AMENDMENTS
330 - 674

Draft report
Nathalie Colin-Oesterlé
(PE650.394v01-00)

Shortage of medicines - how to address an emerging problem
(2020/2071(INI))
Amendment 330
César Luena

Motion for a resolution
Paragraph 6

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Amendment

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Or. es

Amendment 331
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 6

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Amendment

6. Urges the Commission and the Member States to put in place restrictions for medicines produced under bad labour circumstances and environmental standards, from compound manufacturing to packaging and distribution; emphasises the strategic significance and importance of heavily investing in European based companies, in return for binding commitments regarding issues such as transparency, traceability, accessibility and affordability of manufacture and distribution across the entire medical supply chain to ensure medicines are equally available across all regions at a
fair price;

Amendment 332
Piernicola Pedicini, Eleonora Evi

Motion for a resolution
Paragraph 6

Motion for a resolution

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Amendment

6. Urges the Commission and the Member States to introduce measures encouraging producers to diversify their sources of supply and locate their operations in Europe, while considering the authorisation of state aid to finance public independent healthcare research establishments;

Amendment 333
Mairead McGuinness

Motion for a resolution
Paragraph 6

Motion for a resolution

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification; calls on the EU to work on global supply chain quality and integrity, collaborating with non-EEA jurisdictions including at the WTO, which should include an emphasis on the highest of labour and environmental standards in
companies, in the interests of resource diversification; production worldwide;

Amendment 334
Alessandra Moretti

Motion for a resolution
Paragraph 6

Motion for a resolution

6. **Urges** the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to *locate their operations in Europe, from* compound manufacturing to *packaging and distribution*; emphasises the strategic significance of this sector and the importance of *investing in European companies, in the interests of resource diversification*;

Amendment

6. **Acknowledges that the pharmaceutical industry plays an important role for quality manufacturing and supply of medicines to reach all patients in need, to contribute to future innovation, support the resilience, responsiveness and readiness of healthcare systems and help address future challenges including pandemics; Asks the Commission and the Member States, if needed for public interest, to evaluate economic sustainable policies, such as for example tax and financial incentives, in return for appropriate commitments and to authorise state aid to encourage producers to *re-locate in the EU the production of active pharmaceutical ingredients (APIs), medicine and compound manufacturing, packaging and distribution*; observes that any incentive should incorporate public safeguards, such as transparency regarding public contributions and clauses on accessibility and affordability of manufactured medicines to ensure they are equally available at a fair price; emphasises the strategic significance of this sector and the importance to *protect the public interest and affordable access to treatment*;
Amendment 335
Nathalie Colin-Oesterlé

Motion for a resolution
Paragraph 6

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Amendment

6. Urges the Commission and the Member States to introduce measures to support competitiveness and tax and financial incentives in return for appropriate commitments and to authorise, with due respect for international and EU legislation, state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification, with any public incentive having as a counterpart the transparency and traceability of investments, as well as the obligation to supply the European market;

Or. fr

Amendment 336
Kateřina Konečná

Motion for a resolution
Paragraph 6

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Amendment

6. Urges the Commission and the Member States to introduce measures that would encourage producers to diversify their sources of supply, in particular raw materials, and to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource
companies, in the interests of resource diversification; all public funding being conditioned to the full transparency and traceability of investments, as well as to supply obligations on the European market and to accessible prices of medicine;

Amendment 337
Sirpa Pietikäinen

Motion for a resolution
Paragraph 6

Motion for a resolution

6. Urges the Commission and the Member States to introduce 
financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Amendment

6. Invites the Commission and the Member States to introduce measures that would encourage producers to diversify their sources of supply, in particular raw materials, and to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification; all public funding being conditioned to the full transparency and traceability of investments, as well as to supply obligations on the European market and to accessible prices of medicine

Amendment 338
Jessica Polfjärd

Motion for a resolution
Paragraph 6

Motion for a resolution

6. Urges the Commission and the

Amendment

6. Invites the Commission and the
Member States to **introduce tax and financial** incentives in return for appropriate commitments **and to authorise** state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of **investing in** European companies, **in the interests of resource diversification**;

Member States to **consider** incentives for the pharmaceutical industry in return for appropriate commitments **to diversify** their supply chains from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of **promoting** European competitiveness;

Amendment 339
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Nicolae Ştefănuță, Chrysoula Zacharopoulou, Frédérique Ries, Ondřej Knotek, Jan Huitema

Motion for a resolution
Paragraph 6

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments **and to authorise** state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, **in the interests of resource diversification**;

Amendment
6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments **and to authorise** state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies **in order to diversify resources and encourage the development of innovative production technologies capable of enhancing the responsiveness of production lines, in particular the continuous manufacturing process**;
Amendment 340
Adam Jarubas

Motion for a resolution
Paragraph 6

Motion for a resolution

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Amendment

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from API to medicines manufacturing; also urges the Member States to put in place sustainable market policies to secure existing operations; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Or. en

Amendment 341
Ondřej Knotek

Motion for a resolution
Paragraph 6

Motion for a resolution

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Amendment

6. Urges the Commission and the Member States to introduce incentives to support the diversification of supply in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Or. en
Amendment 342
Sara Cerdas

Motion for a resolution
Paragraph 6

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Amendment

6. Urges the Commission and the Member States to incentives supporting the diversification of supply in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Or. en

Amendment 343
Andreas Glück

Motion for a resolution
Paragraph 6

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Amendment

6. Urges the Commission and the Member States to incentives supporting the diversification of supply in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Or. en
Amendment 344  
Bartosz Arłukowicz

Motion for a resolution  
Paragraph 6

Motion for a resolution  
6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Amendment

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification; notes that all incentives should include explicit safeguards, such as information on the level of public contribution, and accessibility clauses to ensure equal access to medicines at a fair price;

Or. pl

Amendment 345  
Marian-Jean Marinescu

Motion for a resolution  
Paragraph 6

Motion for a resolution  
6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the

Amendment

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the
importance of investing in European companies, in the interests of resource diversification; all public funding being conditioned to the full transparency and traceability of investments, as well as to supply obligations on the European market and to accessible prices of medicine;

Amendment 346
Danilo Oscar Lancini, Luisa Regimenti

Motion for a resolution
Paragraph 6

Motion for a resolution

Amendment

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Amendment 347
Esther de Lange

Motion for a resolution
Paragraph 6
Motion for a resolution

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Amendment

6. Urges the Commission and the Member States to introduce incentives supporting the diversification of supply, such as tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Or. en

Amendment 348
Edina Tóth

Motion for a resolution
Paragraph 6

Motion for a resolution

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Amendment

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; and urges Member States to secure existing operations; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Or. en

Amendment 349
Frédérique Ries, Véronique Trillet-Lenoir
Motion for a resolution
Paragraph 6

Motion for a resolution

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Amendment

6. Urges the Commission and the Member States to introduce, as a priority, tax and financial incentives in return for appropriate commitments and to authorise, on an exceptional and temporary basis, state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Or. fr

Amendment 350
Stanislav Polčák

Motion for a resolution
Paragraph 6

Motion for a resolution

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Amendment

6. Urges the Commission and the Member States to introduce tax and financial incentives in return for appropriate commitments and to authorise state aid to encourage environmentally responsible producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;

Or. cs
Amendment 351
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 6 a (new)

Motion for a resolution

6a. Calls on the Commission and Member States to ensure that, if incentives are offered to the medicines industry, these do not affect medicine affordability; stresses the need to make incentives conditional on medicines being available and affordable;

Amendment

Or. en

Amendment 352
Frédérique Ries, Véronique Trillet-Lenoir

Motion for a resolution
Paragraph 6 a (new)

Motion for a resolution

6a. Calls on the Commission to draw up a global assessment report on the practice of the parallel importation of medicines, characterised by purchases made outside the official supply chains, and in particular: (i) analyse their direct or indirect link with the shortage of some medicines; (ii) monitor the application by Member States of the specific provisions relating to parallel imports incorporated into Directive 2011/62/EU, the ‘Falsified Medicines’ Directive; (iii) propose modifications to the system with the aim of improving health safety, by reducing the number of intermediaries (buyers, reconditioners, carriers, etc.) and limiting the use of simplified procedures for parallel import authorisations (PIAs); and (iv) suggest the possible adoption of
preventive measures to limit the parallel trade in medicines within the European Union.

Amendment 353
Alessandra Moretti
Motion for a resolution
Paragraph 6 a (new)

6a. Calls on the Commission and Member States to ensure that market authorisation holders and wholesale distributors comply with the requirement of Directive 2001/83/EC to ensure appropriate and continued supplies of medicines; recalls the public responsibility of marketing authorisation holders and wholesale distributors to ensure an appropriate and prompt marketisation and distribution of medicines in order to guarantee the right to equal treatment to all patients in the EU, regardless of their country of residence; calls on the Commission to clarify the marketing authorisation holder’s obligations under the Directive 2001/83/EC and highlights the need to ensure that market authorisation holders report about all medicines shortages within the established timeframes; stresses the need to apply dissuasive sanctions for non-compliance with these legal obligations; calls on the Commission to explore how the requirement to ensure continued supplies could be strengthened.
Motion for a resolution
Paragraph 6 a (new)

Motion for a resolution

6a. Calls on the Commission to introduce obligations for pharmaceutical companies to notify drug shortages according to Article 23a of Directive 2001/83/EC; underlines that other stakeholders involved in the supply chain such as wholesale distributors, pharmacists, hospitals and patients should also be included in the notification procedure of shortages;
requirements by all actors in the supply chain at national and European level, along with measures to increase transparency in the supply chain;

Or. es

Amendment 356
Nicolae Ștefănuță, Véronique Trillet-Lenoir

Motion for a resolution
Paragraph 6 a (new)

Motion for a resolution  Amendment

6a. Notes that current legislation does not ensure the stable supply of medicines; calls on the Commission to clarify the marketing authorisation holder’s obligations under the Directive 2001/83/EC and develop an enforcement mechanism including sanctions to hold companies accountable;

Or. en

Amendment 357
Sirpa Pietikäinen

Motion for a resolution
Paragraph 6 a (new)

Motion for a resolution  Amendment

6a. Notes that the current legislation does not ensure the stable supply of medicines; calls on the Commission to clarify the marketing authorisation holder’s obligations under the Directive 2001/83/EC and develop an enforcement mechanism including sanctions to hold companies accountable;

Or. en
Amendment 358
Kateřina Konečná

Motion for a resolution
Paragraph 6 a (new)

Motion for a resolution

Amendment

6a. Calls on Member States to ensure that pharmaceutical companies and wholesale distributors comply with the requirement in Directive 2001/83/EC to ensure appropriate and continued supplies of medicines; highlights the need to ensure that pharmaceutical companies report about all medicines shortages within the established timeframes; stresses the need to apply dissuasive sanctions for non-compliance with these legal obligations; calls on the Commission to explore how the requirement to ensure continued supplies could be strengthened;

Or. en

Amendment 359
Piernicola Pedicini, Eleonora Evi

Motion for a resolution
Paragraph 6 a (new)

Motion for a resolution

Amendment

6a. Calls on the Commission to work together with Member States’ national authorities and the relevant stakeholders with a view to reinforcing the obligation for continuous supply to tackle the problem of shortages of medicines, including through a revision of Directive 2001/83/EC addressing earlier notification by companies in all Member States, consumer reporting and effective public communication;

Or. en
Amendment 360
João Ferreira

Motion for a resolution
Paragraph 6 a (new)

Motion for a resolution

Amendment

6a. Calls on the Commission to ensure that its pharmaceutical strategy is guaranteed to combat inadmissible business practices anywhere on the medicines circuit that might undermine transparency and balanced relations between the various public and private entities directly or indirectly involved in ensuring access to medicines, fulfilling an essential public service;

Or. pt

Amendment 361
Christophe Hansen

Motion for a resolution
Paragraph 6 a (new)

Motion for a resolution

Amendment

6a. Underlines that a complete repatriation of medical supply chains is not feasible in a global economy; emphasises the importance of Free Trade Agreements to ensure the diversification of supply chains; urges the Commission to work closely together with the WHO and WTO to establish an international framework to prevent a future breakdown of medical supply chains;

Or. en

Amendment 362
Aldo Patriciello
Motion for a resolution
Paragraph 6 a (new)

Motion for a resolution
Amendment

6a. Urges the Commission and Member States to put the right economic framework in place to secure and modernise existing manufacturing capabilities of medicines, technology and APIs in Europe, for example by rewarding investments in medicines quality and security of supply;

Or. en

Amendment 363
Cindy Franssen, Sirpa Pietikäinen

Motion for a resolution
Paragraph 6 a (new)

Motion for a resolution
Amendment

6a. Stresses the need for full transparency and traceability of public investments in research for medicines in order to reflect these public investments in the availability and price setting for the general public;

Or. en

Amendment 364
Margarita de la Pisa Carrión

Motion for a resolution
Paragraph 6 a (new)

Motion for a resolution
Amendment

6a. Calls on the Commission and Member States to provide an environment that ensures Europe as an attractive location for R&D investment and
industrial development in the pharmaceutical industry;

Amendment 365
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Nicolae Ștefânuță, Chrysoyla Zacharopoulou, Frédérique Ries, Ondřej Knotek, Jan Huitema

Motion for a resolution
Paragraph 6 a (new)

Amendment 366
Cristian-Silviu Bușoi, Dan-Ștefan Motreanu

Motion for a resolution
Paragraph 6 a (new)

Amendment 367
Michèle Rivasi
on behalf of the Greens/EFA Group
Motion for a resolution
Paragraph 6 b (new)

6b. Calls on the Commission and Member States to reflect on the need for manufacturers to diversify their sources of supply for raw materials and the manufacture of health products, including the relocation of production in Europe;

Or. en

Amendment 368
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Nicolae Ștefănuță, Chrysovala Zacharopoulou, Jan Huitema

Motion for a resolution
Paragraph 6 b (new)

6b. Recalls that Articles 81 and 23a of Directive 2001/83/EC establishing a Community Code relating to medicinal products for human use have laid down general obligations for the supply of medicinal products to be borne by marketing authorization holders (MAHs) and distributors, as well as a notification obligation for MAHs in the event of a temporary or permanent supply interruption;

Or. en

Amendment 369
Kateřina Konečná

Motion for a resolution
Paragraph 6 b (new)
Motion for a resolution

Amendment

6b. Calls on the Commission and the Member States to review existing legislation to ensure effective early notification requirements to marketing authorisation holders regarding supply interruptions in order to prevent shortages;

Or. en

Amendment 370
Christophe Hansen

Motion for a resolution
Paragraph 6 b (new)

Motion for a resolution

Amendment

6b. Acknowledges that the EU’s recent trade agreements include clear rules on commercial aspects of intellectual property rights, which generally acknowledge the issuing of compulsory licences in line with the TRIPS agreement; calls upon the Commission to ensure that the implementation of the EU free trade agreements does not interfere with the possibilities of invoking flexibilities provided by the TRIPS agreement, and to provide guidance to Member States in order to encourage voluntary licencing over immediate compulsory licencing;

Or. en

Amendment 371
Alessandra Moretti

Motion for a resolution
Paragraph 6 b (new)
Motion for a resolution

Amendment

6b. Calls on Member States to require market authorisation holders to submit medicines shortage prevention plans for risk mitigation, as part of their obligation to ensure continuous supply as foreseen by Directive 2001/83; stresses the need to make such prevention plans mandatory by EU law; calls for ensuring proactive monitoring of medicines at risk of shortage at EU and national level;

Or. en

Amendment 372
César Luena

Motion for a resolution
Paragraph 6 b (new)

Motion for a resolution

Amendment

6b. Calls on the Commission to monitor compliance with Article 81 of Directive 2001/83/EC on supply shortages and to take action to remedy the shortcomings resulting from failure to comply with legislative obligations such as, for example, the imposition of financial penalties for failure to report on the interruption of supply or failure to comply with the public service obligation;

Or. es

Amendment 373
Sirpa Pietikäinen

Motion for a resolution
Paragraph 6 b (new)
Motion for a resolution

Amendment

6b. Calls on the Commission and Member States to establish a standardised, early warning system at national and EU level enhancing pharmaceutical companies’ obligations to immediately notify any interruptions of supply of medicines;

Or. en

Amendment 374
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 6 c (new)

Amendment

6c. Calls on the Commission and Member States to strengthen their work on the responsibilities of Market Authorisation Holders (MAHs) in relation to the continuous supply obligations set out in Directive 2001/83/EC (Article 81); calls on the Commission and the European Medicines Agency (EMA) to clarify these obligations into enforceable guidelines and encourage Member States ensure compliance, provide sanctions and to explore all options to ensure that continuous supplies are strengthened, particularly in relation to a European network of pharmaceutical suppliers to promote increased competition and security of supply;

Or. en

Amendment 375
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet,
Fabienne Keller, Christophe Grudler, Nicolae Ștefănuță, Chrysoula Zacharopoulou

Motion for a resolution
Paragraph 6 c (new)

Motion for a resolution Amendment

6c. Regrets, however, the disparities observed by the EMA in the transposition of these obligations into national legislations;

Or. en

Amendment 376
César Luena

Motion for a resolution
Paragraph 6 c (new)

Motion for a resolution Amendment

6c. Calls on the Commission to develop a clear definition of medicine shortages or scarcities and to address all the causes of shortages together with the Member States; calls on the Commission, in this regard, to submit a report on the impact of parallel trade and supply quotas, to explore mechanisms to address the withdrawal of effective medicines from the market for purely commercial reasons and to establish a mechanism for reporting annually on shortages of medicines across the EU;

Or. es

Amendment 377
César Luena

Motion for a resolution
Paragraph 6 d (new)
Amendment 378
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 6 d (new)

6d. Urges the Commission to establish and update together with the Member States, the EMA and the relevant stakeholders a list of essential/critical medicines in line with the WHO list, for which there should be a mandatory supply reserve to meet the needs of patients and which it should not be possible to export (e.g. vaccines) provided that the export restriction is necessary in the interest of public health and to mitigate the risk of medicine shortages; calls in this regard for the establishment of procedures for prior notification/export authorisation by wholesalers on a pre-defined list;

Or. es

Amendment 379
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet,
Motion for a resolution
Paragraph 6 d (new)

Motion for a resolution

6d. Considers that the European Green Deal constitutes a major opportunity to encourage pharmaceutical manufacturers to participate in the green recovery plan by producing in compliance with environmental and ecological standards;

Amendment 380
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, Maria Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Nicolae Ștefânuță, Chrysoula Zacharopoulou

Motion for a resolution
Paragraph 6 e (new)

Motion for a resolution

6e. Calls for the revision of Directive 2001/83/EC establishing a Community code relating to medicinal products for human use in order to ensure the notification of shortages, to strengthen the obligations incumbent on marketing authorization holders (MAHs) and to be able to ensure compliance with all of the obligations of actors in the drug supply chain;

Amendment 381
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, Maria Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Nicolae Ștefânuță, Chrysoula Zacharopoulou,
Ondřej Knotek

Motion for a resolution
Paragraph 6 f (new)

Motion for a resolution
Amendment

6f. Calls on the Commission and the Member States to encourage marketing authorisation holders (MAHs) to build up and manage rolling stocks of medicines of major therapeutic interest in the form of finished products; considers that several months of rolling stocks would make it possible to absorb the supply shortfalls and avoid the losses linked to the expiry of the medicines;

Or. en

Amendment 382
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solis Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Nicolae Ştefănuţă, Chrysoula Zacharopoulou

Motion for a resolution
Paragraph 6 g (new)

Motion for a resolution
Amendment

6g. Regrets that compliance with environmental standards (in particular the REACH Regulation) and standards relating to Corporate Social Responsibility (CSR) specific to the Union was one of the reasons of the relocation of pharmaceutical production to third countries; encourages manufacturers to guarantee the safety of their staff and the protection of the environment, in particular by prohibiting the release of toxic substances into the air and water when they relocate their production to the EU territory; considers that compliance with these standards must not lead to a significant increase in the price of
Amendment 383
Christine Schneider

Motion for a resolution
Paragraph 7

7. Notes that security of supply is an essential factor in combating shortages and must be used as a qualitative criterion in connection with the award of public pharmacy contracts and calls for tender for the supply of medicines, as recommended in Article 67 of Directive 2014/24/EU; proposes that investments in the manufacture of active ingredients and medicinal end products in the EU should also be a criterion;

Amendment

7. Notes that security of supply is an essential factor in combating shortages and must be used as a qualitative criterion in connection with the award of public pharmacy contracts and calls for tender for the supply of medicines, as recommended in Article 67 of Directive 2014/24/EU;

Amendment 384
Mairead McGuinness

Motion for a resolution
Paragraph 7

7. Notes that security of supply is an essential factor in combating shortages and must be used as a qualitative criterion in connection with the award of public pharmacy contracts and calls for tender for the supply of medicines, as recommended in Article 67 of Directive 2014/24/EU; proposes that investments in the manufacture of active ingredients and medicinal end products in the EU should also be a criterion;

Amendment

7. Notes that security of supply is an essential factor in combating shortages and must be used as a qualitative criterion in connection with the award of public pharmacy contracts and calls for tender for the supply of medicines, as recommended in Article 67 of Directive 2014/24/EU; proposes that a resilient supply chain should also be a criterion;
Amendment 385
Jessica Polfjärd

Motion for a resolution
Paragraph 7

Amendment

7. Notes that security of supply is an essential factor in combating shortages and must be used as a qualitative criterion in connection with the award of public pharmacy contracts and calls for tender for the supply of medicines, as recommended in Article 67 of Directive 2014/24/EU; proposes that investments in the manufacture of active ingredients and medicinal end products in the EU should also be a criterion;

Amendment

7. Notes that security of supply is an essential factor in combating shortages and must be used as a qualitative criterion in connection with the award of public pharmacy contracts and calls for tender for the supply of medicines, as recommended in Article 67 of Directive 2014/24/EU; emphasises the importance of diversified supplies and sustainable procurement practices;

Amendment 386
Miriam Dalli, Sara Cerdas, Nicolás González Casares, Rovana Plumb, Łukasz Kohut, Milan Brglez, Biljana Borzan, Petar Vitanov, Christel Schaldemose, Jytte Guteland, Demetris Papadakis, Tudor Ciuhodaru, Manuel Pizarro, István Ujhelyi, Mohammed Chahim, Javi López

Motion for a resolution
Paragraph 7

Amendment

7. Notes that security of supply is an essential factor in combating shortages and must be used as a qualitative criterion in connection with the award of public pharmacy contracts and calls for tender for the supply of medicines, as recommended in Article 67 of Directive 2014/24/EU; proposes that investments in the manufacture of active ingredients and medicinal end products in the EU should also be a key criterion;

Amendment

7. Notes that security of supply is an essential factor in combating shortages and must be used as a qualitative criterion in connection with the award of public pharmacy contracts and calls for European joint procurement for the supply of medicines; proposes that investments in the manufacture of active ingredients and medicinal end products in the EU should also be a key criterion;
also be a criterion;

Amendment 387
Pietro Fiocchi

Motion for a resolution
Paragraph 7

Motion for a resolution

7. Notes that security of supply is an essential factor in combating shortages and must be used as a qualitative criterion in connection with the award of public pharmacy contracts and calls for tender for the supply of medicines, as recommended in Article 67 of Directive 2014/24/EU; proposes that investments in the manufacture of active ingredients and medicinal end products in the EU should also be a criterion;

Amendment
7. Notes that security of supply is an essential factor in combating shortages and must be used as a qualitative criterion in connection with the award of public pharmacy contracts and calls for tender for the supply of medicines, as recommended in Article 67 of Directive 2014/24/EU; proposes that investments in the manufacture of active ingredients and medicinal end products to increase supply resilience should also be a criterion; urges the Commission, in the context of Directive 2014/24/EU on public procurement, to promptly propose ad-hoc guidelines for Member States to support sustainable tenders practices for pharmaceuticals;

Amendment 388
Cristian-Silviu Buşoi, Dan-Ştefan Motreanu

Motion for a resolution
Paragraph 7

Motion for a resolution

7. Notes that security of supply is an essential factor in combating shortages and must be used as a qualitative criterion in connection with the award of public pharmacy contracts and calls for tender for

Amendment
7. Notes that security of supply is an essential factor in combating shortages and must be used as a qualitative criterion in connection with the award of public pharmacy contracts and calls for tender for
the supply of medicines, as recommended in Article 67 of Directive 2014/24/EU; proposes that investments in the manufacture of active ingredients and medicinal end products in the EU should also be a criterion; in this context, urges the Commission to propose targeted guidelines for Member States to implement sustainable tenders practices for pharmaceuticals, aimed at ensuring long term sustainability, competition, security of supply and stimulating investments in manufacturing;

Amendment 389
Nathalie Colin-Oesterlé

Motion for a resolution
Paragraph 7

Motion for a resolution

7. Notes that security of supply is an essential factor in combating shortages and must be used as a qualitative criterion in connection with the award of public pharmacy contracts and calls for tender for the supply of medicines, as recommended in Article 67 of Directive 2014/24/EU; proposes that investments in the manufacture of active ingredients and medicinal end products in the EU should also be a criterion; as well as the number, location of production sites, and the application of social, environmental, ethical and quality standards;

Amendment

7. Notes that security of supply is an essential factor in combating shortages and must be used as a qualitative criterion in connection with the award of public pharmacy contracts and calls for tender for the supply of medicines, as recommended in Article 67 of Directive 2014/24/EU; proposes that investments in the manufacture of active ingredients and medicinal end products in the EU should also be a criterion as well as the number, location of production sites, and the application of social, environmental, ethical and quality standards;

Amendment 390
Michèle Rivasi
on behalf of the Greens/EFA Group
Motion for a resolution
Paragraph 7

Motion for a resolution

7. Notes that security of supply is an essential factor in combating shortages and must be used as a qualitative criterion in connection with the award of public pharmacy contracts and calls for tender for the supply of medicines, as recommended in Article 67 of Directive 2014/24/EU; proposes that investments in the manufacture of active ingredients and medicinal end products in the EU should also be a criterion;

Amendment

7. Notes that security of supply is an essential factor in combating shortages and must be used as a qualitative criterion in connection with the award of public pharmacy contracts and calls for tender for the supply of medicines, as recommended in Article 67 of Directive 2014/24/EU; other essential factors are the reinvestment of profits into R&D and promotion of affordability and accessibility; proposes that investments in the manufacture of active ingredients and medicinal end products and to increase resilience in the EU should also be a criterion;

Or. en

Amendment 391
Tiemo Wölken

Motion for a resolution
Paragraph 7

Motion for a resolution

7. Notes that security of supply is an essential factor in combating shortages and must be used as a qualitative criterion in connection with the award of public pharmacy contracts and calls for tender for the supply of medicines, as recommended in Article 67 of Directive 2014/24/EU; proposes that investments in the manufacture of active ingredients and medicinal end products in the EU should also be a criterion;

Amendment

7. Notes that security of supply is an essential factor in combating shortages and must be used as a qualitative criterion in connection with the award of public pharmacy contracts and calls for tender for the supply of medicines, as recommended in Article 67 of Directive 2014/24/EU; proposes that investments in the manufacture of active ingredients and medicinal end products to increase supply resilience should also be a criterion;

Or. en
Amendment 392
Pietro Fiocchi

Motion for a resolution
Paragraph 7a (new)

Motion for a resolution

Amendment

7a. Notes that targeted guidelines should cover clarifications and recommendations to Member States on how to implement multi-winner framework agreements, apply Most Economically Advantageous Tender (MEAT) criteria, recognise investments in security of supply for Europe; introduce sufficient manufacturing lead times that guarantee a continuous supply of medicines to patients; proportionally apply penalties that do not offset the prospective rewards for tender awardees; investigate and consider exclusion of abnormally low bids to the tender process; ensure timely procurement processes to ensure competition of multi-source medicines as soon as they are available;

Or. en

Amendment 393
Manuel Pizarro

Motion for a resolution
Paragraph 7a (new)

Motion for a resolution

Amendment

7a. Notes that for certain biological medicinal products such as blood and plasma derived medicinal products, enabling Europe to increase its capacity to collect blood and plasma will be key to reduce its dependence on plasma imports from third countries; calls on the Commission to accelerate the revision of the Blood, Tissues and Cells legislation [Directive 2002/98/EC and Directive
2004/23/EC] in order to reduce the risk of shortages of these essential life-saving medicinal products;

Or. en

Amendment 394
Frédérique Ries

Motion for a resolution
Paragraph 7 a (new)

7a. Urges the Commission, in the context of the EU public procurement Directive 2014/24/EU, to promptly propose ad-hoc guidance for Member States to support sustainable tenders practices for pharmaceuticals, where tender practices are used, notably on how to best implement the Most Economically Advantageous Tender (MEAT) criteria, looking beyond the lowest price criteria only, such as rewarding quality and security of supply investments;

Or. en

Amendment 395
João Ferreira

Motion for a resolution
Paragraph 7 a (new)

7a. Stresses that the urgent need for medicines and medical equipment must not mean compromising the quality, safety, efficacy and cost-effectiveness of medicines for human use and health products;

Or. pt
Amendment 396
Cristian-Silviu Bușoi, Dan-Ștefan Motreanu

Motion for a resolution
Paragraph 8

Motion for a resolution

8. Notes that procurement procedures with only one successful tenderer may exacerbate vulnerability should supplies be disrupted; calls on the Commission and the Member States to introduce procurement procedures under which contracts may be awarded to a number of successful tenderers, in order to maintain market competition and reduce the risk of shortages, while guaranteeing high-quality treatment for patients;

Amendment

8. Notes that procurement procedures with only one successful tenderer may exacerbate vulnerability should supplies be disrupted; acknowledges that procurement procedures under which contracts may be awarded to a number of successful tenderers could be considered in some specific cases, in order to maintain market competition and reduce the risk of shortages, while guaranteeing high-quality treatment for patients;

Or. en

Amendment 397
Peter Liese, Ljudmila Novak, Maria Spyraki, Christophe Hansen, Sunčana Glavak, Stanislav Polčák, Christian Doleschal, Lídia Pereira, Dolors Montserrat, Hildegard Bentele, Cindy Franssen, Liudas Mažylis

Motion for a resolution
Paragraph 8

Motion for a resolution

8. Notes that procurement procedures with only one successful tenderer may exacerbate vulnerability should supplies be disrupted; calls on the Commission and the Member States to introduce procurement procedures under which contracts may be awarded to a number of successful tenderers, in order to maintain market competition and reduce the risk of shortages, while guaranteeing high-quality treatment for patients;

Amendment

8. Notes that procurement procedures with only one successful tenderer with only one production site of the basic substance may exacerbate vulnerability should supplies be disrupted; calls on the Commission and the Member States to introduce procurement procedures under which contracts may be awarded to a number of successful tenderers where each has at least more than one production site in different countries (including one within the EU) for the tendered medicinal product, in order to maintain market
competition and reduce the risk of shortages, while guaranteeing high-quality treatment for patients;

Or. en

Amendment 398
Joanna Kopcińska

Motion for a resolution
Paragraph 8

Motion for a resolution
8. Notes that procurement procedures with only one successful tenderer may exacerbate vulnerability should supplies be disrupted; calls on the Commission and the Member States to introduce procurement procedures under which contracts may be awarded to a number of successful tenderers, in order to maintain market competition and reduce the risk of shortages, while guaranteeing high-quality treatment for patients;

Amendment
8. Notes that procurement procedures with only one successful tenderer may exacerbate vulnerability should supplies be disrupted; calls on the Commission and the Member States to introduce procurement procedures under which contracts may be awarded to a number of successful tenderers, including joint tenderers, in order to maintain market competition and reduce the risk of shortages, while guaranteeing high-quality treatment for patients;

Or. en

Amendment 399
Luisa Regimenti, Gianantonio Da Re, Silvia Sardone, Annalisa Tardino, Danilo Oscar Lancini, Joëlle Mélin, Annika Bruna, Catherine Griset

Motion for a resolution
Paragraph 8

Motion for a resolution
8. Notes that procurement procedures with only one successful tenderer may exacerbate vulnerability should supplies be disrupted; calls on the Commission and the Member States to introduce procurement procedures under which contracts may be awarded to a number of successful

Amendment
8. Notes that procurement procedures with only one successful tenderer may exacerbate vulnerability should supplies be disrupted; calls on the Commission and the Member States to introduce procurement procedures under which contracts may be awarded to a number of successful
tenderers, in order to maintain market competition and reduce the risk of shortages, while guaranteeing high-quality treatment for patients;

tenderers, in order to maintain market competition and reduce the risk of shortages, while guaranteeing high-quality and affordable treatment for patients;

Or. it

Amendment 400
Kateřina Konečná

Motion for a resolution
Paragraph 8

8. Notes that procurement procedures with only one successful tenderer may exacerbate vulnerability should supplies be disrupted; calls on the Commission and the Member States to introduce procurement procedures under which contracts may be awarded to a number of successful tenderers, in order to maintain market competition and reduce the risk of shortages, while guaranteeing high-quality treatment for patients;

8. Notes that procurement procedures with only one successful tenderer may exacerbate vulnerability should supplies be disrupted; calls on the Commission and the Member States to introduce procurement procedures under which contracts may be awarded to a number of successful tenderers, in order to maintain market competition and reduce the risk of shortages, while guaranteeing high-quality and affordable treatment for patients;

Or. en

Amendment 401
Piernicola Pedicini, Eleonora Evi

Motion for a resolution
Paragraph 8

8. Notes that procurement procedures with only one successful tenderer may exacerbate vulnerability should supplies be disrupted; calls on the Commission and the Member States to introduce procurement procedures under which contracts may be awarded to a number of successful tenderers, in order to maintain market competition and reduce the risk of shortages, while guaranteeing high-quality treatment for patients;

8. Notes that procurement procedures with only one successful tenderer may exacerbate vulnerability should supplies be disrupted; calls on the Commission and the Member States to introduce procurement procedures under which contracts may be awarded to a number of successful tenderers, in order to maintain market competition and reduce the risk of shortages, while guaranteeing high-quality and affordable treatment for patients;
competition and reduce the risk of shortages, while guaranteeing high-quality and affordable treatment for patients;

Amendment 402
Jessica Polfjärd

Motion for a resolution
Paragraph 8

8. Notes that procurement procedures with only one successful tenderer may exacerbate vulnerability should supplies be disrupted; calls on the Commission and the Member States to introduce procurement procedures under which contracts may be awarded to a number of successful tenderers, in order to maintain market competition and reduce the risk of shortages, while guaranteeing high-quality treatment for patients;

Amendment
8. Notes that procurement procedures with only one successful tenderer may exacerbate vulnerability should supplies be disrupted; calls on the Commission and the Member States to consider introducing procurement procedures under which contracts may be awarded to a number of successful tenderers, in order to maintain market competition and reduce the risk of shortages, while guaranteeing high-quality treatment for patients;

Amendment 403
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 8 a (new)

8a. Notes that procurement practices focusing solely on prices have resulted in manufacturers pulling out from national markets leading to a lack of competition, market consolidation and an increased risk of medicines shortages; calls on the Commission and Member States to engage in a structured exchange to apply
alternative criteria to the tendering process such as reliability of supply and the number of location and product sites;

Or. en

Amendment 404
Sirpa Pietikäinen

Motion for a resolution
Paragraph 8 a (new)

Motion for a resolution

Amendment

8a. Notes that procurement practices focusing solely on the price have resulted in manufacturers pulling out of national markets leading to market consolidation and an increasing risk of medicines shortages; calls on the Commission and Member States to engage in a structured exchange to apply other criteria than price in tendering procedures such as reliability of supply and the number and location of production sites;

Or. en

Amendment 405
João Ferreira

Motion for a resolution
Paragraph 8 a (new)

Motion for a resolution

Amendment

8a. Stresses the urgent need to ensure that pharmaceutical patents do not impede supplies in the event of a shortage of medicines; stresses the need to secure necessary supplies at times of crisis or during any present and future epidemic outbreak by replacing pharmaceutical patents for medicines, vaccines and medical equipment with licences for
public laboratories and manufacturers to supply generic copies of branded products without the need to negotiate with patent holders;

Or. pt

Amendment 406
Peter Liese, Ljudmila Novak, Maria Spyraki, Sunčana Glavak, Stanislav Polčák, Christian Doleschal, Lídia Pereira, Dolors Montserrat, Hildegard Bentele, Cindy Franssen, Liudas Mažylis

Motion for a resolution
Paragraph 8 a (new)

Motion for a resolution

8a. Ask the Commission to examine if it is possible to create a legislative framework that encourage and enables healthcare systems to do tenders that award pharmaceutical companies that guarantee the supply of pharmaceuticals in difficult circumstances by focussing on production inside the EU and guarantee at least two different sources for the basic substance; ask the Commission to examine if legislative requirements to ensure more sustainable delivery of pharmaceuticals can be mandated under EU law;

Or. en

Amendment 407
Miriam Dalli, Sara Cerdas, Nicolás González Casares, Rovana Plumb, Łukasz Kohut, Milan Brglez, Biljana Borzan, Petar Vitanov, Christel Schaldemose, Jytte Guteland, Demetris Papadakis, Tudor Ciuhodaru, Manuel Pizarro, István Ujhelyi, Mohammed Chahim, Javi López

Motion for a resolution
Paragraph 8 a (new)
Amendment 408
Adam Jarubas

Motion for a resolution
Paragraph 8 a (new)

8a. Calls on the Commission to expand its joint European response to include joint procurement actions and procedures for all developed vaccines, medication, medical equipment and medical technology; insists that this joint response be a priority post-pandemic, and be easily accessible for citizens in every Member State especially those that are particularly vulnerable from a public health and economic perspective due to their remote location or small size;

Or. en

Amendment 409
Tiemo Wölken

Motion for a resolution

8a. Recalls the existing evidence highlighting the role of sustainable procurement practices in preventing medicines shortages; calls on the Commission to support Member States in the prevention of shortages by developing ad hoc EU Guidelines on procurement of medicines, under the current public procurement directive, aimed at ensuring long-term sustainability, competition, security of supply and stimulating investments in manufacturing;

Or. en
Motion for a resolution
Paragraph 8 a (new)

Motion for a resolution
Amendment

8a. **Highlights the role that public procurement procedures by Member States’ authorities could have in reducing the risk of shortage of medicines, namely with regard to the number of production sites requested in the call for Tenders and the kind of contractual sanctions envisaged for failure to supply;**

Or. en

Amendment 410
Kateřina Konečná

Motion for a resolution
Paragraph 8 a (new)

Motion for a resolution
Amendment

8a. **Calls on the Commission and Member States to develop better procurement systems and guidance to ensure continued availability of old, generic and inexpensive medicines that are still needed in patient care;**

Or. en

Amendment 411
Alessandra Moretti

Motion for a resolution
Paragraph 8 a (new)

Motion for a resolution
Amendment

8a. **Notes that procurement practices focusing solely on price have resulted in manufacturers withdrawing from national markets leading to market consolidation**
and an increasing risk of medicines shortages; calls on the Commission and Member States to engage in a structured exchange to apply criteria other than price in tendering procedures such as reliability of supply;

Amendment 412
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 8 b (new)

Motion for a resolution

8b. Calls on the Commission to issue targeted and binding EU guidelines on the procurement of medicines, recommends that the public procurement Directive should recommend to Member States how to implement multi-winner framework agreements, applying Most Economically Advantageous Tender (MEAT) criteria and strengthen the security of medicines supply for Europe;

Amendment 413
Adam Jarubas

Motion for a resolution
Paragraph 8 b (new)

Motion for a resolution

8b. Urges the Commission, in the context of the EU public procurement Directive 2014/24/EU, to promptly propose ad-hoc guidance for Member States to support sustainable tender practices for pharmaceuticals, where
tender practices are used, notably on how to best implement the Most Economically Advantageous Tender (MEAT) criteria, looking beyond the lowest price criteria only and rewarding quality and security of supply investments;

Amendment 414
Tiemo Wölken

Motion for a resolution
Paragraph 8 b (new)

8b. Calls on the Commission to publish targeted public procurement guidelines for the pharmaceutical sector including the contribution to the security of EU supply and sufficient manufacturing lead-time to guarantee the supply of medicines for patients; underlines that these guidelines should clarify recommendations for Member States on what to consider specifically for the pharmaceutical sector whilst awarding bids; whereas the guidelines should be based on the principle of the Most economically Advantageous Tender (‘MEAT’) criteria, which aims to ensure the best value for money rather than simply the cheapest product;

Amendment 415
Pernille Weiss

Motion for a resolution
Paragraph 9
Motion for a resolution

Amendment

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Or. en

Amendment 416
Bartosz Arłukowicz

Motion for a resolution
Paragraph 9

Motion for a resolution

Amendment

9. Stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Or. pl

Amendment 417
Kateřina Konečná

Motion for a resolution
Paragraph 9
Motion for a resolution

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Amendment

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest;

Or. en

Amendment 418
Frédérique Ries

Motion for a resolution
Paragraph 9

Motion for a resolution

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Or. fr

Amendment 419
Cristian-Silviu Buşoi, Dan-Ştefan Motreanu

Motion for a resolution
Paragraph 9
9. **Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care;** 

9. Stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

**Amendment**

Or. en

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**Amendment 420**

**Aldo Patriciello**

**Motion for a resolution**

**Paragraph 9**

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; 

9. Stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

**Amendment**

Or. en

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**Amendment 421**

**Danilo Oscar Lancini**

**Motion for a resolution**

**Paragraph 9**

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; 

9. Stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

**Amendment**

Or. en
Motion for a resolution

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Amendment

9. Stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Amendment 422
Alessandra Moretti

Motion for a resolution
Paragraph 9

Motion for a resolution

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Amendment

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to address the issue of medicine shortages and contribute to the availability of medicines on the markets of different Member States;

Amendment 423
Peter Liese, Ljudmila Novak, Maria Spyraki, Christophe Hansen, Sunčana Glavak, Stanislav Polčák, Christian Doleschal, Mairead McGuinness, Lidia Pereira, Jessica Polfjärd, Dolors Montserrat, Hildegard Bentele, Liudas Mažylis
Motion for a resolution
Paragraph 9

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Amendment

9. Calls on the Commission to make concrete proposals how models of public private partnership like the US Biomedical Advanced Research and Development Authority can be established in the EU to operate in the public interest; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Or. en

Amendment 424
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 9

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Amendment

9. Calls on the Commission and the Member States to establish a network of European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines for health care; urges the Commission and Member States to ensure that algorithm based technologies used to address medicines shortages are effective and compliant with the European data protection framework;

Or. en

Amendment 425
Pietro Fiocchi
Motion for a resolution
Paragraph 9

Motion for a resolution

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Amendment

9. Calls on the Member States, in the public interest, to create long-term commitments with manufacturers to ensure medicines of strategic importance for health care and in danger of being withdrawn are maintained in the European market;

Or. en

Amendment 426
Piernicola Pedicini, Eleonora Evi

Motion for a resolution
Paragraph 9

Motion for a resolution

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Amendment

9. Calls on the Commission and the Member States to create a publicly-funded independent European pharmaceutical company, operating in the public interest by researching and manufacturing priority medicines of strategic importance but not profitable for the pharmaceutical industry, starting from rare diseases and the development of new antimicrobials; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Or. en
Amendment 427
Adam Jarubas

Motion for a resolution
Paragraph 9

Motion for a resolution

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Amendment

9. Calls on the Member States, in the public interest, to create long-term commitments with manufacturers to ensure medicines of strategic importance for health care and in danger of being withdrawn are maintained in the European market; stresses the key contribution that can be made by new technologies e.g. artificial intelligence applications, in enabling European laboratory researchers to form networks and share their objectives and findings;

Or. en

Amendment 428
Nathalie Colin-Oesterlé

Motion for a resolution
Paragraph 9

Motion for a resolution

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Amendment

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest, on the model of army or hospital pharmacies, to manufacture priority medicines of strategic importance for health care in the absence of an existing industrial production facility and ensuring security of supply; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings; calls on the Commission to make proposals on the establishment
within the Union of public-private partnerships along the lines of the US Biomedical Advanced Research and Development Authority;

Amendment 429
Joanna Kopcińska

Motion for a resolution
Paragraph 9

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Amendment
9. Calls on the Commission and the Member States to consider establishing European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; underlines the necessity of increased diversification at the European level by establishing several new manufacturing businesses to satisfy the EU’s high demand, where every product should have at least two alternative sources of production; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Amendment 430
Miriam Dalli, Sara Cerdas, Nicolás González Casares, Rovana Plumb, Łukasz Kohut, Milan Brglez, Biljana Borzan, Petar Vitanov, Christel Schaldemose, Jytte Guteland, Demetris Papadakis, Tudor Ciuhodaru, Manuel Pizarro, István Ujhelyi, Mohammed Chahim, Javi López, César Luena

Motion for a resolution
Paragraph 9
Motion for a resolution

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Amendment

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care in all Union countries irrespective of economic or spatial differences; stresses the key contribution that can be made by new technologies and artificial intelligence with proper data protection safeguards in enabling European laboratory researchers to form networks and share their objectives and findings;

Or. en

Amendment 431
Margarita de la Pisa Carrión

Motion for a resolution
Paragraph 9

Motion for a resolution

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Amendment

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care to complement the supply, in order to avoid possible shortages of medicines in case of emergency; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Or. en
Amendment 432
Tiemo Wölken

Motion for a resolution
Paragraph 9

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Amendment

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings, whilst fully respecting the General Data Protection Regulation;

Or. en

Amendment 433
Mairead McGuinness

Motion for a resolution
Paragraph 9

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Amendment

9. Calls on the Commission and the Member States to examine the possibility of creating one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Or. en
Amendment 434
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, Maria Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Nicolae Ștefănuță, Chrysoula Zacharopoulou, Frédérique Ries, Ondřej Knotek

Motion for a resolution
Paragraph 9

Motion for a resolution

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Amendment

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture medicinal products of major therapeutic interest for health care; stresses the key contribution that can be made by new technologies, digitalization and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Or. en

Amendment 435
Sirpa Pietikäinen

Motion for a resolution
Paragraph 9

Motion for a resolution

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Amendment

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of major therapeutic interest at a high risk of shortage; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;
Amendment 436
Stanislav Polčák

Motion for a resolution
Paragraph 9

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Amendment

9. Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to provide priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;

Amendment 437
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 9 a (new)

9a. Calls for full transparency at EU and Member State level through a Europe-wide medicines shortages database and an early warning system involving the main supply-chain stakeholders, including manufacturers, healthcare distributors, pharmaceutical wholesalers, pharmacists to prescribers and the competent national authorities, about existing and anticipated shortages, providing their root causes in a harmonised, comparable format;
Amendment 438
Frédérique Ries, Véronique Trillet-Lenoir

Motion for a resolution
Paragraph 9a (new)

9a. Underlines the growing success of public/private partnerships, in particular the European Innovative Medicines Initiative (IMI) within the framework of the research programme, whose aim is precisely to meet the challenge of ensuring safe and effective medicines, and believes that the scope of the IMI could be broadened, from pure research to the production of medicines;

Amendment 439
Alessandra Moretti

Motion for a resolution
Paragraph 9a (new)

9a. Stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings; urges the Commission and the Member States to ensure that algorithm-based technologies used to address medicines shortages are effective and compliant with the European Data Protection framework;
Amendment 440
Edina Tóth

Motion for a resolution
Paragraph 9 a (new)

Motion for a resolution

9a. Calls on the Commission to take action against the spread of falsified medicines from unauthorised websites and vendors that are raising concerns nowadays; this practice can cause serious harm and can lead to severe health problems or worsen the health condition of citizens; EU coordination in mapping and combatting of counterfeit of medicines is essential;

Or. en

Amendment 441
Kateřina Konečná

Motion for a resolution
Paragraph 9 a (new)

Motion for a resolution

9a. Urges the Commission and the Member States to ensure that algorithm-based technologies used to address medicines shortages are effective and compliant with the European Data Protection framework;

Or. en

Amendment 442
Cristian-Silviu Buşoi, Dan-Ştefan Motreanu

Motion for a resolution
Paragraph 10
10. Calls for links to be established between the pharmaceutical industry and other production sectors, such as farming, in a bid to develop the production of active ingredients in the EU; calls for efforts to counter over-specialisation in certain sectors and for substantial investment in research, the bioeconomy and biotechnology, for the purposes of resource diversification;

Amendment 444
Mairead McGuinness

Motion for a resolution
Paragraph 10

10. Calls for an enhanced dialogue between the pharmaceutical industry and other key stakeholders and strategic sectors, such as farming, in a bid to ensure the availability and accessibility of active ingredients in the EU; calls for substantial investment in research, the bioeconomy and biotechnology, for the purposes of resource diversification;
10. Calls for links to be *established* between the pharmaceutical industry and other production sectors, such as *farming*, in a bid to develop the production of active ingredients in the EU; calls for efforts to counter over-specialisation in certain sectors and for substantial investment in research, the bioeconomy and biotechnology, for the purposes of resource diversification;

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**Amendment**

10. Calls for links to be *encouraged* between the pharmaceutical industry and other production sectors, such as *agriculture, horticulture and forestry*, in a bid to develop the production of active ingredients in the EU; calls for efforts to counter over-specialisation in certain sectors and for substantial investment in research, the bioeconomy and biotechnology, for the purposes of resource diversification;

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**Amendment 445**

Romana Jerković

Motion for a resolution

Paragraph 10

10. Calls for links to be established between the pharmaceutical industry and other production sectors, such as farming, in a bid to develop the production of active ingredients in the EU; calls for efforts to counter over-specialisation in certain sectors and for substantial investment in research, the bioeconomy and biotechnology, for the purposes of resource diversification;

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**Amendment**

10. Calls for links to be established between the pharmaceutical industry and other production sectors, such as farming, in a bid to develop the production of active ingredients in the EU; calls for efforts to counter over-specialisation in certain sectors and for substantial investment in research, the bioeconomy and biotechnology, for the purposes of resource diversification; *considers that the industrial recovery of Europe needs to prioritize twin digital and ecological transformation of our societies and building of resilience to external shocks;*

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**Amendment 446**

Michèle Rivasi

on behalf of the Greens/EFA Group
11. Stresses the importance of research and innovation, and calls for the establishment of a genuine European network, given that the price of relocation must not be a deterioration in the quality of medical research;
network, given that the price of relocation must not be a deterioration in the quality of medical research;

highlights the value of global collaboration in research;

Amendment 449
Alessandra Moretti

Motion for a resolution
Paragraph 11

11. Stresses the importance of research and innovation, and calls for the establishment of a genuine European network, given that the price of relocation must not be a deterioration in the quality of medical research;

Amendment

11. Stresses the importance of research and innovation, including off-patent research, in order to achieve secure and appropriate availability of medicines thus guaranteeing the right to equal treatment to all patients in the EU, and calls for appropriate funding to be allocated by EU and national budgets; urges the European Commission and Member States to include availability and affordability related conditions in research funds;

Amendment 450
Jessica Polfjärd

Motion for a resolution
Paragraph 11

11. Stresses the importance of research and innovation, and calls for the establishment of a genuine European medical research network, given that the price of relocation must not be a deterioration in the quality of medical research;

Amendment

11. Stresses the importance of research and innovation, and calls for the establishment of a genuine European medical research network, in order to avoid a deterioration in the quality of European medical research;
Amendment 451
Cristian-Silviu Buşoi, Dan-Ştefan Motreanu

Motion for a resolution
Paragraph 11

Motion for a resolution

11. Stresses the importance of research and innovation, and calls for the establishment of a genuine European network, given that the price of relocation must not be a deterioration in the quality of medical research;

Amendment

11. Stresses the importance of research and innovation, and calls for the establishment of a genuine European network to support high quality medical research in Europe with an emphasis on innovation;

Or. en

Amendment 452
Miriam Dalli, Sara Cerdas, Nicolás González Casares, Rovana Plumb, Łukasz Kohut, Milan Brglez, Biljana Borzan, Petar Vitanov, Christel Schaldemose, Jytte Guteland, Demetris Papadakis, Tudor Ciuhodaru, Manuel Pizarro, István Ujhelyi, Mohammed Chahim, Javi López, César Luena

Motion for a resolution
Paragraph 11

Motion for a resolution

11. Stresses the importance of research and innovation, and calls for the establishment of a genuine European network, given that the price of relocation must not be a deterioration in the quality of medical research;

Amendment

11. Stresses the importance of research and innovation, and calls for the establishment of a genuine European network, given that the price of relocation must not be a deterioration in the quality of medical research; calls on the Commission to provide increased financial resources under Horizon Europe and other EU programmes to strengthen support for rare diseases through increased research, clinical trials, best practices sharing, and medication development; insists that best practices, clinical trials, and medication pertaining to rare diseases be available to all citizens regardless of their Member State;
Motion for a resolution
Paragraph 11

11. Stresses the importance of research and innovation, and calls for the establishment of a genuine European network, given that the price of relocation must not be a deterioration in the quality of medical research;

Amendment

11. Stresses the importance of research and innovation, and calls for the establishment of a genuine European network, given that the price of relocation must not be a deterioration in the quality of medical research, and emphasises that a stable research and development system can have a positive impact on production capacities and stability of supply; supports such an ecosystem based on stable intellectual property, targeted incentives for unmet medical needs, qualified scientific staff and robust public research institutes;

Amendment 453
Christine Schneider

Motion for a resolution
Paragraph 11

11. Stresses the importance of research and innovation, and calls for the establishment of a genuine European network, given that the price of relocation must not be a deterioration in the quality of medical research;

Amendment

11. Stresses the importance of research and innovation, and calls for the establishment of a genuine European network, given that the price of relocation must not be a deterioration in the quality of medical research, and emphasises that a stable research and development system can have a positive impact on production capacities and stability of supply; supports such an ecosystem based on stable intellectual property, targeted incentives for unmet medical needs, qualified scientific staff and robust public research institutes;

Amendment 454
Tiemo Wölken

Motion for a resolution
Paragraph 11

11. Stresses the importance of research and innovation, and calls for the establishment of a genuine European network, given that the price of relocation must not be a deterioration in the quality of medical research;

Amendment

11. Stresses the importance of research and innovation, and calls for the establishment of a genuine European network, given that the price of relocation must not be a deterioration in the quality of medical research; stresses that when research is wholly or partially funded by EU funding and other public funds, the results need to stay within the public domain and have clear affordability and
accessibility conditions attached to them;

Amendment 455
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Fredrick Federley, Billy Kelleher, Nicolae Ştefănuţă, Chrysoula Zacharopoulou, Karin Karlsbro, Frédérique Ries, Jan Huitema

Motion for a resolution
Paragraph 11


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Amendment 456
Clare Daly, Mick Wallace

Motion for a resolution
Paragraph 11


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Motion for a resolution
Paragraph 11

11. Stresses the importance of research and innovation, and calls for the establishment of a genuine European network, given that the price of relocation must not be a deterioration in the quality of medical research;
Motion for a resolution
Paragraph 11

11. Stresses the importance of research and innovation, and calls for the establishment of a genuine European network, given that the price of relocation must not be a deterioration in the quality of medical research;

Amendment

11. Stresses the importance of research and innovation, including the off-patent segment, and calls for the establishment of a genuine European network, given that the price of relocation must not be a deterioration in the quality of medical research;

Or. en

Amendment 460
Tiemo Wölken

Motion for a resolution
Paragraph 11

11. Stresses the importance of research and innovation, and calls for the establishment of a genuine European network, given that the price of relocation must not be a deterioration in the quality of medical research;

Amendment

11. Stresses the importance of high quality medical research and innovation, and calls for the establishment of a genuine European network, given that the price of relocation must not be a deterioration in the quality of medical research;

Or. en

Amendment 461
Marian-Jean Marinescu

Motion for a resolution
Paragraph 11 a (new)

11a. Calls on the Commission to take the first steps to enhance transparency of research and development costs of medicines;
Amendment 462
Esther de Lange

Motion for a resolution
Paragraph 11 a (new)

Motion for a resolution

11a. Calls on the Commission and the Member States to screen foreign direct investments in medicines manufacturing plants as part of Europe's critical health infrastructure.

Amendment 463
Cristian-Silviu Bușoi, Dan-Ștefan Motreanu

Motion for a resolution
Paragraph 11 a (new)

Motion for a resolution

11a. Stresses the importance of ensuring in times of health crisis, outbreaks and pandemics, that therapies and vaccines can become rapidly available to wider populations, particularly those with the greatest needs; acknowledges the importance of further strengthening dialogue in order to achieve this; therefore calls on the Commission to further strengthen dialogue with relevant stakeholders, with international actors to assess new treatments and vaccines as well as with the European Medicines Agency, in order to find ways to rapidly align scientific assessments between national agencies, including on collaboration in the pre-assessment phase prior to availability of critical clinical data, on the alignment of post-approval
data generation, and on flexible approaches to upscaling manufacturing of treatments and vaccines;

Amendment 464
Kateřina Konečná

Motion for a resolution
Paragraph 11 a (new)

Motion for a resolution

Amendment

11a. Calls on the Commission to ensure that, when EU public money is spent on research, the results of that research are not protected by intellectual property rights and price accessibility to patients is guaranteed for the products developed; stresses the importance of public research and development activities and institutions and of cooperation at international level, while expressing concerns over the dominant role of multinationals in the pharmaceutical sector; urges all pharmaceutical companies to pool their data and knowledge in a collective effort to identify, test, develop and manufacture vaccines and treatments to curb COVID-19;

Amendment 465
João Ferreira

Motion for a resolution
Paragraph 11 a (new)

Motion for a resolution

Amendment

11a. Stresses the need to ensure that health professionals and the general public have access to safe, effective and
good quality medicines and health products by monitoring and regulating continued compliance with good clinical practice regarding the authorisation of clinical trials and the conduct thereof, in line with the highest health protection standards;

Or. pt

Amendment 466
Tiemo Wölken

Motion for a resolution
Paragraph 11 a (new)

11a. Contends that, especially during global health emergencies, publicly-funded scientific research should not be constrained by patent protection since it may constitute an undue and disproportionate obstacle to a quicker achievement of results and be in contradiction with the purpose of public financial support, in particular tackling the urgent medicine needs of EU citizens;

Or. en

Amendment 467
Clare Daly, Mick Wallace

Motion for a resolution
Paragraph 11 a (new)

11a. Calls for reform of the TRIPS agreement so poor countries can have equitable and affordable access to the technologies and medicines they need; calls for public health medicines to be exempt from the patent system to ensure
that poor countries have the legal right to produce and import generic versions of life-saving medicines;

Or. en

Amendment 468
Mairead McGuinness

Motion for a resolution
Paragraph 11 a (new)

Motion for a resolution Amendment

11a. Notes the impact on the supply of medicines of the UK's withdrawal from the EU, particularly for Ireland, and calls for targeted actions to ensure continued and rapid access to safe medicines and medical devices for patients, including a secure and consistent supply of radioisotopes;

Or. en

Amendment 469
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 11 a (new)

Motion for a resolution Amendment

11a. Calls on the Commission and the Member States to consider implementing an EU wide formulary (list) of approved medicines, indicating which products are interchangeable and key information on the composition, description, prescribing and timely administration of medicines;

Or. en
Amendment 470
Linea Søgaard-Lidell

Motion for a resolution
Paragraph 11 a (new)

Motion for a resolution

11a. Calls for strengthening of the European Medicines Market to speed up patients’ access to medicines, make care more affordable, maximise savings in national health budgets and avoid administrative burdens for pharmaceutical companies;

Amendment

Amendment 471
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, Maria Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Fredrick Federley, Billy Kelleher, Nicolae Ștefănuță, Chrysoula Zacharopoulou, Ondřej Knotek, Karin Karlsbro

Motion for a resolution
Paragraph 11 a (new)

Motion for a resolution

11a. Calls for strengthening of the European Medicines Market to speed up patient access to medicines, make care more affordable, maximise savings in national health budgets and avoid administrative burdens for generic and biosimilar companies;

Or. en

Amendment

Amendment 472
Cindy Franssen

Motion for a resolution
Paragraph 11 a (new)
Motion for a resolution

11a. Stresses the responsibility of the pharmaceutical industry regarding shortages of medicines in order to ensure the continuity in delivering; urges the industry to make a back-up plan in case of a shortage of any medicine;

Amendment 473
Piernicola Pedicini, Eleonora Evi

Motion for a resolution
Paragraph 11 a (new)

Motion for a resolution

11a. Stresses the importance of promoting independent, peer-reviewed scientific research on the medical use of cannabis, including through the study of the effects of standardised and magistral preparations;

Amendment 474
Tiemo Wölken

Motion for a resolution
Paragraph 11 b (new)

Motion for a resolution

11b. Stresses the need to ensure adequate provisions for medicine supply chains across the EU-UK borders are included in the future relationship agreement with the United Kingdom, as well as ensuring contingency plans are in place in case of a ‘no deal’;
Amendment 475
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Nicolae Ștefănuță, Chrysoula Zacharopoulou, Ondřej Knotek, Frédérique Ries

Motion for a resolution
Paragraph 11 b (new)

11b. Points out that generic and biosimilar medicines enable increased competition, reduced prices and savings for healthcare systems, thus helping to improve access to medicines for patients

Amendment 476
Esther de Lange

Motion for a resolution
Paragraph 11 b (new)

11b. Calls on the Commission to increase its involvement in supporting critical health infrastructure protection in Member States and to start applying the European Programme for Critical Infrastructure Protection (EPCIP) to the health infrastructure sector;

Amendment 477
Piernicola Pedicini, Eleonora Evi
Motion for a resolution
Paragraph 11 b (new)

Motion for a resolution Amendment

11b. Stresses the importance of encouraging clinical trials for medicines used off-label to ensure their safe and optimal use;

Or. en

Amendment 478
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 11 b (new)

Motion for a resolution Amendment

11b. Calls for European wide tracking of public financial resources used for R&D for each medicinal product as well as final net price charged;

Or. en

Amendment 479
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Nicolae Ştefănuţă, Chrysooula Zacharopoulou, Ondřej Knotek

Motion for a resolution
Paragraph 11 c (new)

Motion for a resolution Amendment

11c. Deplores the litigation cases aiming to delay generic entry; calls on the Commission to ensure that the end of the innovator's period of commercial exclusivity is respected;
Amendment 480
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 11 c (new)

Amendment

11c. Calls for EU legislative action to ensure that reinvestment of profits, affordability and accessibility become standard requirements on contracts related to public funding for R&D of medicinal products between public institutions and pharmaceutical companies;

Amendment 481
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Fredrick Federley, Billy Kelleher, Nicolae Ștefănuță, Chrysoula Zacharopoulou, Ondřej Knotek, Karin Karlsbro

Motion for a resolution
Paragraph 11 d (new)

Amendment

11d. Stresses that the added value and economic impact of biosimilar medicines on the sustainability of healthcare systems should be analysed, their market entry should not be delayed, and, where necessary, measures to support their introduction to the market should be examined;
Amendment 482
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 11 d (new)

Motion for a resolution

Amendment

11d. Calls for additional funding into Horizon 2020 to be specifically dedicated to clinical trials and new medicinal products that have a clear societal value with public sharing of research results;

Or. en

Amendment 483
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 11 e (new)

Motion for a resolution

Amendment

11e. Calls for a revision of EU Regulation (EC) No 141/2000 on orphan medicinal products to reverse the ‘burden of proof’ for the ten-year market exclusivity clause in order that the holder of the market authorisation has to prove that the product is not sufficiently profitable to cover R&D costs;

Or. en

Amendment 484
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Nicolae Ştefănuță, Chrysovala Zacharopoulou, Frédérique Ries, Jan Huitema

Motion for a resolution
Paragraph 11 e (new)
Motion for a resolution

Amendment

11e. Calls on the Member States to adopt a common position and start negotiations on the proposal for a Regulation of the Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU;

Or. en

Amendment 485
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Nicolae Ștefânuță, Chrysoula Zacharopoulou

Motion for a resolution
Paragraph 11 f (new)

Motion for a resolution

Amendment

11f. Calls on the Commission to present a revision of Directive 89/105/EEC on the transparency of measures regulating the prices of medicinal products in order to ensure effective controls and full transparency of the procedures used to determine the prices and reimbursement of medicines in the Member States;

Or. en

Amendment 486
Margarita de la Pisa Carrión

Motion for a resolution
Subheading 2

Motion for a resolution

Amendment

More vigorous action at European level to better coordinate and supplement Member States’ health policies

More vigorous action at European level to better collaborate and supplement Member States’ health policies
Amendment 487
Cristian-Silviu Busoi, Dan-Stefan Motreanu

Motion for a resolution
Paragraph 12

Motion for a resolution
Amendment

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment 488
Nathalie Colin-Oesterle

Motion for a resolution
Paragraph 12

Motion for a resolution
Amendment

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment 489
Mairead McGuinness

Motion for a resolution
Paragraph 12

Motion for a resolution
Amendment

12. Recommends the introduction of greater transparency in the medicine production and distribution chain and the creation of a European unit for preventing and managing shortages;
Motion for a resolution

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment

12. Recommends that the Commission and the EMA work with Member States and the industry to bring about greater transparency in the distribution chain; recommends that the Commission creates a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Or. en

Amendment 490
Luisa Regimenti, Gianantonio Da Re, Silvia Sardone, Annalisa Tardino, Annika Bruna, Catherine Griset

Motion for a resolution
Paragraph 12

Motion for a resolution

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment

12. Recommends the introduction of a European database to bring about greater transparency in the distribution chain and an early warning system on shortages of existing and planned medicines to ensure that breaks in supply are better managed;

Or. it

Amendment 491
Rob Rookem

Motion for a resolution
Paragraph 12

Motion for a resolution

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment

12. Recommends greater transparency in the distribution chain to prevent and resolve breaks in supply;
supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment 492
Christophe Hansen

Motion for a resolution
Paragraph 12

Motion for a resolution

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment

12. Recommends the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment 493
Jessica Polfjärd

Motion for a resolution
Paragraph 12

Motion for a resolution

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment

12. Recommends the introduction of greater coordination and information sharing practices to bring about greater transparency in the distribution chain; notes the importance of developing a European strategy to prevent and resolve breaks in supply;
Amendment 494
Sirpa Pietikäinen

Motion for a resolution
Paragraph 12

Motion for a resolution

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment

12. Recommends the introduction of centralised management under the leadership of the European Medicines Agency (EMA) to bring about greater transparency in the production and distribution chains of medicines and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve supply disruptions;

Or. en

Amendment 495
Margarita de la Pisa Carrión

Motion for a resolution
Paragraph 12

Motion for a resolution

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment

12. Recommends the introduction of centralised management of information to bring about greater transparency in the distribution chain and the definition and development of a European strategy to prevent manage and resolve breaks in supply;

Or. en

Amendment 496
Adam Jarubas

Motion for a resolution
Paragraph 12

AM\1206741EN.docx  85/175  PE652.628v01-00
12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment

12. Recommends advancing coordination in the EU to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Or. en

Amendment 497
João Ferreira

Motion for a resolution
Paragraph 12

Motion for a resolution

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with supporting Member State strategies to prevent and resolve breaks in supply;

Or. pt

Amendment 498
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 12

Motion for a resolution

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with

Amendment

12. Recommends the introduction of centralised management under the leadership of the European Medicines Agency (EMA) to bring about greater transparency in the price-setting of
developing a European strategy to prevent and resolve breaks in supply; medicinal products and the distribution chain; also recommends the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment 499
Alessandra Moretti

Motion for a resolution
Paragraph 12

Motion for a resolution

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment

12. Calls on Member States, in close collaboration with the Commission and other affected stakeholders, to explore alternative approaches to ensuring adequate stocks, such as the effective enforcement of existing regulatory requirements on all actors in the supply chain at national level, as well as measures to increase transparency within the supply chain; recommends the introduction of centralised management under the leadership of the European Medicines Agency (EMA) to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment 500
Tiemo Wölken

Motion for a resolution
Paragraph 12
Motion for a resolution

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply; underlines that full transparency must be ensured about the causes of shortages including the market withdrawal of a medicine due to economic reasons:

Amendment

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply; underlines that full transparency must be ensured about the causes of shortages including the market withdrawal of a medicine due to economic reasons:

Or. en

Amendment 501
Danilo Oscar Lancini

Motion for a resolution
Paragraph 12

Motion for a resolution

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment

12. Recommends the introduction of centralised management to bring about greater transparency and more interaction between competent authorities and industry about potential disruption or interruption of supply in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Or. en

Amendment 502
Nicolae Ștefănuță, Véronique Trillet-Lenoir

Motion for a resolution
Paragraph 12
Motion for a resolution

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment

12. Recommends the introduction of centralised management under the leadership of the European Medicines Agency (EMA) to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Or. en

Amendment 503
Bartosz Arłukowicz

Motion for a resolution
Paragraph 12

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment

12. Recommends the introduction of centralised management, under the auspices of the European Medicines Agency (EMA), to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Or. pl

Amendment 504
Tiemo Wölken

Motion for a resolution
Paragraph 12

12. Recommends the introduction of centralised management to bring about

Amendment

12. Recommends the introduction of centralised management coordinated by
greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

the European Medicine Agency to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Or. en

Amendment 505
Joëlle Mélin

Motion for a resolution
Paragraph 12

Motion for a resolution

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment

12. Recommends the introduction of management coordinated by the ECDC or the EMA to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Or. fr

Amendment 506
Piernicola Pedicini, Eleonora Evi

Motion for a resolution
Paragraph 12

Motion for a resolution

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment

12. Recommends the introduction of centralised management under the EMA to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Or. en
Amendment 507
Andreas Glück

Motion for a resolution
Paragraph 12

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve *breaks in* supply;

Amendment

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve supply *disruptions*;

Or. en

Amendment 508
Ondřej Knotek, Véronique Trillet-Lenoir

Motion for a resolution
Paragraph 12

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve *breaks in* supply;

Amendment

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve supply *disruptions*;

Or. en

Amendment 509
Sara Cerdas

Motion for a resolution
Paragraph 12
Motion for a resolution

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve supply disruptions;

Or. en

Amendment 510
Stanislav Polčák

Motion for a resolution
Paragraph 12

Motion for a resolution

12. Recommends the introduction of centralised management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Amendment

12. Recommends the introduction of shared management to bring about greater transparency in the distribution chain and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve breaks in supply;

Or. en

Amendment 511
Jan Huitema, Véronique Trillet-Lenoir

Motion for a resolution
Paragraph 12 a (new)

Motion for a resolution

12a. Recalls that the EMA and the National Medicines Agencies have agreed on the following definition of a shortage: "a shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand at a
national level”; calls on the Commission, the EMA and the National Medicines Agencies, the Member States and the pharmaceutical supply chain actors to come up with a common definition of a shortage to better take into account patients’ needs while avoiding different national definitions and approaches;

Amendment 512
Nathalie Colin-Oesterlé
Motion for a resolution
Paragraph 12 a (new)

Amendment
12a. Calls on the Commission and the Member States to reflect on the establishment of harmonised shortage management plans obliging producers to identify medicines of major therapeutic interest requiring the introduction of preventive and corrective measures in order to avoid or alleviate any disruption in supplies;

Amendment 513
Margarita de la Pisa Carrión
Motion for a resolution
Paragraph 12 a (new)

Amendment
12a. Stresses the need to maintain open borders via green lanes, facilitating crossing borders to those pharmaceutical or medical companies distributing and supplying medicines and/or personal protection equipment (PPE), to avoid
possible shortages of medicines;

Amendment 514
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Fredrick Federley, Billy Kelleher, Nicolae Ştefănuță, Chrysoula Zacharopoulou, Karin Karlsbro, Ondřej Knotek, Frédérique Ries, Dominique Riquet, Jan Huitema

Motion for a resolution
Paragraph 12 a (new)

Motion for a resolution Amendment

12a. Welcomes the recent creation green lanes, set up to facilitate the transport of all goods, in order to allow the smooth running of the transport not only of medicines but also of raw materials, intermediate products and related materials, including packaging;

Or. en

Amendment 515
Kateřina Konečná

Motion for a resolution
Paragraph 12 a (new)

Motion for a resolution Amendment

12a. Recommends the creation of a permanent system for monitoring of medicine shortages in the EU, coordinated by the EMA, with additional resources;

Or. en
Amendment 516
Tiemo Wölken

Motion for a resolution
Paragraph 12 a (new)

Motion for a resolution

12a. Calls on the Commission and Member States to introduce mandatory shortage preventions plans for pharmaceutical companies;

Amendment

Or. en

Amendment 517
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solis Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Fredrick Federley, Billy Kelleher, Nicolae Ștefănuță, Chrysoula Zacharopoulou, Frédérique Ries, Karin Karlsbro

Motion for a resolution
Paragraph 12 b (new)

Motion for a resolution

12b. Calls for the establishment of European lists of 'medicinal products of major therapeutic interest' along the lines of the 'WHO model list of essential medicines'; suggests that the EMA shortage risk indicators (manufacturing and quality) be used to identify high risk products,

Amendment

Or. en

Amendment 518
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solis Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Nicolae Ștefănuță, Chrysoula Zacharopoulou, Ondřej Knotek

Motion for a resolution
Paragraph 12 c (new)
Motion for a resolution

12c. Calls for the introduction of a specific statute for certain mature medicines which would be accompanied by incentives for manufacturers to maintain their marketing on the European market and ensure diversification of European production;

Amendment 519
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Fredrick Federley, Billy Kelleher, Nicolae Ștefănuță, Chrysoula Zacharopoulou, Frédérique Ries, Karin Karlsbro, Ondřej Knotek, Jan Huitema

Motion for a resolution
Paragraph 12 d (new)

12d. Encourages the development of shortage prevention and management plans across all Member States; believes that these plans could result from an analysis of manufacturing and distribution risks and include measures on building up stocks, diversifying sources of supply for raw materials and creating other manufacturing sites to ensure resilience from production;

Amendment 520
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Fredrick Federley, Billy Kelleher, Nicolae Ștefănuță, Chrysoula Zacharopoulou, Ondřej Knotek, Frédérique Ries, Karin Karlsbro
Motion for a resolution
Paragraph 12 e (new)

12e. Underlines that several Member States have already established alert systems which facilitate the anticipation and prevention of shortages; calls for the establishment of alert systems to anticipate shortage of medicines at national and European levels;

Or. en

Amendment 521
Cristian-Silviu Buşoi, Dan-Ştefan Motreanu

Motion for a resolution
Paragraph 13

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

deleted

Or. en

Amendment 522
Pernille Weiss

Motion for a resolution
Paragraph 13

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

deleted
prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

Amendment 523
Nathalie Colin-Oesterlé

Motion for a resolution
Paragraph 13

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

13. calls on the Commission to establish a financial programme to build up a stock of medicines of strategic importance for health care to ensure that patients have access to treatment; calls on the Commission to examine the possibility of a harmonised price for these essential medicines in order to make up for the shortages;

Or. fr

Amendment 524
Jessica Polfjärd

Motion for a resolution
Paragraph 13

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

13. Calls on the Commission to develop European health strategies that take into particular consideration the treatment of cancer and infections and the need to counter recurrent shortages and ensure that patients have access to treatment;

Or. en
Amendment 525
Pietro Fiocchi

Motion for a resolution
Paragraph 13

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections strengthening their strategic supply chains rather than creating further concentration, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

Or. en

Amendment 526
Adam Jarubas

Motion for a resolution
Paragraph 13

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections strengthening their strategic supply chains rather than creating further concentration, in a bid to counter recurrent shortages and ensure that patients have access to treatment

Or. en

Amendment 527
Joanna Kopcińska

Motion for a resolution
Paragraph 13

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;
13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

Or. en

Amendment 528
Aldo Patriciello

Motion for a resolution
Paragraph 13

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

emphasises that any attempt at price harmonisation must be adjusted for purchasing power parity in all Member States;

Or. en

Amendment 529
Peter Liese, Inese Vaidere, Ljudmila Novak, Maria Spyraki, Christophe Hansen, Sunčana Glavak, Stanislav Polčák, Christian Doleschal, Mairéad McGuinness, Lidia Pereira, Dolores Montserrat, Hildegarde Bentele, Liudas Mažylis

Motion for a resolution
Paragraph 13
Motion for a resolution

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

Amendment

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment; calls on the Commission to also examine, whether a harmonised price for those drugs may solve the problems of shortages for those life-saving drugs;

Or. en

Amendment 530
Luisa Regimenti, Gianantonio Da Re, Silvia Sardone, Annalisa Tardino, Danilo Oscar Lancini, Joëlle Mélin, Annika Bruna, Catherine Griset

Motion for a resolution
Paragraph 13

Motion for a resolution

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

Amendment

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are tailored to the purchasing power of each Member State, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

Or. it

Amendment 531
Christophe Hansen

Motion for a resolution
Paragraph 13

Motion for a resolution

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

Amendment

13. Calls on the Commission to develop European health strategies on the
basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

Amendment 532
Edina Tóth

Motion for a resolution
Paragraph 13

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

Amendment

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

Or. en

Amendment 533
César Luena

Motion for a resolution
Paragraph 13

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

Amendment

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

Or. es
Amendment 534
Kateřina Konečná

Motion for a resolution
Paragraph 13

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

Amendment
13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer, infections, rare diseases and other areas particularly affected by shortages, whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

Or. en

Amendment 535
Mairead McGuinness

Motion for a resolution
Paragraph 13

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

Amendment
13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer, infections whose prices are harmonised, taking account of differences in clinical approach across the Member States, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

Or. en

Amendment 536
Inese Vaidere

Motion for a resolution
Paragraph 13
13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

Amendment

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices to consumers are harmonised across the Union, in a bid to counter recurrent shortages and ensure that patients have equal access to treatment;

Or. en

Amendment 537
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 13

13. Calls on the Commission to develop European health strategies on the basis of a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

Amendment

13. Calls on the Commission to develop European health strategies based on a common basket of drugs for the treatment of cancer and infections whose prices are harmonised, in a bid to counter recurrent shortages and ensure that patients have access to treatment;

Or. en

Amendment 538
Marian-Jean Marinescu

Motion for a resolution
Paragraph 13 a (new)

13a. Calls on the Commission to elaborate an European harmonised framework for a transparent pharmaceutical pricing policy taking in...
account the public money contribution for both research and subsidizing activities; moreover calls on the Commission to propose an European harmonized framework for a mechanism for national pricing and reimbursement systems in order to achieve a fair and sustainable pricing and procurement;

Or. en

Amendment 539
Inese Vaidere

Motion for a resolution
Paragraph 13 a (new)

Motion for a resolution
Amendment

13a. Calls on the Commission to further extend the joint procurement procedures on behalf of the Member States for medicines and medical equipment; particularly to establish joint procurement for medicines to treat rare diseases in order to ensure that these medicines are available in all Member States and at an equal price;

Or. en

Amendment 540
Tudor Ciuhodaru

Motion for a resolution
Paragraph 13 a (new)

Motion for a resolution
Amendment

13a. Calls on the Commission to develop a European system for monitoring the need for medicines to prevent cancer and infections, accompanied by an early warning system in case of malfunctions at European
Amendment 541
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Nicolae Ștefănuță, Chrysoula Zacharopoulou

Motion for a resolution
Paragraph 14

**Motion for a resolution**

14. Calls on the Commission to create a European contingency reserve of medicines of strategic importance for health care, supplies of which are critical, along the lines of the ‘RescEU’ mechanism, in order to alleviate shortages outside crisis periods;

**Amendment**

14. Calls on the Commission to create a European contingency reserve of medicines of strategic importance for health care, supplies of which are critical, along the lines of the ‘RescEU’ mechanism, in order to alleviate shortages outside crisis periods;

Amendment 542
Alessandra Moretti

Motion for a resolution
Paragraph 14

**Motion for a resolution**

14. Calls on the Commission to create a European contingency reserve of medicines **of strategic importance for health care, supplies of which are critical**, along the lines of the ‘RescEU’ mechanism, in order to alleviate shortages outside crisis periods;

**Amendment**

14. Calls on the Commission to create a European contingency reserve of medicines along the lines of the ‘RescEU’ mechanism, in order to alleviate shortages outside crisis periods, **and to require marketing authorization holders to ensure stocks of medicine in the form of finished product, particularly for those medicines for which no or only limited alternatives are available, and where discontinuation of supply will result in a potential risk for public health; calls on the Commission to ensure transparency around the"
functioning of this mechanism and the criteria to distribute stocks; urges the Commission to develop guidance and a monitoring system to ensure that national initiatives on stockpiling are proportionate to the needs; in this regard welcomes the Commission proposal for the EU4Health Programme;

Or. en

Amendment 543
Cristian-Silviu Bușoi, Dan-Ștefan Motreanu

Motion for a resolution
Paragraph 14

14. Calls on the Commission to create a European contingency reserve of medicines of strategic importance for health care, supplies of which are critical, along the lines of the ‘RescEU’ mechanism, in order to alleviate shortages outside crisis periods;

Amendment

14. Calls on the Commission to create a European contingency reserve of medicines of strategic importance for health care, supplies of which are critical, along the lines of the ‘RescEU’ mechanism; emphasises that such mechanism should be proportionate and appropriate, and therefore should allow sufficient time to build up (e.g. manufacturing lead times could be greater than 36 months for certain vaccines), be subject to close consultation with supply chain stakeholders before being set up, and any medicines purchased through EU mechanisms should carefully be managed with respect to shelf lives and avoidance of wastage;

Or. en

Amendment 544
Luisa Regimenti, Gianantonio Da Re, Silvia Sardone, Annalisa Tardino, Joëlle Mélin, Annika Bruna, Catherine Griset

Motion for a resolution
Paragraph 14
14. Calls on the Commission to create a European contingency reserve of medicines of strategic importance for health care, supplies of which are critical, along the lines of the ‘RescEU’ mechanism, in order to alleviate shortages outside crisis periods;

Amendment

14. Calls on the Commission to create, as part of the ‘RescEU’ mechanism, a European strategic reserve of medicines of major therapeutic importance and at high risk of shortage, to act as a contingency stock for Member States in critical situations;

Or. it

Amendment 545
João Ferreira

Motion for a resolution
Paragraph 14

Motion for a resolution

14. Calls on the Commission to create a European contingency reserve of medicines of strategic importance for health care, supplies of which are critical, along the lines of the ‘RescEU’ mechanism, in order to alleviate shortages outside crisis periods;

Amendment

14. Calls on the Commission to support the creation of Member State contingency reserves of medicines of strategic importance for health care, supplies of which are critical, along the lines of the ‘RescEU’ mechanism, in order to alleviate shortages outside crisis periods;

Or. pt

Amendment 546
Joanna Kopcińska

Motion for a resolution
Paragraph 14

Motion for a resolution

14. Calls on the Commission to create a European contingency reserve of medicines of strategic importance for health care, supplies of which are critical, along the lines of the ‘RescEU’ mechanism, in order to alleviate shortages outside crisis periods;

Amendment

14. Calls on the Commission to create a European contingency reserve of medicines of strategic importance for health care, supplies of which are critical, based on the Member States’ reserves of strategic medicines, in order to alleviate
outside crisis periods; shortages outside crisis periods;

Amendment 547
Manuel Pizarro

Motion for a resolution
Paragraph 14

Motion for a resolution

14. Calls on the Commission to create a European contingency reserve of medicines of strategic importance for health care, supplies of which are critical, along the lines of the ‘RescEU’ mechanism, in order to alleviate shortages outside crisis periods;

Amendment

14. Calls on the Commission to create a European contingency reserve of medicines of strategic importance for health care, such as the ones included in the World Health Organisation Model List of Essential Medicines for adults and for paediatric populations, supplies of which are critical, along the lines of the ‘RescEU’ mechanism, in order to alleviate shortages outside crisis periods;

Or. en

Amendment 548
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 14

Motion for a resolution

14. Calls on the Commission to create a European contingency reserve of medicines of strategic importance for health care, supplies of which are critical, along the lines of the ‘RescEU’ mechanism, in order to alleviate shortages outside crisis periods;

Amendment

14. Calls on the Commission to assess the option to create a European contingency reserve of medicines of strategic importance for health care, supplies of which are critical, along the lines of the ‘RescEU’ mechanism, in order to alleviate shortages outside crisis periods; stresses the importance of ensuring adequate consultation of patients and consumer groups in this process;

Or. en
Amendment 549
Miriam Dalli, Sara Cerdas, Nicolás González Casares, Rovana Plumb, Łukasz Kohut, Milan Brglez, Biljana Borzan, Petar Vitanov, Christel Schaldemose, Jytte Guteland, Demetris Papadakis, Tudor Ciuhodaru, Manuel Pizarro, István Ujhelyi, Mohammed Chahim, Javi López, César Luena

Motion for a resolution
Paragraph 14

14. Calls on the Commission to create a European contingency reserve of medicines of strategic importance for health care, supplies of which are critical, along the lines of the ‘RescEU’ mechanism, in order to alleviate shortages outside crisis periods; insists that the use of such a reserve be transparent, accountable, and fair for all Member States;

Amendment

14. Calls on the Commission to create a European contingency reserve of medicines of strategic importance for health care, supplies of which are critical, along the lines of the ‘RescEU’ mechanism, in order to alleviate shortages outside crisis periods; insists that the use of such a reserve be transparent, accountable, and fair for all Member States;

Amendment 550
Mairead McGuinness

Motion for a resolution
Paragraph 14

14. Calls on the Commission to create a European contingency reserve of medicines of strategic importance for health care, supplies of which are critical, along the lines of the ‘RescEU’ mechanism, in order to alleviate shortages outside crisis periods;

Amendment

14. Calls on the Commission to create a European contingency reserve of medicines of strategic importance for health care, taking account of differences in clinical approach across the Member States, supplies of which are critical, along the lines of the ‘RescEU’ mechanism, in order to alleviate shortages outside crisis periods;
Amendment 551  
Jessica Polfjärd  

Motion for a resolution  
Paragraph 14

14. Calls on the Commission to create a European contingency reserve of medicines of strategic importance for health care, supplies of which are critical, along the lines of the ‘RescEU’ mechanism, in order to alleviate shortages outside crisis periods; acknowledges that such reserves must be proportionate to their objective;

Amendment 552  
Tudor Ciuhodaru  

Motion for a resolution  
Paragraph 14

14. Calls on the Commission to create a European contingency reserve of medicines of strategic importance for health care, supplies of which are critical, along the lines of the ‘RescEU’ mechanism, in order to alleviate shortages and unjustified price hikes in such cases outside crisis periods;

Amendment 553  
Nathalie Colin-Oesterlé  

Motion for a resolution  
Paragraph 14

14. Calls on the Commission to create a European contingency reserve of medicines of strategic importance for health care, supplies of which are critical, along the lines of the ‘RescEU’ mechanism, in order to alleviate shortages and unjustified price hikes in such cases and outside crisis periods;
Motion for a resolution
Paragraph 14

14. Calls on the Commission to create a European contingency reserve of medicines of strategic importance for health care, supplies of which are critical, along the lines of the ‘RescEU’ mechanism, in order to alleviate shortages outside crisis periods; and to make it an emergency European pharmacy;

Amendment 554
Cristian-Silviu Bușoi, Dan-Ștefan Motreanu

Motion for a resolution
Paragraph 14 a (new)

14a. Calls on Member States, in close collaboration with the Commission and other affected stakeholders, to simultaneously explore alternative approaches to ensuring adequate stocks, such as the effective enforcement of existing regulatory requirements on all actors in the supply chain at national level, as well as measures to increase transparency within the supply chain;

Amendment 555
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 14 a (new)
Motion for a resolution

Amendment

14a. Calls on the Commission to ensure transparency around the functioning of RescEU and the criteria to distribute stocks; urges the Commission to develop guidance and a monitoring system to ensure that national initiatives on stockpiling are proportionate to the needs and do not create unintended consequences in other Member States;

Or. en

Amendment 556
Marian-Jean Marinescu

Motion for a resolution
Paragraph 14 a (new)

Motion for a resolution

Amendment

14a. Calls on the Commission to reinforce the harmonised definition of medicine shortage, proposed by the EMA and HMA joint task force in 2019;

Or. en

Amendment 557
Kateřina Konečná

Motion for a resolution
Paragraph 14 a (new)

Motion for a resolution

Amendment

14a. Calls on the Commission and Member States to adopt a common definition of medicines shortages in the EU, and a common minimum set of data requirements for reporting and cataloguing shortages;
Amendment 558
Cristian-Silviu Bușoi, Dan-Ștefan Motreanu

Motion for a resolution
Paragraph 14 b (new)

Amendment

14b. Recalls that EMA and National Medicines Agencies have agreed on the following definition of a shortage: “a shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand at a national level”; calls on EMA and National Medicines Agencies to revise their definition of shortages to better take into account patient need, as follows: “a shortage of a medicinal product for human use occurs when supply does not meet patient need at national level for a period of more than two weeks”;

Amendment 559
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 14 b (new)

Amendment

14b. Calls on the Commission to revise the European rules on data and market exclusivity and include an exception clause to ensure that Member States can make use of compulsory licensing for medicinal products for rare diseases and to accelerate the generic production and supply of lifesaving medicines in times of shortages;
Amendment 560
Cristian-Silviu Bușoi, Dan-Ștefan Motreanu

Motion for a resolution
Paragraph 15

15. Calls on the Commission and the Member States to adopt a joint definition of ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;

Amendment 561
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Nicolae Ștefănuță, Chrysoula Zacharopoulou

Motion for a resolution
Paragraph 15

15. Calls on the Commission and the Member States to adopt a joint definition of ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of
15. Calls on the Commission and the Member States to adopt a joint definition of ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;

Amendment 563
Danilo Oscar Lancini

Motion for a resolution
Paragraph 15

15. Calls on the Commission and the Member States to adopt a joint definition of ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;
chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;

chain; calls for a European regulatory authority to determine together with Member States the demand, to align and commit with the industry on the available capacity and lead times, and in case of gap between demand and capacity to support remediation actions via relevant regulatory flexibilities;

Or. en

Amendment 564
Jessica Polfjärd

Motion for a resolution
Paragraph 15

Motion for a resolution
Amendment

15. Calls on the Commission and the Member States to adopt a joint definition of ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;

15. Calls on the Commission and the Member States to adopt a joint definition of ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; acknowledges that the particular medicines falling under these categories may differ between Member States;

Or. en

Amendment 565
Joanna Kopcińska

Motion for a resolution
Paragraph 15

Motion for a resolution
Amendment

15. Calls on the Commission and the Member States to adopt a joint definition of ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;

15. Calls on the Commission and the Member States to adopt a joint definition of ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; acknowledges that the particular medicines falling under these categories may differ between Member States;
health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;

Amendment 566
Luisa Regimenti, Gianantonio Da Re, Silvia Sardone, Annalisa Tardino, Danilo Oscar Lancini, Joëlle Mélin, Annika Bruna, Catherine Griset

Motion for a resolution
Paragraph 15

15. Calls on the Commission and the Member States to adopt a joint definition of ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;

Or. it

Amendment 567
Rob Rooker

Motion for a resolution
Paragraph 15

15. Calls on the Commission and the Member States to adopt a joint definition of ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;
Member States to adopt a joint definition of ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;
Motion for a resolution

15. Calls on the Commission and the Member States to adopt a joint definition of ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;

Amendment

15. Calls on the Commission and the Member States to adopt a joint definition of ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for setting quotas for the allocation of medicines from that reserve to the Member States;

Or. en

Amendment 570
Stanislav Polčák

Motion for a resolution
Paragraph 15

Motion for a resolution

15. Calls on the Commission and the Member States to adopt a joint definition of ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;

Amendment

15. Calls on the Commission and the Member States to adopt a joint definition of ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for EMA to be designated to carry out the task of setting a mechanism of just distribution of medicines from that reserve to the Member States affected by disruption or shortage of supply;

Or. en

Amendment 571
Adam Jarubas
15. Calls on the Commission and the Member States to adopt a joint definition of 'medicines of strategic importance for health care' and of 'criticality', emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;

Amendment

15. Calls on the Commission and the Member States to adopt a joint definition of 'medicines of strategic importance for health care' and of 'criticality', emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European medicines supply committee to be designated to carry out the allocation of medicines from that reserve to the Member States.

Amendment 572
Mairead McGuinness

Motion for a resolution
Paragraph 15

15. Calls on the Commission and the Member States to adopt a joint definition of 'medicines of strategic importance for health care' and of 'criticality', emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;

Amendment

15. Calls on the Commission and the Member States to adopt a joint definition of 'medicines of strategic importance for health care' and of 'criticality', emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to ensure the fair and transparent allocation of medicines from that reserve to the Member States.

Amendment 573
Miriam Dalli, Sara Cerdas, Nicolás González Casares, Rovana Plumb, Łukasz Kohut,
Motion for a resolution
Paragraph 15

15. Calls on the Commission and the Member States to adopt a joint definition of ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States; calls for scheduled, independent and transparent reviews from the European regulatory authority so as to make sure designated medicinal quotas are quantifiable and puts all Member States on a level playing field and not give any advantage to one Member State over another;

Or. en

Amendment 574
Bartosz Arłukowicz

Motion for a resolution
Paragraph 15

15. Calls on the Commission and the Member States to adopt a joint definition of ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;
authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;

authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States, and which would have, in strictly defined situations, the ability to purchase medicines and distribute them to the Member States;

Amendment 575
Piernicola Pedicini, Eleonora Evi

Motion for a resolution
Paragraph 15

15. Calls on the Commission and the Member States to adopt a joint definition of ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;

Amendment
15. Calls on the Commission and the Member States to jointly adopt a consistent and workable definition of ‘medicine shortages’, ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;

Amendment 576
Alessandra Moretti

Motion for a resolution
Paragraph 15

15. Calls on the Commission and the Member States to adopt a joint definition of ‘medicines of strategic importance for'...
health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;

strategic importance for health care’ and of ‘criticality’ while taking into account patients’ needs, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;

Or. en

Amendment 577
Tiemo Wölken

Motion for a resolution
Paragraph 15

15. Calls on the Commission and the Member States to adopt a joint definition of ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;

Or. en

Amendment 578
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 15

15. Calls on the Commission and the Member States to adopt a joint definition of ‘medicine shortages’ relevant for all stakeholders and ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;
15. Calls on the Commission and the Member States to adopt a joint definition of ‘medicines of strategic importance for health care’ and of ‘criticality’, emphasising the value of these medicines for public health, the lack of alternatives and the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;

Amendment

15a. Calls for the adoption of common definitions of 'supply disruption' and 'stock-out' of medicines as well as a grid of criteria for assessing the risk associated with each of these situations;

Amendment 579
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Fredrick Federley, Billy Kelleher, Nicolae Ștefănuță, Chrysoula Zacharopoulou, Ondřej Knotek, Frédérique Ries, Karin Karlsbro, Jan Huitema

Motion for a resolution
Paragraph 15 a (new)

Amendment 580
Sirpa Pietikäinen

Motion for a resolution
Paragraph 15 a (new)
Motion for a resolution

Amendment

15a. Calls on the Commission and the Member States to adopt the following common definition of ‘medicines of major therapeutic interest’ (MMTI): medicines or classes of medicines for which an interruption of treatment is likely to jeopardise the vital prognosis of patients in the short or medium term, or represents a significant change in patient outcomes with regard to the severity or potential evolution of the disease;

Or. en

Amendment 581
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Fredrick Federley, Billy Kelleher, Nicolae Ștefănuță, Chrysoula Zacharopoulou, Karin Karlsbro, Ondřej Knotek, Frédérique Ries

Motion for a resolution
Paragraph 15 b (new)

Motion for a resolution

Amendment

15b. Calls for the adoption of a common definition of 'medicinal products of major therapeutic interest' with reference to their usefulness in public health, the absence of an alternative and the fragility of the production chain;

Or. en

Amendment 582
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Nicolae Ștefănuță, Chrysoula Zacharopoulou

Motion for a resolution
Paragraph 16
16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of stock management; **considers that the European Medicines Agency (EMA) could be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff**;

Amendment

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of stock management;

Sirpa Pietikäinen

Motion for a resolution

Paragraph 16

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice **in the area of stock management**; considers that the European Medicines Agency (EMA) **could be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff**;

Amendment

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice **by means of a European Joint Action on preventing medicine shortages and to provide for the preparation and publication of European shortage management and prevention plans by marketing authorisation holders for medicines of major therapeutic interest**; considers that the European Medicines Agency (EMA) **should be designated as the regulatory authority tasked with coordinating exchanges between Member States to preventing shortages of essential medicines, with a correspondingly wider remit and more staff**;

Or. en
Amendment 584
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 16

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice **in the area of stock management**; considers that the European Medicines Agency (EMA) could be designated as the regulatory authority tasked with **preventing** shortages of essential medicines, with a correspondingly **wider remit and more staff**;

Amendment

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice **to prevent shortages**, considers that the European Medicines Agency (EMA) could be designated as the regulatory authority tasked with **coordinating and monitoring medicines shortages at EU level during emergencies and beyond to prevent and manage** shortages of medicines, with a correspondingly **stronger mandate and better infrastructure**; reiterates that the EMA should be entirely publicly funded as a prerequisite to its independence;

Or. en

Amendment 585
Adam Jarubas

Motion for a resolution
Paragraph 16

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice **in the area of stock management**; considers that the European Medicines Agency (EMA) could be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly **wider remit and more staff**;

Amendment

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice **to prevent shortages**; considers that a **European medicines supply committee, composed of National Authorities (CMDh) and the European Medicines Agency (EMA)**, could be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly **wider remit and more staff**; **calls on the**
committee to ensure a close two way dialogue with the pharmaceutical supply chain to prevent shortages;

Amendment 586
Joanna Kopcińska

Motion for a resolution
Paragraph 16

Motion for a resolution

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of stock management; considers that the European Medicines Agency (EMA) could be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff;

Amendment

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of stock management; considers that the European Medicines Agency (EMA) could have increased resources and responsibilities to help Member States, working in conjunction with the European Centre for Disease Prevention and Control, better prevent shortages of essential life-saving medicines and commonly used drugs in light of possible future epidemics and pandemics;

Amendment 587
Piernicola Pedicini, Eleonora Evi

Motion for a resolution
Paragraph 16

Motion for a resolution

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of stock management; considers that the European Medicines Agency (EMA) could

Amendment

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of stock management; considers that the European Medicines Agency (EMA)
be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff; should be designated as the regulatory authority coordinating pan-European activity aiming at tackling medicines shortages at EU level, with a correspondingly enhanced mandate;
be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff;

_the body best suited to take the responsibility of the European response to medicines shortages_; considers that the European Medicines Agency (EMA) _should_ be designated as the regulatory authority _coordinating and monitoring medicines shortages at EU level during emergencies and beyond_, tasked _also_ with preventing shortages of essential medicines, with a correspondingly _stronger mandate_, _wider remit_, _better infrastructures_, and more staff;

**Amendment 590**

Luisa Regimenti, Gianantonio Da Re, Silvia Sardone, Annalisa Tardino, Joëlle Mélin, Annika Bruna, Catherine Griset

Motion for a resolution
Paragraph 16

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of stock management; considers that the European Medicines Agency (EMA) could be designated as the regulatory authority tasked with preventing shortages of essential medicines, _with a correspondingly wider remit and more staff_;

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of stock management; considers that the European Medicines Agency (EMA) could be designated as the regulatory authority tasked with preventing shortages of essential medicines, _at no additional cost to the Union budget_;

**Amendment 591**

Rob Rooken

Motion for a resolution
Paragraph 16
Motion for a resolution

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of stock management; considers that the European Medicines Agency (EMA) could be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff.

Amendment

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of stock management; considers that the European Medicines Agency (EMA) could be designated as the regulatory authority tasked with preventing shortages of essential medicines;

Or. en

Amendment 592
Miriam Dalli, Sara Cerdas, Nicolás González Casares, Rovana Plumb, Łukasz Kohut, Milan Brglez, Biljana Borzan, Petar Vitanov, Christel Schaldemose, Jytte Guteland, Demetris Papadakis, Tudor Ciuhodaru, Manuel Pizarro, István Ujhelyi, Mohammed Chahim, Javi López, César Luena

Motion for a resolution
Paragraph 16

16. Calls on the Commission and Member States to ensure the setting up of common, European medical stocks; calls on the Commission and the Member States to develop innovative and coordinated joint strategies and to step up exchanges of good practice in the area of stock management; stresses that ensuring all Member States have fair and transparent access to these stocks through joint European coordination is crucial to managing vulnerabilities and risks to the supply chain; considers that the European Medicines Agency (EMA) could be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff;

Amendment

16. Calls on the Commission and Member States to ensure the setting up of common, European medical stocks; calls on the Commission and the Member States to develop innovative and coordinated joint strategies and to step up exchanges of good practice in the area of stock management; stresses that ensuring all Member States have fair and transparent access to these stocks through joint European coordination is crucial to managing vulnerabilities and risks to the supply chain; considers that the European Medicines Agency (EMA) could be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff;
Amendment 593
Cristian-Silviu Bușoi, Dan-Ștefan Motreanu

Motion for a resolution
Paragraph 16

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of stock management; considers that the European Medicines Agency (EMA) could be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff;

Amendment

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of stock management; considers that the European Medicines Agency (EMA) could also be designated as the regulatory authority tasked with supporting the prevention of shortages of essential medicines through coordination across Member States, with a correspondingly wider remit and more staff; also acknowledges that the ultimate decision about what is "essential" would need to remain with Member States, due to the national therapeutic environment;

Amendment 594
Bartosz Arłukowicz

Motion for a resolution
Paragraph 16

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of stock management; considers that the European Medicines Agency (EMA) could be designated as the regulatory authority tasked with preventing shortages of

Amendment

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of stock management; considers that the European Medicines Agency (EMA) could be designated as the regulatory authority tasked with preventing shortages of
essential medicines, with a correspondingly wider remit and more staff; feels that better and closer cooperation is needed on medicine shortages between national agencies and the EMA;
European Medicines Agency (EMA) could be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff; preventing both insufficient stock and stockpiling; considers that the European Medicines Agency (EMA) could be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff;

Amendment 597
Joëlle Mélin

Motion for a resolution
Paragraph 16

Motion for a resolution

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of stock management; considers that the European Medicines Agency (EMA) could be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff;

Amendment

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of stock management; considers that the European Centre for Disease Prevention and Control (ECDC) or the European Medicines Agency (EMA) could be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff;

Or. fr

Amendment 598
Tiemo Wölken

Motion for a resolution
Paragraph 16

Motion for a resolution

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of

Amendment

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of
stock management; **considers** that the European Medicines Agency (EMA) **could** be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff; stock management; **emphasizes** that the European Medicines Agency (EMA) **should** be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff;

Amendment 599
Edina Tóth

Motion for a resolution
Paragraph 16

**Motion for a resolution**

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of **stock management**; considers that the European Medicines Agency (EMA) **could** be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff;

Amendment

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area **to prevent shortages**; considers that the European Medicines Agency (EMA) **could** be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff;

Amendment 600
Nicolae Ţăfănuţă, Véronique Trillet-Lenoir

Motion for a resolution
Paragraph 16

**Motion for a resolution**

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of **stock management**; considers that the European Medicines Agency (EMA) **could** be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff;

Amendment

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of **stock management**; considers that the European Medicines Agency (EMA) **could** be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff;
be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff; should be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff;

Amendment 601
Joëlle Mélin

Motion for a resolution
Paragraph 16

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of stock management; considers that the European Medicines Agency (EMA) could be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff;

Amendment

16. Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of stock management; considers that the European Medicines Agency (EMA) could be designated as the alert authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff;

Amendment 602
João Ferreira

Motion for a resolution
Paragraph 16 a (new)

16a. Calls on the Commission and Member States to seek closer collaboration and exchanges of best practice in efforts to mitigate the impact of medicine shortages, for example by giving pharmacists greater latitude to better manage patient care and ensure continuity of treatment;
Amendment 603
Adam Jarubas

Motion for a resolution
Paragraph 16 a (new)

16a. Following good practices of the Commission, of EMA and CMDh guidance to support availability of medicines used in the COVID-19 pandemic, calls on the Commission and relevant authorities to optimise the regulatory system and to simplify regulatory processes to ensure a reduction of the administrative burden of maintaining medicinal products on the market, to react quickly to patients’ needs and ensure prompt supply and access to high quality treatments; simplification can be achieved by amending the existing Regulation (EC) No 1234/2008 (Variations Regulation) and the Variations Classification Guidelines and making the most of the telematics tools at pan-European level;

Amendment 604
Biljana Borzan

Motion for a resolution
Paragraph 16 a (new)

16a. Points out that the EU has no equivalent of the US Biomedical Advanced Research and Development

Amendment
Authority (BARDA), which is responsible for procurement and development of countermeasures against bioterrorism, chemical, nuclear and radiological threats as well as pandemic influenza and emerging diseases; believes that the creation of an EU equivalent to BARDA should be considered;

Amendment 605
Sirpa Pietikäinen

Motion for a resolution
Paragraph 16 a (new)

16a. Calls on the Commission to study and establish a fund for orphan medicines that would be financed by the Member States, to procure collectively on behalf of the Member States the orphan medicines for all the EU;

Amendment 606
Sirpa Pietikäinen

Motion for a resolution
Paragraph 16 b (new)

16b. Calls on the Commission and the Member States to develop innovative and coordinated strategies and to step up exchanges of good practice in the area of stock management; recognises the European Medicines Agency (EMA) the body best suited to take the responsibility of the European response to medicines shortages; considers that the European
Medicines Agency (EMA) should be designated as the regulatory authority coordinating and monitoring medicines shortages at EU level during emergencies and beyond with a correspondingly stronger mandate and better infrastructure; notes that EMA should be entirely publicly funded as a prerequisite to its independence;

Or. en

Amendment 607
Adam Jarubas

Motion for a resolution
Paragraph 16 b (new)

Motion for a resolution Amendment

16b. Calls on the Commission and relevant authorities to provide regulatory flexibility to mitigate medicines shortages when they occur, by allowing targeted measures such as more flexibility for multi-language packs, different pack size and e-leaflet, to ensure that patients are able to access high-quality and safe medicines faster;

Or. en

Amendment 608
Aldo Patriciello

Motion for a resolution
Paragraph 17

Motion for a resolution Amendment

17. Calls for further invitations to tender to be issued at European level in an effort to counter shortages, as has been done following the onset of the COVID-19 virus, with simplified

deleted
procedures in the interests of improved response times;

Or. en

Amendment 609
Alessandra Moretti

Motion for a resolution
Paragraph 17

17. Calls for further invitations to tender to be issued at European level in an effort to counter shortages, as has been done following the onset of the COVID-19 virus, with simplified procedures in the interests of improved response times;

Amendment

17. Calls for further joint procurements to be issued at European level in an effort to counter shortages, as has been done following the onset of the COVID-19 virus, with simplified procedures in the interests of improved response times; calls for EU joint procurement to be used more routinely to ensure supply and access to medicines and medical devices when considered appropriate; in this regard calls on the Commission to propose a Regulation to revise the Cross Border Health Threats Decision, which establishes Joint Procurement Mechanism;

Or. en

Amendment 610
Jessica Polfjärd

Motion for a resolution
Paragraph 17

17. Calls for further invitations to tender to be issued at European level in an effort to counter shortages, as has been done following the onset of the COVID-19 virus, with simplified procedures in the interests of improved response times;

Motion for a resolution

17. Notes that it may be necessary for further invitations to tender to be issued at European level in an effort to counter shortages, as has been done following the onset of the COVID-19 virus, with simplified procedures in the interests of
interests of improved response times; acknowledges that such measures should primarily be considered to alleviate future Union-wide health crises, such as pandemics;

Amendment 611
Nathalie Colin-Oesterlé

Motion for a resolution
Paragraph 17

Motion for a resolution

17. Calls for further invitations to tender to be issued at European level in an effort to counter shortages, as has been done following the onset of the COVID-19 virus, simplifying procedures in the interests of improved response times;

Amendment

17. Calls for further invitations to tender to be issued at European level, following a reasoned opinion and under the control of the Commission, in an effort to counter shortages, as initiated for the COVID-19 virus, simplifying procedures to ensure improved response times;

Or. fr

Amendment 612
Danilo Oscar Lancini

Motion for a resolution
Paragraph 17

Motion for a resolution

17. Calls for further invitations to tender to be issued at European level in an effort to counter shortages, as has been done following the onset of the COVID-19 virus, with simplified procedures in the interests of improved response times;

Amendment

17. Recalls the invitations to tender issued at European level following the onset of the COVID-19 virus, with simplified procedures in the interests of improved response times;

Or. en
Amendment 613
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Fredrick Federley, Billy Kelleher, Nicolae Ştefănuţă, Chrysoula Zacharopoulou, Frédérique Ries, Karin Karlsbro

Motion for a resolution
Paragraph 17

    17. Calls for further *invitations to tender to be issued* at European level in an effort to counter shortages, as has been done following the onset of the COVID-19 virus, with simplified procedures in the interests of improved response times;
    17. Calls for further *joint procurements* at European level in an effort to counter shortages, as has been done following the onset of the COVID-19 virus, with simplified *and transparent* procedures in the interests of improved response times;

Amendment 614
Mairead McGuinness

Motion for a resolution
Paragraph 17

    17. Calls for further invitations to tender to be issued at European level in an effort to counter shortages, as has been done following the onset of the COVID-19 virus, with simplified procedures in the interests of improved response times;
    17. Calls for further invitations to tender to be issued at European level in an effort to counter shortages, as has been done following the onset of the COVID-19 virus, with simplified procedures in the interests of improved response times; *notes the potential for Member States, in particular smaller Member States, to use joint procurement to address affordability as a cause of shortages*;

Amendment 615
Andreas Glück
17. Calls for further invitations to tender to be issued at European level in an effort to counter shortages during a time of crisis, as has been done following the onset of the COVID-19 virus, with simplified procedures in the interests of improved response times;
virus, with simplified procedures in the interests of improved response times; of the COVID-19 virus, with simplified procedures in the interests of improved response times;

Amendment 618
Frédérique Ries, Véronique Trillet-Lenoir

Motion for a resolution
Paragraph 17

Amendment

17. Calls for further invitations to tender to be issued at European level in an effort to counter shortages, as has been done following the onset of the COVID-19 virus, simplifying procedures in the interests of improved response times;

Or. fr

Amendment 619
Tiemo Wölken

Motion for a resolution
Paragraph 17 a (new)

Amendment

17a. Calls on the Commission to consider measures such as expedient compulsory licensing of essential medicinal products on legitimate grounds of public health needs and fundamental rights as a way to allow Member States to more easily respond to shortage of medicines, including when it results from or is caused by public health crisis; recalls that this is one of the public health flexibilities in the field of patent protection already included in the World Trade Organisation’s TRIPS Agreement,
further reaffirmed by the 2001 Doha Declaration; similarly, calls on the Commission to reflect on how increasing the level of transparency of voluntary licensing agreements could improve this response strategy;

Amendment 620
Alessandra Moretti

Motion for a resolution
Paragraph 17 a (new)

Motion for a resolution
Amendment

17a. Recognises the importance of drawing lessons from the COVID-19 crisis in order to be better prepared for and deal with future pandemics more effectively; therefore calls on the Commission, in close collaboration with Member States, to launch a EU pandemic preparedness plan, in order to ensure a coordinated and effective European pandemic response, with appropriate response mechanisms already in place;

Amendment 621
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Nicolae Ștefănuță, Chrysoula Zacharopoulou, Frédérique Ries

Motion for a resolution
Paragraph 17 a (new)

Motion for a resolution
Amendment

17a. Calls for the full and rapid application of Regulation (EU) No 536/2014 of the European Parliament and
of the Council of 16 April 2014 on clinical trials for medicinal products for human use; considers that this Regulation would facilitate the launch of large clinical trials carried out in a harmonised and coordinated manner at EU level;

Amendment 622
Joëlle Mélin, Luisa Regimenti

Motion for a resolution
Paragraph 17 a (new)

17a. Calls on the Commission to encourage producers, on a voluntary basis, to introduce a labelling system - visible to and identifiable by patients/consumers - concerning the place of origin and production of medical products and active ingredients, in order to avoid the risks of falsified medicines and to meet consumers' expectations;

Amendment 623
Nicolae Ștefănuță, Véronique Trillet-Lenoir

Motion for a resolution
Paragraph 17 a (new)

17a. Calls on the Commission to speed up the implementation of the European Telematics Strategy with the aim to fully digitalize the entire regulatory system (both at EMA and national regulatory authorities level); considers that the key is to allow better coordination between authorities and industry in order to have a
more robust and prompt reaction in times of crises;

Amendment 624
Biljana Borzan
Motion for a resolution
Paragraph 17 a (new)

Motion for a resolution
Amendment
17a. Calls on the Commission and Member States to revisit the idea of transparency of net pricing and reimbursement of different treatments, to allow Member States equal footing when negotiating with pharmaceutical companies for treatments that are not jointly procured;

Amendment 625
Mairead McGuinness
Motion for a resolution
Paragraph 17 a (new)

Motion for a resolution
Amendment
17a. Calls on the Commission and the EMA to work with industry to ensure that medicines made available in one Member State are available in all other Member States, in particular smaller Member States;
Amendment 626
Radan Kanev

Motion for a resolution
Paragraph 17 a (new)

Motion for a resolution
Amendment

17a. Notes the need to assess and to promote effective stock management of medicines shortages in cases of “parallel exports” and the potential beneficial effect of generic substitution by pharmacies proved to be deficient in some member states during the spread of the COVID-19 virus;

Or. en

Amendment 627
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 17 a (new)

Motion for a resolution
Amendment

17a. Considers it essential that more focus is given to the possible illegality of supply quota systems and to whether they are used as means of pressure to introduce legislation to ban parallel exports; calls on the Commission to introduce minimum requirements for Market Authorisation Holders (MAHs) to initiate investigations to identify the true root causes of the shortages and to impose sanctions upon those manufacturers who cause shortages by failing to manufacture enough without justified reason;

Or. en
Amendment 628
Piernicola Pedicini, Eleonora Evi

Motion for a resolution
Paragraph 17 a (new)

Motion for a resolution

Amendment

17a. Calls on the Commission and the Council to assess the impact of intra-EU parallel trade and supply quotas on medicines unavailability and consumer access, in particular by addressing the issue of essential medicines disappearing from a Member States and then re-appearing at higher prices;

Or. en

Amendment 629
Christine Schneider

Motion for a resolution
Paragraph 17 a (new)

Motion for a resolution
Amendment

17a. Calls on the Commission to undertake a comprehensive study on the causes of supply shortages, taking particular account of the role of parallel trade in creating supply shortages which allows wholesalers to purchase medical products in one Member State and sell them in another;

Or. de

Amendment 630
Kateřina Konečná

Motion for a resolution
Paragraph 17 a (new)
Motion for a resolution

17a. Calls on the Commission to do a careful assessment about the impact of parallel trade on patients’ and consumers’ access to medicines in the different Member States; calls for such a study to inform the need for better guidance to Member States on parallel trade; in this regard calls on the Commission to assess the possibility of withdrawal of the movement of medicine from the restrictions applied under Articles 34 and 35 TFEU;

Or. en

Amendment 631
Cristian-Silviu Bușoi, Dan-Ștefan Motreanu

Motion for a resolution
Paragraph 17 a (new)

Motion for a resolution
17a. Stresses that, in addition to the underlying vulnerabilities that have been exposed by the COVID-19 crisis, there are also other factors that increase the risk of shortages; notes that one of these is parallel trade, whereby wholesalers are allowed to buy medical products in one Member States, and sell them in other Member States; recognises that parallel trade may be one of the reasons for the occurrence of shortages because it hinders the visibility on medicine stocks to relevant authorities; therefore, calls on the Commission and Member States to abolish the distortive effects of national schemes incentivising parallel imports from lower income to higher income Member States or imposing significant national stockpiling obligations limiting supply for other EU markets in order to ensure that medicines reach all EU
patients in a timely manner;

Amendment 632
Edina Tóth

Motion for a resolution
Paragraph 17 a (new)

Motion for a resolution

Amendment

17a. Calls on the Commission to take appropriate action on parallel trade in favour to prevent and address medicine shortages;

Amendment 633
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Nicolae Ștefănăuță, Chrysoula Zacharopoulou, Jan Huitema

Motion for a resolution
Paragraph 17 b (new)

Motion for a resolution

Amendment

17b. Notes that the differences in the price of a medicine from one Member State to another have led to the development of parallel exports, which can increase the risk of supply stress and cause of shortages; recalls that the free movement of goods within the Union allows certain wholesaler-distributors called "short-liners" to buy medicines in one Member State and to resell them more expensive in neighbouring countries; calls for the adoption of preventive measures to limit the parallel trade of medicines within the Union;
Amendment 634
Alessandra Moretti

Motion for a resolution
Paragraph 17 b (new)

Motion for a resolution

17b. Calls on the Commission and Member States to take action against the distortive effects caused by parallel imports in some Member States in order to ensure that medicines reach all patients in the EU in a timely way;

Amendment

Or. en

Amendment 635
Tiemo Wölken

Motion for a resolution
Paragraph 17 b (new)

Motion for a resolution

17b. Calls on the Commission to assess whether, for the specific purpose of safeguarding public health against the risk of essential medicines shortage, reducing the time of patent protection, as well as secondary patents, or conditioning the granting of such protection in view of the amount of production that takes place with the Union could help achieve that objective;

Amendment

Or. en

Amendment 636
Piernicola Pedicini, Eleonora Evi
18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of problems, shortages and requirements in each Member State, with a view to preventing stockpiling;

Amendment

18. Calls on the Commission to establish a transparent mechanism to monitor, assess and anticipate EU level and Member States existing and potential shortages, including by providing real data on patients’ needs and hospital capacity; all the information provided by national, regional and local authorities, as well as doctors, pharmacists and stakeholders, should be uploaded onto a common centralised digital platform, publicly available, ensuring an alignment across the data provided from different sources, as well as a streamlined and effective early warning system at both national and EU levels; welcomes the introduction by the EMA of the SPOC and i-SPOC enhanced monitoring system for availability of medicines during the COVID-19 pandemic and calls for its elaboration into a permanent standardised structure for intensifying shortage surveillance after the crisis; calls for all existing information systems to be improved so as to provide a clear overview of problems, shortages and requirements in each Member State, with a view to preventing the need for stockpiling or for export restrictions measures, which further exacerbate the problem;
an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of problems, shortages and requirements in each Member State, with a view to preventing stockpiling;

single innovative centralised digital platform for reporting and notifying harmonised information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; such a platform should be efficient, easy to work with, transparent and avoid duplications; welcomes the introduction by the EMA of the SPOC and i-SPOC systems, which should be integrated in the EU telematics strategy; calls for existing information systems to be improved so as to provide a clear overview of demand and shortages in each Member State, with a view to preventing stockpiling; in this context, encourages the Commission to make use and implement the digital and telematics tools at pan-European level, as well as to consider to amend the Regulation (EC) No.1234/2008 (Variations Regulation) and the Variations Classification Guidelines;

Amendment 638
Adam Jarubas

Motion for a resolution
Paragraph 18

Motion for a resolution

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of problems, shortages and requirements in each Member State, with a view to preventing stockpiling;

Amendment

18. Calls on the Commission to set up a single innovative centralised digital platform for reporting and notifying harmonised information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; such a platform should be efficient, easy to work with, transparent and avoid duplications; welcomes the introduction by the EMA of the SPOC and i-SPOC systems, which should be integrated in the EU telematics strategy; calls for existing information systems to be improved so as to provide a clear overview of demand and shortages in each Member State, with a view to preventing stockpiling;
stockpiling; systems to be improved so as to provide a clear overview of demand and shortages in each Member State, with a view to preventing stockpiling

Amendment 639
Stanislav Polčák

Motion for a resolution
Paragraph 18

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of problems, shortages and requirements in each Member State, with a view to preventing stockpiling;

Amendment

18. Calls on the Commission to set up an innovative centralised digital platform for sharing more standardised information provided by national agencies and all stakeholders regarding any potential disruption or interruption of supply of medicines and medical equipment at a very early stage, in order to be able to anticipate when a potential disruption is likely to turn into a shortage with an actual impact on patients; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of problems, shortages and requirements in each Member State;

Amendment 640
Ondřej Knotek, Véronique Trillet-Lenoir

Motion for a resolution
Paragraph 18

18. Calls on the Commission to set up an innovative centralised digital platform

Amendment

18. Calls on the Commission to set up an innovative centralised digital
for **sharing** information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of problems, shortages and requirements in each Member State, with a view to preventing stockpiling;

**monitoring** platform for **reporting and notifying** harmonised information provided by national agencies and all stakeholders, **including manufacturers, wholesalers and pharmacists** regarding shortages of medicines and medical equipment; **such a platform should be efficient, user-friendly and transparent**; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of problems, shortages and requirements in each Member State, with a view to preventing stockpiling;

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**Amendment 641**
Andreas Glück

**Motion for a resolution**
Paragraph 18

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of **problems**, shortages and requirements in each Member State, with a view to preventing stockpiling;

Amendment

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders **including manufacturers, wholesalers and pharmacists**, regarding shortages of medicines and medical equipment; **such a platform should be efficient, easy to work with and transparent**; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of **demands**, shortages and requirements in each Member State, with a view to preventing stockpiling;
Amendment 642
Joanna Kopcińska

Motion for a resolution
Paragraph 18

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of problems, shortages and requirements in each Member State, with a view to preventing stockpiling;

Amendment

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to intensify market surveillance and to provide a clear overview of problems, shortages and requirements in each Member State, with a view to ensuring a well-designed supply chain from the manufacturer, to the wholesaler to the healthcare entity.

Or. en

Amendment 643
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 18

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of problems, shortages and requirements in each Member State, with a view to

Amendment

18. Calls on the Commission to set up an innovative centralised digital platform for the reporting and notifying harmonised information provided by national agencies that enables those agencies and stakeholders to share information on actual or expected shortages of medicines and medical equipment as well as available stocks; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; which
Member State, with a view to preventing stockpiling;

should be integrated in the EU telematics strategy and should be interconnected with the National Medicines Verification Organisation (NMVO) system; calls for existing information systems to be improved so as to provide a clear overview of problems, shortages and available stocks in each Member State;

Or. en

Amendment 644
Bartosz Arłukowicz

Motion for a resolution
Paragraph 18

Motion for a resolution

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of difficulties, shortages and requirements in each Member State, with a view to preventing stockpiling;

Amendment

18. Calls on the Commission to set up an innovative centralised digital platform for reporting, notifying and sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; stresses that this platform should be effective, easy to use, secure and transparent; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of difficulties, shortages and requirements in each Member State, with a view to preventing stockpiling; calls on the Commission and the Member States to establish a standardised early-warning system at national and EU level, strengthening the obligations of pharmaceutical companies to immediately report any interruption in the supply of medicines;

Or. pl

Amendment 645
Nathalie Colin-Oesterlé
Motion for a resolution
Paragraph 18

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of difficulties, shortages and requirements in each Member State, with a view to preventing stockpiling;

Amendment 646
Cristian-Silviu Bușoi, Dan-Ștefan Motreanu

Motion for a resolution
Paragraph 18

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of difficulties, shortages and requirements in each Member State, with a view to preventing stockpiling; calls on the Commission and the Member States to set up an early warning system both at national and European level in order to reinforce the obligation to notify pharmaceutical companies of any interruption or tension in the supply of medicines;

Or. fr
Member State, with a view to preventing stockpiling; in particular, calls for the Commission to evaluate current projects improving information systems (including the European Medicines Agency's substance, product, organisation and referential (SPOR) data) and thereby ensure that drug shortage related use cases are prioritised;

Amendment 647
Tiemo Wölken

Motion for a resolution
Paragraph 18

Motion for a resolution

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of problems, shortages and requirements in each Member State, with a view to preventing stockpiling;

Amendment

18. Calls on the Commission to set up an innovative centralised digital platform for reporting and notifying information in a harmonised way, as well as sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; points out that such a platform should be efficient, easy to work with, transparent and avoid duplications; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be evaluated and if needed improved so as to provide a clear overview of problems, shortages and requirements in each Member State, with a view to preventing stockpiling;

Amendment 648
Alessandra Moretti

Motion for a resolution
Paragraph 18
18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of problems, shortages and requirements in each Member State, with a view to preventing stockpiling;

Amendment 649
Marian-Jean Marinescu

Motion for a resolution
Paragraph 18

18. Calls on the Commission to set up an innovative centralised digital platform, based on the existing database of the National Medicines Verification Organization for sharing information provided by national agencies and all stakeholders including manufacturers, wholesalers and pharmacists, regarding available stocks regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of problems, shortages and requirements in each Member State, with a view to preventing stockpiling;
preventing stockpiling

Amendment 650
Mairead McGuinness

Motion for a resolution
Paragraph 18

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of problems, shortages and requirements in each Member State, with a view to preventing stockpiling;

Amendment

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding demand for and shortages of medicines and medical equipment; welcomes the work of the joint EMA-HMA taskforce on the availability of medicines and introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of demand, problems, shortages and requirements in each Member State, with a view to preventing stockpiling and anticipating shortages before they occur;

Amendment 651
Miriam Dalli, Sara Cerdas, Nicolás González Casares, Rovana Plumb, Łukasz Kohut, Milan Brglez, Biljana Borzan, Petar Vitanov, Christel Schaldemose, Jytte Guteland, Demetris Papadakis, Tudor Ciuhodaru, Manuel Pizarro, István Ujhelyi, Mohammed Chahim, Javi López, César Luena

Motion for a resolution
Paragraph 18

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by

Amendment

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by
national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of problems, shortages and requirements in each Member State, with a view to preventing stockpiling;
18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of difficulties, shortages and requirements in each Member State, with a view to preventing stockpiling; and unjustified price hikes in times of crisis;

Amendment 654
Tiemo Wölken

Motion for a resolution
Paragraph 18

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of difficulties, shortages and requirements in each Member State, with a view to preventing stockpiling; and unjustified price hikes in times of crisis;

Amendment

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of difficulties, shortages and requirements in each Member State, with a view to preventing stockpiling; and unjustified price hikes in times of crisis;

Or. en
Amendment 655
Luisa Regimenti, Gianantonio Da Re, Silvia Sardone, Annalisa Tardino, Joëlle Mélin, Annika Bruna, Catherine Griset

Motion for a resolution
Paragraph 18

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of difficulties, shortages and requirements in each Member State, with a view to preventing stockpiling;

Amendment

18. Calls on the Commission to set up an innovative centralised digital platform, which can be consulted by the public, for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of difficulties, shortages and requirements in each Member State, with a view to preventing stockpiling;

Or. it

Amendment 656
Kateřina Konečná

Motion for a resolution
Paragraph 18

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of difficulties, shortages and requirements in each Member State, with a view to preventing stockpiling;

Amendment

18. Calls on the Commission to set up an innovative centralised and publicly accessible digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of difficulties, shortages and requirements in each Member State, with a view to preventing stockpiling;
Amendment 657
Cindy Franssen

Motion for a resolution
Paragraph 18

**Motion for a resolution**

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of problems, shortages and requirements in each Member State, with a view to preventing stockpiling;

**Amendment**

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding available stocks and shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of problems, shortages and requirements in each Member State, with a view to preventing stockpiling;

Amendment 658
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Nicolae Ştefănuţă, Chrysoula Zacharopoulou

Motion for a resolution
Paragraph 18

**Motion for a resolution**

18. Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as

**Amendment**

18. Calls on the Commission to set up an innovative centralised digital **monitoring** platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be
to provide a clear overview of problems, shortages and requirements in each Member State, with a view to preventing stockpiling;

Improved so as to provide a clear overview of problems, shortages and requirements in each Member State, with a view to preventing stockpiling;

Amendment 659
Véronique Trillet-Lenoir, Martin Hojsík, Susana Solís Pérez, María Soraya Rodríguez Ramos, Irena Joveva, Irène Tolleret, Bernard Guetta, Laurence Farreng, Sylvie Brunet, Fabienne Keller, Christophe Grudler, Nicolae Ştefânuţă, Chrysoula Zacharopoulou, Ondřej Knotek

Motion for a resolution
Paragraph 18 a (new)

Motion for a resolution

18a. Recommends the development of a catalogue of shortages in all the Member States which would allow the EMA to easily update its public catalogue of shortages assessed by its Committee for Medicinal Products for Human Use (CHMP) and / or its Committee for the pharmacovigilance risk assessment (PRAC);

Amendment

Or. en

Amendment 660
Esther de Lange

Motion for a resolution
Paragraph 18 a (new)

Motion for a resolution

18a. Calls for structural cooperation in the field of pharmaceutical policy between EU Member States, respecting the competences between the national and EU-level, through transparent, and where possible joint, price negotiations for medicines, especially for orphan

Amendment

Or. en
Motion for a resolution
Paragraph 18 a (new)

18a. Calls on the Commission to coordinate a Pan-European response on medicines shortages to ensure equitable and sustainable access to medicines; considers 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; stresses that this Pan-European approach must focus on coordinating Member State policy measures to address the root causes of medicines shortages;

Amendment 662
João Ferreira

Motion for a resolution
Paragraph 18 a (new)

18a. Calls on the Member States to develop effective governance systems to improve collaboration between all supply chain operators and the national
authorities in order to increase the efficiency and effectiveness of joint notification and evaluation procedures; calls on the Member States and the European Medicines Agency (EMA) to further step up their collaboration to improve notification, monitoring and reporting procedures regarding medicine shortages;

Amendment 663
Kateřina Konečná

Motion for a resolution
Paragraph 18 a (new)

Motion for a resolution
Amendment

18a. Calls on the Commission to launch a multi-stakeholder consultation platform to identify root causes, including but not limited to supply chain issues, that increase the risk of medicine shortages; considers that such a platform should include all stakeholders, including patients, health professionals and other relevant civil society organisations and focus particularly on assessing in detail the experience of patients and the impact of shortages on their health, treatment and care across the EU and across diseases;

Inese Vaidere

Amendment 664

Motion for a resolution
Paragraph 18 a (new)
Motion for a resolution

Amendment

18a. Calls on the Commission and the Member States to guarantee through the new "EU4Health" programme that equal access to treatment is available to all patients across the Union, particularly in case of severe illness, and that price of treatment does not play a role in access to quality care; urges Member States to show solidarity by increasing access to cross-border treatment;

Or. en

Amendment 665
Alessandra Moretti

Motion for a resolution
Paragraph 18 a (new)

Motion for a resolution

Amendment

18a. Calls on the Commission together with the EMA to setup a comprehensive and user-friendly database informing on expected or current medicines shortages and for it to be available to health care authorities at all levels, together with appropriate information about existing alternatives; stresses the need to ensure transparency about the causes of medicines shortages;

Or. en

Amendment 666
Margarita de la Pisa Carrión

Motion for a resolution
Paragraph 18 a (new)
Motion for a resolution

18a. Calls on the Commission and Member States to re-balance stocks based on patients’ and hospitals’ needs instead of stockpiling; notes that to ensure a fair allocation at EU level, it is necessary to have an equitable distribution of medicines based on shared protocols on the use of medicines to give priority to those who urgently require it;

Or. en

Amendment 667
Radan Kanev

Motion for a resolution
Paragraph 18 a (new)

Motion for a resolution

18a. Calls on the Commission and the Member States to adopt a joint position regarding the potential beneficial effect of common policy for medicines shortages action and promotion of generic substitution policy combined with respective limitations in cases where the substitution is not feasible;

Or. en

Amendment 668
Cristian-Silviu Busoi, Dan-Ștefan Motreanu

Motion for a resolution
Paragraph 18 a (new)

Motion for a resolution

18a. Calls on the ECDC to release modelling data about the likely progression of the COVID-19 pandemic
in each Member State as well as patient need data and hospital capacity data in the Member States;

Amendment 669
Clare Daly, Mick Wallace

Motion for a resolution
Paragraph 18 a (new)

18a. Considers it essential to abandon the public-private partnership model for the development of medicines and to sufficiently fund public research in medicines for the public good;

Amendment 670
Michèle Rivasi
on behalf of the Greens/EFA Group

Motion for a resolution
Paragraph 18 a (new)

18a. Calls on the Commission to place an obligation on all MAHs to make a formal notification of expected and potential shortages to be enshrined in EU law as well as an obligation to maintain safety stock surplus of 2-3 months for medicines of significant therapeutic interest;
Amendment 671
Piernicola Pedicini, Eleonora Evi

Motion for a resolution
Paragraph 18 a (new)

Motion for a resolution

Amendment

18a. Calls on the Commission and the Council to establish and update together with the Member States, EMA and relevant stakeholders an evolving list of essential medicines which are short of supply;

Or. en

Amendment 672
Margarita de la Pisa Carrión

Motion for a resolution
Paragraph 18 b (new)

Motion for a resolution

Amendment

18b. Stresses the need to establish proper pandemic preparedness plans under medical supervision for critical medicines at EU level based on solidarity between Member States, and ensuring that non-pandemic related medicines continue to reach the patients in need;

Or. en

Amendment 673
Clare Daly, Mick Wallace

Motion for a resolution
Paragraph 18 b (new)

Motion for a resolution

Amendment

18b. Calls for the abandonment of the Stability and Growth Pact, which has
impeded Member States from properly funding their health services, has driven the privatisation agenda, and contributed to the disastrous response of the EU to the COVID-19 pandemic;

Amendment 674
Margarita de la Pisa Carrión

Motion for a resolution
Paragraph 18 c (new)

Motion for a resolution

18c. Considers that the European Centre for Disease Control (ECDC) should release modelling data about the likely progression of the pandemic in each Member State in order to anticipate demand to adjust the manufacturing capacity and distribution channels accordingly to supply those medicines needed to the right regions at the right time;

Amendment

Or. en