transport routes, thereby reducing emissions, mitigating the impact on the

Amendment

2. Stresses that boosting the industrial production of the Member States through favourable economic conditions in the context of national fiscal policies would ensure a more efficient supply of stocks of medicines and medical equipment, and would lead to a more efficient and sustainable logistics network, while
environment, and improving the functioning of the internal market; reducing the length of transport routes, thereby reducing emissions, mitigating the impact on the environment, and improving the functioning of the internal market;

Or. en

Amendment 41
Sara Cerdas, Isabel García Muñoz, Andris Ameriks, Patrizia Toia, Inma Rodríguez-Piñero, István Ujhelyi

Draft opinion
Paragraph 2

2. Stresses that boosting the industrial production of the Member States through favourable economic conditions in the context of national fiscal policies would lead to a more efficient and sustainable logistics network, while reducing the length of transport routes, thereby reducing emissions, mitigating the impact on the environment, and improving the functioning of the internal market;

2. Stresses that boosting the industrial production of the Member States through favourable economic, social and environmental conditions would lead to a more efficient and sustainable logistics network, while reducing the length of transport routes, thereby reducing emissions, mitigating the impact on the environment, and improving the functioning of the internal market;

Or. en

Amendment 42
José Ramón Bauzá Díaz, Elsi Katainen, Nicola Danti, Ilhan Kyuchyuk, Jan-Christoph Oetjen, Ondřej Kovařík, Caroline Nagtegaal, Clotilde Armand

Draft opinion
Paragraph 3

3. Calls on the Member States to adopt strategic plans to upgrade their existing infrastructure for an efficient supply of medicines; deems it necessary to remove bottlenecks, boost intermodality (while favouring the shift to rail), finance the main hubs (ports, airports and

3. Calls on the Member States, in close cooperation with the Commission and with all interested stakeholders involved, to take coordinated measures and to adopt strategic plans to upgrade their existing infrastructure for an efficient supply of medicines; including by
intermodal platforms), and enhance the delivery of various types of goods, including dangerous goods crucial for the production of the chemical and pharmaceutical industry; foreseeing the creation of European common strategic reserves, building on rescEU stockpile's initiative; deems it necessary to remove bottlenecks, boost intermodality, finance the main hubs, and enhance the delivery of various types of goods, including dangerous goods crucial for the production of the chemical and pharmaceutical industry; calls on the Member States to ensure that medical facilities and medical staff in place are reinforced, in order to be able to carry out the increasing traffic volumes while restrictions are lifted;

Amendment 43
Tilly Metz

Draft opinion
Paragraph 3

Draft opinion

3. Calls on the Member States to adopt strategic plans to upgrade their existing infrastructure for an efficient supply of medicines; deems it necessary to remove bottlenecks, boost intermodality (while favouring the shift to rail), finance the main hubs (ports, airports and intermodal platforms), and enhance the delivery of various types of goods, including dangerous goods crucial for the production of the chemical and pharmaceutical industry;

Amendment

3. Calls on the Commission to coordinate the adoption of strategic plans to upgrade Member States' existing infrastructure for an efficient supply of medicines; deems it necessary to remove bottlenecks, boost intermodality (while favouring the shift to rail), finance the main hubs including intermodal platforms, and take special account of delivery chains that rely on frequent and timely delivery because the impossibility of stockpiling, for instance for radioisotopes; believes that the introduction of unconventional distribution and delivery plans should be considered, e.g. the combination of time-sensitive medicine deliveries via scheduled mixed traffic;
Amendment 44
Elżbieta Katarzyna Łukacijewska

Draft opinion
Paragraph 3

3. Calls on the Member States to adopt strategic plans to upgrade their existing infrastructure for an efficient supply of medicines; deems it necessary to remove bottlenecks, boost intermodality (while favouring the shift to rail), finance the main hubs (ports, airports and intermodal platforms), and enhance the delivery of various types of goods, including dangerous goods crucial for the production of the chemical and pharmaceutical industry;

Amendment

3. Calls on the Member States to adopt a strategic plan to upgrade the existing infrastructure for an efficient supply of medicines, and believes that it is necessary to remove all the existing bottlenecks, tackle existing obstacles to fully integrated and well functioning Single European Transport Area for all modes of transport, to boost the intermodality (whilst favouring the shift to rail), finance the main hubs (ports, airports, intermodal platforms), and to enhance the delivery of various types of goods, including dangerous ones which are crucial for the production of the chemical and pharmaceutical industry;

Or. en

Amendment 45
Sara Cerdas, Isabel García Muñoz, Andris Ameriks, Inma Rodríguez-Piñero, István Ujhelyi

Draft opinion
Paragraph 3

3. Calls on the Member States to adopt strategic plans to upgrade their existing infrastructure for an efficient supply of medicines; deems it necessary to remove bottlenecks, boost intermodality (while favouring the shift to rail), finance the main hubs (ports, airports and intermodal platforms), and enhance the delivery of various types of goods, including dangerous goods crucial for the production of the chemical and pharmaceutical industry;

Amendment

3. Calls on the Commission to work in coordination with the Member States in order to adopt strategic plans to upgrade their existing infrastructure for an efficient supply of medicines with a better use of all transport modes; deems it necessary to remove bottlenecks, boost intermodality (while favouring the shift to rail), finance the main hubs (ports, airports and intermodal platforms), and enhance the delivery of various types of goods,
Amendment 46
Marco Campomenosi, Roman Haider

Draft opinion
Paragraph 3

3. Calls on the Member States to adopt strategic plans to upgrade their existing infrastructure for an efficient supply of medicines; deems it necessary to remove bottlenecks, boost intermodality (while favouring the shift to rail), finance the main hubs (ports, airports and intermodal platforms), and enhance the delivery of various types of goods, including dangerous goods crucial for the production of the chemical and pharmaceutical industry;

Or. en

Amendment 47
Maria Grapini

Draft opinion
Paragraph 3

3. Calls on the Member States to adopt strategic plans to upgrade their existing infrastructure for an efficient supply of medicines, including inexpensive, essential medicines; deems it necessary to remove bottlenecks, boost intermodality (while favouring the shift to rail), finance the main hubs (ports, airports and intermodal platforms), and enhance the delivery of various types of goods, including dangerous goods crucial for the production of the chemical and pharmaceutical industry;

Or. en
intermodal platforms), and enhance the delivery of various types of goods, including dangerous goods crucial for the production of the chemical and pharmaceutical industry;

the main hubs (ports, airports and intermodal platforms), and enhance the delivery of various types of goods, including dangerous goods crucial for the production of the chemical and pharmaceutical industry;

Or. en

Amendment 48
Elissavet Vozemberg-Vrionidi

Draft opinion
Paragraph 3

3. Calls on the Member States to adopt strategic plans to upgrade their existing infrastructure for an efficient supply of medicines; deems it necessary to remove bottlenecks, boost intermodality (while favouring the shift to rail), finance the main hubs (ports, airports and intermodal platforms), and enhance the delivery of various types of goods, including dangerous goods crucial for the production of the chemical and pharmaceutical industry;

3. Calls on the Member States to adopt strategic plans to upgrade their existing infrastructure for an efficient supply of medicines; deems it necessary to remove bottlenecks, boost intermodality (while favouring the shift to rail), finance the main hubs (ports, airports and intermodal platforms), and to ensure the uninterrupted import and export of essential goods, such as medicines and medical goods;

Or. en

Amendment 49
José Ramón Bauzá Díaz, Nicola Danti, Ilhan Kyuchyuk, Jan-Christoph Oetjen, Ondřej Kovařík, Caroline Nagtegaal, Clotilde Armand

Draft opinion
Paragraph 3 a (new)

3 a. Welcomes the contribution of the armed forces of Member States to the supply chain of medicines and protective equipment during the COVID-19
outbreak; therefore, calls on the Commission and the Member States, in close cooperation with the European Medicines Agency, to enhance the cooperation for the use of national military resources, where available and necessary, to assist the supply chain of medicines and protective equipments among Member States, as part of PESCO cooperation framework;

Amendment 50
Maria Grapini

Draft opinion
Paragraph 4

Draft opinion

4. Highlights the importance of IT systems in facilitating the exchange of information between the various actors involved in the transport logistics chain, including the customs authorities, with a view to optimising the distribution of medicines in the Member States and planning supply times more efficiently;

Amendment

4. Highlights the importance of IT systems in facilitating the exchange of information between the various actors involved in the transport logistics chain, including the customs authorities, and of completion of the proposal for a regulation of the European Parliament and of the Council establishing the ‘Customs’ programme for cooperation in the field of customs and of the proposal for a regulation of the European Parliament and of the Council establishing, as part of the Integrated Border Management Fund, the instrument for financial support for customs control equipment, with a view to optimising the distribution of medicines in the Member States and planning supply times more efficiently;

Amendment 51
Tilly Metz
Draft opinion
Paragraph 4

4. Highlights the importance of IT systems in facilitating the exchange of information between the various actors involved in the transport logistics chain, including the customs authorities, with a view to optimising the distribution of medicines in the Member States and planning supply times more efficiently;

Amendment

4. Highlights the importance of IT systems in facilitating the trackability, supervision and timely delivery of transported medicines as well as the exchange of information between the various actors involved in the transport logistics chain, with a view to optimising the distribution of medicines in the Member States and planning supply times more efficiently; in this regard, deems it important to ensure a better overview of transport and stockpiling of medicines in the Union; considers that the Commission should designate a European agency as responsible to ensuring the supply and smooth transportation of medicines in the Union;

Or. en

Amendment 52
Sara Cerdas, Andris Ameriks, Isabel García Muñoz, Patrizia Toia, Inma Rodríguez-Piñero, István Ujhelyi

Draft opinion
Paragraph 4

4. Highlights the importance of IT systems in facilitating the exchange of information between the various actors involved in the transport logistics chain, including the customs authorities, with a view to optimising the distribution of medicines in the Member States and planning supply times more efficiently;

Amendment

4. Highlights the importance of IT systems in facilitating the exchange of information between the various actors involved in the transport logistics chain, including the customs authorities, with a view to optimising the distribution of medicines in the Member States and planning supply times more efficiently; calls on the Commission to develop mechanisms in cooperation with Member States in order to ensure a fast and safe transport of medicines; notes also the
importance of having contingency plans that ensure the unobstructed transport of medicines when the transport sector is conditioned;

Amendment 53
Henna Virkkunen, Sara Skyttedal, Pernille Weiss

Draft opinion
Paragraph 4

Draft opinion

4. Highlights the importance of IT systems in facilitating the exchange of information between the various actors involved in the transport logistics chain, including the customs authorities, with a view to optimising the distribution of medicines in the Member States and planning supply times more efficiently;

Amendment

4. Highlights the importance of IT systems in facilitating the exchange of information between the various actors involved in the transport logistics chain, including the customs authorities, with a view to optimising the distribution of medicines in the Member States and planning supply times more efficiently; stresses that medical supply chains can be improved through investments in skills, health data infrastructure, supporting regulatory framework and intellectual property policies that foster innovation;

Amendment 54
José Ramón Bauzá Díaz, Nicola Danti, Ilhan Kyuchyuk, Jan-Christoph Oetjen, Ondřej Kovařík, Caroline Nagtegaal, Clotilde Armand

Draft opinion
Paragraph 4

Draft opinion

4. Highlights the importance of IT systems in facilitating the exchange of information between the various actors involved in the transport logistics chain, including the customs authorities, with a

Amendment

4. Highlights the importance of IT systems in facilitating the exchange of information between the various actors involved in the transport logistics chain, including the customs authorities, with a
view to optimising the distribution of medicines in the Member States and planning supply times more efficiently; *calls on the Commission to carefully evaluate the benefits as well as the risks that artificial intelligence may bring for the fast and reliable delivery of medical supplies;*

**Amendment 55**
Josianne Cutajar

**Draft opinion**
Paragraph 4 a (new)

Draft opinion

4 a. *Highlights the importance of safe, reliable and clear data for both the transport and health sector; welcomes the EC Data Strategy, in particular the projects for a mobility and health data space; invites the Commission to work on creating synergies between the two data spaces, with the objective of maximising efficiency in transporting medicines, avoiding shortages and allowing for expedient crisis management; invites the Commission to explore the possibility of a European digital platform to facilitate logistical coordination between medicine distributors and transport operators;*

**Amendment 56**
José Ramón Bauzá Díaz, Nicola Danti, Ilhan Kyuchyuk, Jan-Christoph Oetjen, Ondřej Kovařík, Caroline Nagtegaal, Clotilde Armand

**Draft opinion**
Paragraph 5
5. Notes the importance of guaranteeing high safety standards for both transport infrastructure and employees, making it possible to manage significant volumes in the supply chain without disruptions or posing risks to health;

Amendment

5. Notes the importance of guaranteeing high safety standards for both transport infrastructure, for transport workers and employees, making it possible to manage significant volumes in the supply chain without disruptions of the supply chains and without prejudice for the competent authorities to take proportionate and adapted measures to minimise the risks of contagion; furthermore, notes the importance of the careful management of the ambient and cold-chain warehouse capacity in inbound and outbound transport infrastructure and, if necessary, the introduction of emergency or self-certification of additional capacity of pharmaceutical products;

Or. en
Amendment 58
Clare Daly, Mick Wallace

Draft opinion
Paragraph 5

Draft opinion

5. Notes the importance of guaranteeing high safety standards for both transport infrastructure and employees, making it possible to manage significant volumes in the supply chain without disruptions or posing risks to health;

Amendment

5. Notes the importance of guaranteeing high safety standards for both transport infrastructure and employees, making it possible to manage significant volumes in the supply chain without disruptions or posing risks to health; stresses the need to preserve the working conditions established before the crisis in terms of working time and rest and to privilege branch agreements for any modification of the working conditions required by the supply continuity;

Or. en

Amendment 59
Elissavet Vozemberg-Vrionidi

Draft opinion
Paragraph 5

Draft opinion

5. Notes the importance of guaranteeing high safety standards for both transport infrastructure and employees, making it possible to manage significant volumes in the supply chain without disruptions or posing risks to health;

Amendment

5. Notes the importance of guaranteeing non-discriminatory high safety standards for both transport infrastructure and transport workers, making it possible to manage significant volumes in the supply chain without disruptions or posing risks to health;

Or. en

Amendment 60
Kosma Złotowski
5 a. Calls on the Commission to provide financial and organisational support to the Member States and transport operators in urgent cases, to prioritise and provide reserved space in all cargoes for essential goods (such as medicines, active pharmaceutical ingredients, medical equipment, etc.)
Member States, in extraordinary circumstances in order to ensure reserved space in all cargo to essential goods (such as medicines, active pharmaceutical ingredients, medical equipment, etc).

Amendment 63
Elżbieta Katarzyna Łukacijewska

Draft opinion
Paragraph 5 b (new)

Draft opinion

Amendment

5 b. calls for the efficiency enhancement of regulatory procedures and swift implementation of fast-track processes to timely mitigate the medicines shortage;

Amendment 64
José Ramón Bauzá Díaz, Elsi Katainen, Nicola Danti, Ilhan Kyuchyuk, Jan-Christoph Oetjen, Caroline Nagtegaal, Clotilde Armand

Draft opinion
Paragraph 6

Draft opinion

Amendment

6. Stresses the importance of catering to specific transport needs at local and regional levels, particularly in rural, mountain and insular areas that are more difficult to access and involve higher delivery costs; notes that there are new automated delivery tools, such as via drones, available on the market that could help operators to access these areas;

6. Stresses the importance of catering to specific transport needs at local and regional levels, particularly in rural, mountain, sparsely populated and insular areas that are more difficult to access and involve higher delivery costs; notes the importance of their inclusion to the digital transition and also the need to accelerating the uptake of new solutions adapted to the needs of these areas, allowing connectivity, accessibility and affordability; stresses that the access to
medicines in these areas should not in any case be hampered;

**Amendment 65**
Cláudia Monteiro de Aguiar

**Draft opinion**
**Paragraph 6**

*Draft opinion*

6. Stresses the importance of catering to specific transport needs at local and regional levels, particularly in rural, mountain and insular areas that are more difficult to access and involve higher delivery costs; notes that there are new automated delivery tools, such as via drones, available on the market that could help operators to access these areas;

*Amendment*

6. Stresses the importance of catering to specific transport needs at local and regional levels, particularly in rural, mountain and insular areas and outermost regions that are more difficult to access and involve higher delivery costs; believes that the strategic plans to upgrade Member States infrastructure should deliver concrete actions for these areas and regions; notes that there are new automated delivery tools, such as via drones, available on the market that could help operators to access these areas;

**Amendment 66**
Maria Grapini

**Draft opinion**
**Paragraph 6**

*Draft opinion*

6. Stresses the importance of catering to specific transport needs at local and regional levels, particularly in rural, mountain and insular areas that are more difficult to access and involve higher delivery costs; notes that there are new automated delivery tools, such as via drones, available on the market that could help operators to access these areas;

*Amendment*

6. Stresses the importance of catering to specific transport needs at local and regional levels, particularly in rural, mountain and insular areas, but also in outermost regions that are more difficult to access and involve higher delivery costs; notes that there are new automated delivery tools, such as via drones, available on the market that could help operators to access these areas;
help operators to access these areas; market that could help operators to access these areas;

Amendment 67
Sara Cerdas, Isabel García Muñoz, Inma Rodríguez-Piñero, István Ujhelyi, Andris Ameriks

Draft opinion
Paragraph 6

Draft opinion

6. Stresses the importance of catering to specific transport needs at local and regional levels, particularly in rural, mountain and insular areas that are more difficult to access and involve higher delivery costs; notes that there are new automated delivery tools, such as via drones, available on the market that could help operators to access these areas;

Amendment

6. Stresses the importance of catering to specific transport needs at local and regional levels, particularly in rural, mountain, insular and outermost regions areas that are more difficult to access and involve higher delivery costs; notes that there are new automated delivery tools, such as via drones, available on the market that could help operators to access these areas;

Or. en

Amendment 68
Tilly Metz

Draft opinion
Paragraph 6

Draft opinion

6. Stresses the importance of catering to specific transport needs at local and regional levels, particularly in rural, mountain and insular areas that are more difficult to access and involve higher delivery costs; notes that there are new automated delivery tools, such as via drones, available on the market that could help operators to access these areas;

Amendment

6. Stresses the importance of catering to specific transport needs at local and regional levels, particularly in peripheral, rural, mountain and insular areas that are more difficult to access and involve higher delivery costs; notes that new automated delivery tools, such as drones, could play a beneficial part in accessing these areas, institutions as well as patients;
Amendment 69
Kosma Złotowski

Draft opinion
Paragraph 6 a (new)

Proposed text:

6 a. Underlines that restricting the supply of transport services by creating market or administrative barriers poses a serious threat to the continuity of supply of medicines, medical devices and other medical products and may be a reason for their shortage in the common market;

Amendment:

6 a. Notes that the COVID-19 outbreak has laid bare the weaknesses of the European production system, highlighting the importance of delivering medicines swiftly in urgent and exceptional circumstances that could arise in the future; calls on the Commission to establish plans and protocols with a multi-dimensional approach to respond to the causes of shortage of medicines but also to prepare the Union to address future exceptional periods;

Amendment 70
Cláudia Monteiro de Aguiar

Draft opinion
Paragraph 7

Proposed text:

7. Notes that the COVID-19 outbreak has laid bare the weaknesses of the European production system, highlighting the importance of delivering medicines swiftly in urgent and exceptional circumstances that could arise in the future.

Amendment:

7. Notes that the COVID-19 outbreak has laid bare the weaknesses of the European production system, highlighting the importance of delivering medicines swiftly in urgent and exceptional circumstances that could arise in the future; calls on the Commission to establish plans and protocols with a multi-dimensional approach to respond to the causes of shortage of medicines but also to prepare the Union to address future exceptional periods;
Amendment 71
Sara Cerdas, István Ujhelyi, Andris Ameriks, Isabel García Muñoz

Draft opinion
Paragraph 7

Draft opinion

7. Notes that the COVID-19 outbreak has laid bare the weaknesses of the European production system, highlighting the importance of delivering medicines swiftly in urgent and exceptional circumstances that could arise in the future.

Amendment

7. Notes that the COVID-19 outbreak is highlighting the importance of delivering medicines swiftly in urgent and exceptional circumstances that could arise in the future; calls on the European Commission to prepare an agreement with drug-producing third countries, to ensure the transport of medicines overcoming any constraints that may occur, such as this case of the COVID pandemic.

Or. en

Amendment 72
Henna Virkkunen, Sara Skyttedal, Pernille Weiss

Draft opinion
Paragraph 7

Draft opinion

7. Notes that the COVID-19 outbreak has laid bare the weaknesses of the European production system, highlighting the importance of delivering medicines swiftly in urgent and exceptional circumstances that could arise in the future.

Amendment

7. Notes that the COVID-19 outbreak has laid bare the weaknesses of the European production system, highlighting the importance of delivering medicines swiftly in urgent and exceptional circumstances that could arise in the future; highlights the importance of R&D investments to ensure that the pharmaceutical industry can respond to tomorrow’s needs.

Or. en

Amendment 73
Elżbieta Katarzyna Łukacijewska
Draft opinion  
Paragraph 7

7. Notes that the COVID-19 outbreak has laid bare the weaknesses of the European production system, highlighting the importance of delivering medicines swiftly in urgent and exceptional circumstances that could arise in the future.

Amendment 74
José Ramón Bauzá Díaz, Elsi Katainen, Nicola Danti, Ilhan Kyuchyuk, Jan-Christoph Oetjen, Ondřej Kovařík, Caroline Nagtegaal, Clotilde Armand

Draft opinion  
Paragraph 7

7. Notes that the COVID-19 outbreak has laid bare the weaknesses of the European production system, highlighting the importance of delivering medicines swiftly in urgent and exceptional circumstances that could arise in the future.

Amendment 75
Maria Grapini

Draft opinion  
Paragraph 7

7. Notes that the COVID-19 outbreak has laid bare the weaknesses of the European production system, highlighting the importance of delivering medicines swiftly in urgent and exceptional circumstances that could arise in the future.
has laid bare the weaknesses of the European production system, highlighting the importance of delivering medicines swiftly in urgent and exceptional circumstances that could arise in the future.

has laid bare the weaknesses of the European production system, and considers that a new industrial and transport policy is needed in order to ensure the swift delivery of medicines in urgent and exceptional circumstances that could arise in the future.

Amendment 76
Elissavet Vozemberg-Vrionidi

Draft opinion
Paragraph 7

Draft opinion

7. Notes that the COVID-19 outbreak has laid bare the weaknesses of the European production system, highlighting the importance of delivering medicines swiftly in urgent and exceptional circumstances that could arise in the future.

Amendment

7. Notes that the COVID-19 outbreak highlighted the importance of ensuring circulation and timely delivery of goods in extraordinary circumstances.

Amendment 77
Kosma Zlotowski

Draft opinion
Paragraph 7

Draft opinion

7. Notes that the COVID-19 outbreak has laid bare the weaknesses of the European production system, highlighting the importance of delivering medicines swiftly in urgent and exceptional circumstances that could arise in the future.

Amendment

7. Notes that the COVID-19 outbreak made the weakness of the European goods distribution system during extraordinary circumstances, highlighting the importance of timely delivery of medicines in urgent and exceptional circumstances that could occur in the future;
Amendment 78
Cláudia Monteiro de Aguiar

Draft opinion
Paragraph 7 – point 1 (new)

(1) Calls on the Commission to extend the competences of the ECDC in the area of public health; notes that in the future ECDC should be the centre of coordination and evaluation of the Union in situations of health crises, which can lead to medicines shortages, such as the one we have experienced;

Or. en

Amendment 79
Elżbieta Katarzyna Łukacijewska

Draft opinion
Paragraph 7 a (new)

7 a. Calls on the Commission to immediately activate European and global cooperation during crisis events, to prioritise the intra-EU or extra-EU circulation of essential goods, such as medicines, active pharmaceutical ingredients, intermediates, key starting materials ingredients, etc., to maintain road, ports, rail, airport traffic flowing by creating priority “Green lanes” between Member States and between EU and relevant third countries, and within those countries, for these essential goods;

Or. en
Amendment 80
Elissavet Vozemberg-Vrionidi

Draft opinion
Paragraph 7 a (new)

7 a. Calls on the Commission to immediately activate European and global cooperation, during crisis events, to prioritise the circulation intra-EU or extra-EU of essential goods, such as medicines, active pharmaceutical ingredients, intermediates, key starting materials ingredients, etc, to maintain road, ports, airport traffic flowing by creating priority “Green lanes” within Member States and between EU and third countries, and within those countries, for these essential goods.

Or. en

Amendment 81
Kosma Złotowski

Draft opinion
Paragraph 7 a (new)

7 a. Underlines that flexibility in the approach to rules on working and rest time in road transport had played an essential role in making the distribution chain for medicines and medical devices more efficient when the COVID-19 pandemic erupted; stresses that European rules in this area should take greater account of such emergencies and provide for flexibility in the approach to working time issues;

Or. en
Amendment 82  
Marco Campomenosi, Roman Haider  
Draft opinion  
Paragraph 7 a (new)  

Draft opinion  

Amendment  

7 a. Stresses the need to reduce transport costs, while preserving the level of service, minimising the number of kilometres of the routes, having ready and effective response tools to changes, both in ordinary operations and in exceptional periods of crisis, such as for COVID-19;  

Or. en

Amendment 83  
Marian-Jean Marinescu  
Draft opinion  
Paragraph 7 a (new)  

Draft opinion  

Amendment  

7 a. Insists that the Commission establishes shortage of medicines as one of the pillars of its new planned pharmaceutical strategy;  

Or. en

Amendment 84  
Elżbieta Katarzyna Łukacijewska  
Draft opinion  
Paragraph 7 b (new)  

Draft opinion  

Amendment  

7 b. Emphasis the importance of implementing specific measures to maintain, first and foremost, fully functioning and healthy European multi-
supplier market with the full enforcement of „Green lanes” for medicine products transportation, as well as facilitation of the fastest modes of transport to carry especially time sensitive cargo, such as medicines;

Or. en

Amendment 85
Marco Campomenosi, Roman Haider

Draft opinion
Paragraph 7 b (new)

Draft opinion

Amendment

7 b. Calls for the implementation of innovative solutions to enable the safe transport of temperature-sensitive drugs, tracing the products through a constant remote monitoring in real time of medicines and their temperature from production to the final customer;

Or. en

Amendment 86
Marian-Jean Marinescu

Draft opinion
Paragraph 7 b (new)

Draft opinion

Amendment

7 b. Encourages the Commission to create a fair pricing model for essential medicines, taking into account that prices should be more in line with the costs of research and development and considering the added therapeutic value;

Or. en
Amendment 87
Marco Campomenosi, Roman Haider

Draft opinion
Paragraph 7 c (new)

Draft opinion
Amendment

7 c. Calls for a revision of the EU Guidelines on Good Distribution Practice (GDP) of medicinal products for human use, taking into account the need to improve the efficiency of the supply chain, to reduce the products losses, and to implement innovative solutions, also in light of the recent COVID-19 outbreak;

Or. en

Amendment 88
Marian-Jean Marinescu

Draft opinion
Paragraph 7 c (new)

Draft opinion
Amendment

7 c. Believes it is important that the Commission addresses the issue of legal parallel trade in order to prevent shortages due to exports caused by high differences in terms of prices of a medicine, between Member States;

Or. en

Amendment 89
Elżbieta Katarzyna Łukacijewska

Draft opinion
Paragraph 7 c (new)

Draft opinion
Amendment

7 c. Calls on the Commission and the
Member States to ensure that healthcare workers, including pharmaceutical employees, are authorised to cross internal borders if they work in a neighbouring country;

Or. en

Amendment 90
Marco Campomenosi, Roman Haider

Draft opinion
Paragraph 7 d (new)

7 d. Calls on the Member States to implement strategies improving prevention and management of shortages caused by disruptions in the supply chain, to develop guidance for companies on reporting of shortages, and to favour the exchange of best practices among regulatory authorities to better coordinate actions between Member States;

Or. en

Amendment 91
Marco Campomenosi, Roman Haider

Draft opinion
Paragraph 7 e (new)

7 e. Calls on the Commission to revise Directive 2008/68/EC on the inland transport of dangerous goods adopting specific measures for the supply of dangerous goods in support of the chemical and pharmaceutical industry;

Or. en
Amendment 92
Marco Campomenosi, Roman Haider

Draft opinion
Paragraph 7 f (new)

Draft opinion
Amendment

7 f. Calls on the Commission to revise Directive 92/106/EEC on the establishment of common rules for certain types of combined transport of goods between Member States assessing possible provisions aimed at improving the logistics chain for the transport of medicines;

Or. en

Amendment 93
Marco Campomenosi, Roman Haider

Draft opinion
Paragraph 7 g (new)

Draft opinion
Amendment

7 g. Calls on the Commission to address the problem of the shortage of medicines in the work programmes adopted within the Multi-Annual Financial Framework 2021-2027, in particular by increasing the focus on aspects linked to research and innovation under Horizon Europe and other programmes;

Or. en

Amendment 94
Marco Campomenosi, Roman Haider

Draft opinion
Paragraph 7 h (new)

Draft opinion

Amendment

7 h. Calls on the Commission to implement an observatory, monitoring and coordinating actions at European-level, about the shortages of medicines, without any increase of the EU’s budget.

Or. en

Amendment 95
Marco Campomenosi, Roman Haider

Draft opinion
Paragraph 7 i (new)

Draft opinion

Amendment

7 i. Calls on the Commission and Member States to closely coordinate to protect the resilience and sustainability of the healthcare supply chain, which ensures the continuous availability of medicines, as well as their safe distribution and fair allocation to all dispensing points within Member States.

Or. en

Amendment 96
Marco Campomenosi, Roman Haider

Draft opinion
Paragraph 7 j (new)

Draft opinion

Amendment

7 j. Calls for transparency at EU level through the introduction of a Europe-wide medicines shortages database and an early warning system involving the main supply chain stakeholders, from manufacturers, full-service healthcare
distributors / pharmaceutical full-line wholesalers, pharmacists to prescribers and the national competent authorities, about existing and anticipated shortages, providing their root causes in a harmonised, comparable manner.

Amendment 97
Marco Campomenosi, Roman Haider
Draft opinion
Paragraph 7 k (new)

Draft opinion

Amendment

7 k. Calls on the Member States to ensure that all main stakeholders of the healthcare supply chain (manufacturers, full-service healthcare distributors /pharmaceutical full-line wholesalers, pharmacists) to be recognised as critical infrastructure to maintain the continuous and safe supply of medicines in extraordinary circumstances, such as the ones currently experienced in the COVID-19 crisis or even taking into account the distribution of an upcoming vaccine.

Amendment 98
Marco Campomenosi, Roman Haider
Draft opinion
Paragraph 7 l (new)

Draft opinion

Amendment

7 l. Notes that the COVID-19 outbreak has laid bare the weaknesses of the European production system, highlighting the importance of delivering medicines swiftly in urgent and exceptional
circumstances that could arise in the future, thereby stressing the importance and availability of existing and established infrastructure, including logistical hubs, warehouses and networks, for the safe and efficient distribution of medical supplies, including also the possibility for keeping stocks of medicines for emergency use.

Or. en