



**2016/2057(INI)**

21.10.2016

# **AMENDMENTS**

## **303 - 617**

**Draft report**  
**Soledad Cabezón Ruiz**  
(PE587.690v01-00)

EU options for improving access to medicines  
(2016/2057(INI))



**Amendment 303**  
**Karl-Heinz Florenz, Peter Liese**  
**Motion for a resolution**  
**Paragraph 13**

*Motion for a resolution*

*Amendment*

**13. Believes that a fair price should cover the cost of the drug development and production, plus a margin of profit;** *deleted*

Or. de

**Amendment 304**  
**Monica Macovei**  
**Motion for a resolution**  
**Paragraph 13**

*Motion for a resolution*

*Amendment*

**13. Believes that a fair price should cover the cost of the drug development and production, plus a margin of profit;** *deleted*

Or. en

**Amendment 305**  
**Christofer Fjellner**  
**Motion for a resolution**  
**Paragraph 13**

*Motion for a resolution*

*Amendment*

**13. Believes that a fair price should cover the cost of the drug development and production, plus a margin of profit;**

**13. Believes that prices of medicines should reflect the value they bring to patients, healthcare systems as well as society, further the prices should provide an incentive to invest in new therapies;**

Or. en

**Amendment 306**  
**Nicola Caputo, Marc Tarabell, Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 13**

*Motion for a resolution*

13. Believes that a fair price should *cover the cost of the drug development and production, plus a margin of profit;*

*Amendment*

13. Believes that a fair price should *be in line with the value they bring to patients, societies and systems, as well as act as a driver to ensure patient access, reward for innovation and sustainable healthcare;*

Or. en

**Amendment 307**  
**Françoise Grossetête**

**Motion for a resolution**  
**Paragraph 13**

*Motion for a resolution*

13. Believes that a fair price should cover the cost of the drug development and production, *plus a margin of profit;*

*Amendment*

13. Believes that a fair price should cover *complex factors, such as* the cost of the drug development and production, *the risk inherent in pharmaceutical research, the added value that the treatment represents and the results for patients;*

Or. fr

**Amendment 308**  
**Margrete Auken**

**Motion for a resolution**  
**Paragraph 13**

*Motion for a resolution*

13. Believes that a fair price should cover the cost of the drug *development and* production, plus a margin of profit;

*Amendment*

13. Believes that *the failure of the market to systematically invest in needed innovation demonstrates the inefficacy of policies linking the price to the costs of R&D and that* a fair price should cover the cost of the drug production, plus a

*reasonable margin of profit; therefore calls on to the Commission and Member States to explore the implementation of delinkage mechanisms, characterized by the uncoupling of R&D costs and the end prices of health products, to finance research and development as mentioned in the report of the United Nations Secretary General's high level Panel on access to medicines - Promoting innovation and access to health technologies;*

Or. en

### **Amendment 309**

**Karin Kadenbach, Soledad Cabezón Ruiz**

#### **Motion for a resolution**

#### **Paragraph 13**

##### *Motion for a resolution*

13. Believes that a fair price should *cover* the cost of the drug development and production, *plus a margin of profit*;

##### *Amendment*

13. **13.** Believes that a fair price *for a medicine delivering additional benefit to patients* should *take into account* the cost of the drug development and production;

Or. en

### **Amendment 310**

**José Inácio Faria, Marian Harkin, Yana Toom**

#### **Motion for a resolution**

#### **Paragraph 13**

##### *Motion for a resolution*

13. Believes that a fair price should *cover* the cost of the drug development and production, *plus a margin of profit*;

##### *Amendment*

13. Believes that a fair price *for a medicine delivering additional benefit to patients* should *take into account* the cost of the drug development and production;

Or. en

**Amendment 311**  
**Carlos Zorrinho**

**Motion for a resolution**  
**Paragraph 13**

*Motion for a resolution*

13. Believes that a fair price should cover the cost of the drug development and production, plus a margin of profit;

*Amendment*

13. Believes that a fair price should cover the cost of the drug development and production, plus a margin of profit ***taking into account the public financing received in the first steps of the product development, if applicable;***

Or. en

**Amendment 312**  
**Damiano Zoffoli, Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 13**

*Motion for a resolution*

13. Believes that a fair price should cover the cost of the drug development and production, plus a margin of profit;

*Amendment*

13. Believes that a fair price ***for a medicine delivering additional benefits to patients*** should cover the cost of the drug development and production, plus a margin of profit;

Or. en

**Amendment 313**  
**Nikolay Barekov, Bolesław G. Piecha**

**Motion for a resolution**  
**Paragraph 13**

*Motion for a resolution*

13. Believes that a fair price should cover the cost of the drug development and

*Amendment*

13. Believes that a fair price should cover the cost of the drug development and

production, plus a margin of profit;

production, plus a margin of profit, *taking also into account the dedicated population, its efficiency and the level of innovation*;

Or. en

#### **Amendment 314**

**Andrey Kovatchev, Cristian-Silviu Buşoi, Kateřina Konečná, Biljana Borzan, Karin Kadenbach**

#### **Motion for a resolution**

##### **Paragraph 13**

###### *Motion for a resolution*

13. Believes that *a fair price* should cover the cost of the drug development and production, plus a margin of profit;

###### *Amendment*

13. Believes that *prices of medicines* should be adequate to the specific economic situation of the country where they are marketed;

Or. en

#### **Amendment 315**

**Annie Schreijer-Pierik**

#### **Motion for a resolution**

##### **Paragraph 13**

###### *Motion for a resolution*

13. Believes that a fair price should cover the cost of the drug development and production, plus a margin of profit;

###### *Amendment*

13. Believes that a fair price should cover the cost of the drug development and production, plus a *fair* margin of profit;

Or. nl

#### **Amendment 316**

**Cristian-Silviu Buşoi**

#### **Motion for a resolution**

##### **Paragraph 13**

*Motion for a resolution*

13. Believes that *a fair price* should cover the cost of the drug development and production, plus a margin of profit;

*Amendment*

13. Believes that *the price of a medicine* should provide an incentive for manufacturers to invest in developing new therapies and improving existing ones, while ensuring best outcomes for patients, healthcare professionals and payers;

Or. en

**Amendment 317**

**Karin Kadenbach, Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 13 a (new)**

*Motion for a resolution*

*13a. Stresses the importance of transparency across the field (including as regards clinical data, R&D costs and public funding, marketing strategies, actual prices and reimbursement levels) to improve access to medicines with additional patient and health system relevant benefits;*

Or. en

**Amendment 318**

**Biljana Borzan**

**Motion for a resolution**  
**Paragraph 13 a (new)**

*Motion for a resolution*

*13a. Underlines the importance of transparency across the field (including as regards clinical data, research and development costs and public funding, marketing strategies, pricing and reimbursement) to improve access to*

*Amendment*



*medicines with additional patient and health system relevant benefits;*

Or. en

**Amendment 319**  
**Margrete Auken**

**Motion for a resolution**  
**Paragraph 13 a (new)**

*Motion for a resolution*

*Amendment*

**13a.** *Calls on the Commission to set up, in cooperation with Member States, a public and regularly updated database with the different prices across the EU of patented and generic medicines and biosimilars, also indicating the geographical distribution of purchase and sales volumes thereof;*

Or. en

**Amendment 320**  
**Kateřina Konečn**

**Motion for a resolution**  
**Paragraph 13 a (new)**

*Motion for a resolution*

*Amendment*

**13a.** *Stresses the importance of transparency across the field (including as regards clinical data, R&D costs and public funding, marketing strategies, actual prices and reimbursement levels) to improve access to medicines with additional patient and health system relevant benefits;*

Or. en

**Amendment 321**

**José Inácio Faria, Jasenko Selimovic, Anneli Jäätteenmäki, Marian Harkin, Yana Toom**

**Motion for a resolution**

**Paragraph 13 a (new)**

*Motion for a resolution*

*Amendment*

**13a. Stresses the importance of transparency, including as regards clinical data, R&D costs and public funding, marketing strategies, actual prices and reimbursement levels, to improve access to medicines with relevant additional benefits for patient and health systems;**

Or. en

**Amendment 322**

**Soledad Cabezón Ruiz**

**Motion for a resolution**

**Paragraph 13 a (new)**

*Motion for a resolution*

*Amendment*

**13a. Points out that even when a new medicine is of high added value, prices should not be so high that they prevent sustainable access to them in the EU;**

Or. es

**Amendment 323**

**Cristian-Silviu Buşoi, Andrey Kovatchev**

**Motion for a resolution**

**Paragraph 13 a (new)**

*Motion for a resolution*

*Amendment*

**13a. points out that patient access to innovative therapies within the European**

*Union would be better supported through a differential pricing policy, which could take into account the varying levels of affordability, disease prevalence and healthcare priorities between EU Member States; calls on the Council and the Commission to build on the reflection started by the Belgian Presidency of the EU in 2010, with a view to identifying practical ways to implement differential pricing within the existing legal framework of the TFEU.*

Or. en

**Amendment 324**

**José Inácio Faria, Anneli Jäätteenmäki, Frédérique Ries, Marian Harkin, Lieve Wierinck, Yana Toom**

**Motion for a resolution  
Paragraph 13 b (new)**

*Motion for a resolution*

*Amendment*

*13b. Encourages Members States to engage in early dialogue and horizon scanning with industry, patients and payers and to anticipatorily incorporate in their determination of the cost-effectiveness of new medicines the forecasted evolution in the pharmaceutical innovation pipeline while giving due regard to budgetary impact considerations;*

Or. en

**Amendment 325**

**Soledad Cabezón Ruiz**

**Motion for a resolution  
Paragraph 13 b (new)**

*Motion for a resolution*

*Amendment*

**13b. Points out that patients are the weakest link in access to medicines and difficulties with accessing medicines should not have negative repercussions for them;**

Or. es

**Amendment 326**  
**Margrete Auken**

**Motion for a resolution**  
**Paragraph 13 b (new)**

*Motion for a resolution*

*Amendment*

**13b. Calls on the Commission to enhance detailed control of use of R&D public funding for medicines, and to make sure that research funds are not invested in marketing;**

Or. en

**Amendment 327**  
**Cristian-Silviu Buşoi, Andrey Kovatchev**

**Motion for a resolution**  
**Paragraph 13 b (new)**

*Motion for a resolution*

*Amendment*

**13b. stresses that the wide use of International Reference Pricing by EU Member States and parallel trade acts as a deterrent to differential pricing and may have a detrimental effect on patient access in low- and middle-income EU countries; calls on the Commission and Member States to explore alternatives to International Reference Pricing or, as a minimum, a more rational use of this**

*mechanism based on reference baskets representing clusters of countries with a similar socio-economic profile.*

Or. en

**Amendment 328**  
**Cristian-Silviu Buşoi, Andrey Kovatchev**

**Motion for a resolution**  
**Paragraph 13 c (new)**

*Motion for a resolution*

*Amendment*

*13c. highlights that International Reference Pricing is one of the main obstacles to the increased transparency of pharmaceutical prices; points out that confidential contractual agreements with pharmaceutical companies have proven to be a useful tool to address affordability concerns and to improve patient access to innovative therapies, mitigating the undesired effects of International Reference Pricing to some extent.*

Or. en

**Amendment 329**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 13 c (new)**

*Motion for a resolution*

*Amendment*

*13c. Points out that Directive 89/105/EEC has not been revised in 20 years, and in the meantime important changes have taken place in the medicine system in Europe;*

Or. es

**Amendment 330**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 13 d (new)**

*Motion for a resolution*

*Amendment*

**13d.** *Points out that competition among generic drugs is important when it comes to controlling public budgets and those drugs should be placed on the market without unnecessary or unjustified delays;*

Or. es

**Amendment 331**  
**Karl-Heinz Florenz, Peter Liese, Andrey Kovatchev**

**Motion for a resolution**  
**Paragraph 14**

*Motion for a resolution*

*Amendment*

14. Welcomes initiatives such as the Innovative Medicines Initiative (IMI), **but regrets that only a few of them are entirely public;**

14. Welcomes initiatives such as the Innovative Medicines Initiative (IMI), **which aim to develop new medicines that address the unmet medical needs of patients, e.g. new antimicrobial agents;**

Or. de

**Amendment 332**  
**Françoise Grossetête, Frédérique Ries, Elisabetta Gardini, Cristian-Silviu Buşoi**

**Motion for a resolution**  
**Paragraph 14**

*Motion for a resolution*

*Amendment*

14. Welcomes initiatives such as the Innovative Medicines Initiative (IMI), **but regrets that only a few of them are entirely public;**

14. Welcomes initiatives such as the Innovative Medicines Initiative (IMI), **which bring together the private and public sectors in order to stimulate research and accelerate patients' access to**

*innovative therapies;*

Or. en

**Amendment 333**

**Lieve Wierinck, Gesine Meissner, Ulrike Müller**

**Motion for a resolution**

**Paragraph 14**

*Motion for a resolution*

14. Welcomes initiatives such as the Innovative Medicines Initiative (IMI), **but regrets that only a few of them are entirely public;**

*Amendment*

14. Welcomes initiatives such as the Innovative Medicines Initiative (IMI);

Or. en

**Amendment 334**

**Margrete Auken**

**Motion for a resolution**

**Paragraph 14**

*Motion for a resolution*

14. Welcomes initiatives such as the Innovative Medicines Initiative (IMI), but regrets **that only a few of them are entirely public;**

*Amendment*

14. Welcomes initiatives such as the Innovative Medicines Initiative (IMI), but regrets **the low level of public return on public investment in the absence of access conditionalities to EU public funding;**

Or. en

**Amendment 335**

**Notis Marias**

**Motion for a resolution**

**Paragraph 14**

*Motion for a resolution*

14. Welcomes initiatives such as the Innovative Medicines Initiative (IMI), but *regrets* that only a few of them are entirely public;

*Amendment*

14. Welcomes initiatives such as the Innovative Medicines Initiative (IMI), but *deplores the fact* that only a few of them are entirely public;

Or. el

**Amendment 336**

**Lynn Boylan**

**Motion for a resolution**

**Paragraph 14**

*Motion for a resolution*

14. *Welcomes* initiatives such as the Innovative Medicines Initiative (IMI), but regrets that only a few of them are entirely public;

*Amendment*

14. *Notes* initiatives such as the Innovative Medicines Initiative (IMI), but regrets that only a few of them are entirely public;

Or. en

**Amendment 337**

**Kateřina Konečná**

**Motion for a resolution**

**Paragraph 14**

*Motion for a resolution*

14. Welcomes initiatives such as the Innovative Medicines Initiative (IMI), but regrets that only a few of them are entirely public;

*Amendment*

14. Welcomes initiatives such as the Innovative Medicines Initiative (IMI), but regrets that only a few of them are entirely public; *Recognises that pharmaceutical innovation is driven by both public and private investments in a complementary manner, and private investors carry the high risk of failure in the development stage;*

Or. en



**Amendment 338**

**Nessa Childers**

**Motion for a resolution**

**Paragraph 14**

*Motion for a resolution*

14. Welcomes initiatives such as the Innovative Medicines Initiative (IMI), but regrets that only a few of them are entirely public;

*Amendment*

14. Welcomes initiatives such as the Innovative Medicines Initiative (IMI), but regrets that only a few of them are entirely public; ***further notes that IMI2 is largely financed by EU taxpayers, stressing the necessity of enhanced EU leadership in prioritizing public health needs of IMI2 research and the inclusion of broad data sharing and pro-public health IP management policies;***

Or. en

**Amendment 339**

**Soledad Cabezón Ruiz**

**Motion for a resolution**

**Paragraph 14 – subparagraph 1 (new)**

*Motion for a resolution*

*Amendment*

***(1) Points out that originator companies are complaining about having to repeat the added value assessment for each Member State and that administrative burden can result in delays in accessing medicines;***

Or. es

**Amendment 340**

**Enrico Gasbarra**

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

*Motion for a resolution*

*Amendment*

**14a.** *Calls on the Commission to give renewed political impetus to the proposal to amend Directive 89/105, with a view to making prices more transparent and thus more affordable; calls on the Commission to increase efforts, in accordance with legislation currently in force, to guarantee public access to suitable information on the safety and effectiveness of medicines;*

Or. it

**Amendment 341**  
**Lynn Boylan**

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

*Motion for a resolution*

*Amendment*

**14a.** *Highlights with concern that IMI projects have been perceived as replicating work which individual companies would have had to undertake anyway, thereby subsidising private companies with EU money; calls on the Commission in this regard to ensure that IMI projects deliver real added-value for EU citizens*

Or. en

**Amendment 342**  
**Soledad Cabezón Ruiz**

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

*Motion for a resolution*

*Amendment*

**14a.** *Points out that an opaque and fragmented market with different medicine, authorisation and pricing and reimbursement assessments may be contributing to inefficiencies as a whole and to inequality among European citizens;*

Or. es

**Amendment 343**

**Lynn Boylan, Kateřina Konečná**

**Motion for a resolution**

**Paragraph 14 b (new)**

*Motion for a resolution*

*Amendment*

**14b.** *Calls on the EU, as a public funder of research, to require that knowledge generated from such research is made freely and widely available through publication and online access;*

Or. en

**Amendment 344**

**Soledad Cabezón Ruiz**

**Motion for a resolution**

**Paragraph 14 b (new)**

*Motion for a resolution*

*Amendment*

**14b.** *Points out the need for Member States to deal with the medicine system in a coordinated manner in order to address similar challenges;*

Or. es

**Amendment 345**  
**Nikolay Barekov, Bolesław G. Piecha**

**Motion for a resolution**  
**Paragraph 15**

*Motion for a resolution*

15. Recalls that transparency in all EU and national institutions and agencies is crucial, and that experts involved in the authorisation process should have no conflicts of interest;

*Amendment*

15. Recalls that transparency in all EU and national institutions and agencies is crucial, and that experts involved in the authorisation process, ***pricing and setting the reimbursement rates*** should have no conflicts of interest;

Or. en

**Amendment 346**  
**Margrete Auken**

**Motion for a resolution**  
**Paragraph 15**

*Motion for a resolution*

15. Recalls that transparency in all EU and national institutions and agencies is crucial, and that experts involved in the authorisation process should have no conflicts of interest;

*Amendment*

15. Recalls that transparency in all EU and national institutions and agencies is crucial ***to the well functioning of democracy***, and that experts involved in the authorisation process should have no conflicts of interest;

Or. en

**Amendment 347**  
**Andrey Kovatchev, Cristian-Silviu Buşoi, Kateřina Konečná, Biljana Borzan, Karin Kadenbach**

**Motion for a resolution**  
**Paragraph 16**

*Motion for a resolution*

16. Highlights the European procedure for joint procurement of medicines used for

*Amendment*

16. Highlights the European procedure for joint procurement of medicines used for

the acquisition of vaccines in accordance with Decision No 1082/2013/EU;

the acquisition of vaccines in accordance with Decision No 1082/2013/EU;  
***encourages the possible use of the procedure in case of shortages of infant vaccines;***

Or. en

**Amendment 348**  
**José Inácio Faria, Jasenko Selimovic**

**Motion for a resolution**  
**Paragraph 16**

*Motion for a resolution*

16. Highlights the European procedure for joint procurement of medicines used for the acquisition of vaccines in accordance with Decision No 1082/2013/EU;

*Amendment*

16. Highlights the European procedure for joint procurement of medicines used for the acquisition of vaccines in accordance with Decision No 1082/2013/EU;  
***encourages Members States to make full use of this tool;***

Or. en

**Amendment 349**  
**Alberto Cirio**

**Motion for a resolution**  
**Paragraph 16**

*Motion for a resolution*

16. Highlights the European procedure for joint procurement of ***medicines used for the acquisition of vaccines*** in accordance with Decision No 1082/2013/EU;

*Amendment*

16. Highlights the ***possibility for a voluntary*** European procedure for joint procurement of ***medical countermeasures for serious cross border health threats*** in accordance with Decision No 1082/2013/EU;

Or. en

**Amendment 350**

**Lieve Wierinck, Gesine Meissner, Frédérique Ries, Marian Harkin, Yana Toom, Jasenko Selimovic**

**Motion for a resolution**

**Paragraph 16**

*Motion for a resolution*

16. Highlights the European procedure for joint procurement of *medicines used for the acquisition of vaccines* in accordance with Decision No 1082/2013/EU;

*Amendment*

16. Highlights the European procedure for joint procurement of *medical countermeasures for serious cross border health threats* in accordance with Decision No 1082/2013/EU;

Or. en

**Amendment 351**

**Cristian-Silviu Buşoi, Andrey Kovatchev**

**Motion for a resolution**

**Paragraph 16 a (new)**

*Motion for a resolution*

*Amendment*

*16a. recalls the importance of the digital health agenda and the need to prioritise the development and the implementation of eHealth and mHealth related solutions to ensure safe, reliable, accessible, modern and sustainable new health care models to patients, care givers, healthcare professionals and payers;*

Or. en

**Amendment 352**

**Lynn Boylan, Kateřina Konečná**

**Motion for a resolution**

**Paragraph 16 a (new)**

*Motion for a resolution*

*Amendment*

**16a.** *Highlights the negative impact that Member States' austerity policies and budgetary cuts have had on citizens access to healthcare and access to medicines; condemns the situation which has been fostered in healthcare systems whereby the value of a life is equated to wealth, whereby those who are financially better off can receive faster and better quality treatment than those on lower incomes;*

Or. en

**Amendment 353**  
**Francesc Gambús**

**Motion for a resolution**  
**Paragraph 16 a (new)**

*Motion for a resolution*

*Amendment*

**16a.** *Calls on the Commission to study the coordination of drug procurement among the Member States that have signed the joint procurement agreement, particularly for diseases such as hepatitis C, Crimean–Congo haemorrhagic fever and enteroviruses;*

Or. es

**Amendment 354**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 16 a (new)**

*Motion for a resolution*

*Amendment*

**16a.** *Points out that the entry of generic drugs into the Market may lead to a 25%*

*price reduction in the first year and 40% in the second, and a 20% saving in the first year and 25% in the second, and that there is concern that placing drugs of that type on the market is not as fast as it should be, as it takes seven months on average from the end of the originator's exclusive licence;*

Or. es

**Amendment 355**

**José Inácio Faria**

**Motion for a resolution**

**Paragraph 16 a (new)**

*Motion for a resolution*

*Amendment*

*16a. Notes with concern that the EU lags behind the USA in what regards a standardized and transparent reporting mechanism on the causes of medicines shortages; invites the Commission and Member States to propose and put in place such an instrument for evidence-based policy-making;*

Or. en

**Amendment 356**

**Elisabetta Gardini, Cristian-Silviu Buşoi, Alojz Peterle, Giovanni La Via, Alberto Cirio, Aldo Patriciello, Alessandra Mussolini**

**Motion for a resolution**

**Paragraph 16 a (new)**

*Motion for a resolution*

*Amendment*

*16a. Highlights the role of the European Union in monitoring and providing guidance on economic policies within the framework of the European Semester, and welcomes the production of country-specific recommendations in the*



*field of healthcare sustainability;*

Or. en

**Amendment 357**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 16 a (new)**

*Motion for a resolution*

*Amendment*

**16a. Recalls the lack of transparency - among Member States on the reimbursement systems and the delay in the marketing authorisation go against the Directive 89/105/CEE;**

Or. en

**Amendment 358**  
**Daciana Octavia Sârbu**

**Motion for a resolution**  
**Paragraph 16 a (new)**

*Motion for a resolution*

*Amendment*

**16a. Points out that improved coordination between national HTAs could reduce the time taken for medicines to become available to patients;**

Or. en

**Amendment 359**  
**Carlos Zorrinho**

**Motion for a resolution**  
**Paragraph 16 a (new)**

*Motion for a resolution*

*Amendment*

**16a.** *Underlines the need for further cooperation at EU level to improve access to medicines;*

Or. en

**Amendment 360**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 16 b (new)**

*Motion for a resolution*

*Amendment*

**16b.** *Recalls that the Doha Declaration of 30 August 2003 on the TRIPS Agreement and public health ‘clarifies’ that: ‘the Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health for all. The TRIPS Agreement does not and should not prevent members from taking measures to protect public health and, in particular, to promote access to medicines for all’;*

Or. es

**Amendment 361**  
**José Inácio Faria**

**Motion for a resolution**  
**Paragraph 16 b (new)**

*Motion for a resolution*

*Amendment*

**16b.** *Highlights the role of the European Union in monitoring and providing guidance on economic policies within the framework of the European Semester, and welcomes the adoption of country-specific recommendations in the*

*area of healthcare systems sustainability;*

Or. en

**Amendment 362**  
**Lynn Boylan, Kateřina Konečná**

**Motion for a resolution**  
**Paragraph 16 b (new)**

*Motion for a resolution*

*Amendment*

***16b. Condemns the transforming of health as an inherent right for all people, to a market based commodity that is subject to cost and profiteering which creates a social divide by promoting differential treatment based on a patient's ability to pay;***

Or. en

**Amendment 363**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 16 b (new)**

*Motion for a resolution*

*Amendment*

***16b. Notes that the ERIPID project needs more transparency from Members States to include the real prices paid by them;***

Or. en

**Amendment 364**  
**Herbert Dorfmann**

**Motion for a resolution**  
**Subheading 6 a (new)**

*Motion for a resolution*

*Amendment*

***Calls for regulations in the cross-border trade of medicines to ensure that patients living in a Member State other than their usual Member State of residence have access to them;***

Or. de

**Amendment 365**

**Damiano Zoffoli, Soledad Cabezón Ruiz**

**Motion for a resolution**

**Paragraph 17**

*Motion for a resolution*

17. Calls for EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, and to guarantee the sustainability of EU public health care systems;

*Amendment*

17. Calls for EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, and to guarantee the sustainability of EU public health care systems; ***stresses that patient access to medical products is a shared responsibility of all actors of the healthcare system, including national authorities, physicians, patient organizations and manufacturers, and that optimal solutions for patient access can better emerge through collaboration between these stakeholders.***

***Stress the important to enhance voluntary cooperation between member states aimed at greater transparency, to safeguard common interests as well as ensuring the sustainability of national health system.***

Or. en

**Amendment 366**

**Cristian-Silviu Buşoi**

**Motion for a resolution**  
**Paragraph 17**

*Motion for a resolution*

17. Calls for EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, **and** to guarantee the sustainability of EU public health care systems;

*Amendment*

17. calls for EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, to guarantee the sustainability of EU public health care systems **and to ensure future investment in pharmaceutical innovation**;

Or. en

**Amendment 367**  
**Notis Marias**

**Motion for a resolution**  
**Paragraph 17**

*Motion for a resolution*

17. Calls for EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, and to guarantee the sustainability of EU public health care systems;

*Amendment*

17. Calls for EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, and to guarantee the sustainability of EU public health care systems, **and also for funding by the Union for investment in research and for the improvement of the health systems of its Member States**;

Or. el

**Amendment 368**  
**Margrete Auken**

**Motion for a resolution**  
**Paragraph 17**

*Motion for a resolution*

17. Calls **for EU-wide** measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, and to guarantee the sustainability of EU public health care systems;

*Amendment*

17. Calls **on the Commission to ensure the implementation of** measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, and to guarantee the sustainability of EU public health care systems;

Or. en

**Amendment 369**

**Andrey Kovatchev, Cristian-Silviu Buşoi, Kateřina Konečná**

**Motion for a resolution**

**Paragraph 17**

*Motion for a resolution*

17. Calls for EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, **and** to guarantee the sustainability of EU public health care systems;

*Amendment*

17. Calls for EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, to guarantee the sustainability of EU public health care systems, **and to ensure future investment in pharmaceutical innovation;**

Or. en

**Amendment 370**

**Karl-Heinz Florenz, Peter Liese, Andrey Kovatchev**

**Motion for a resolution**

**Paragraph 17**

*Motion for a resolution*

17. Calls for EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative

*Amendment*

17. Calls for **national and, if necessary,** EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely

therapies, and to guarantee the sustainability of EU public health care systems;

access to essential and innovative therapies, and to guarantee the sustainability of EU public health care systems;

Or. de

**Amendment 371**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 17**

*Motion for a resolution*

17. Calls for EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, and to guarantee the sustainability of EU public health care systems;

*Amendment*

17. Calls for EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, and to guarantee the sustainability of EU public health care systems ***and industry competitiveness***

Or. en

**Amendment 372**  
**Georg Mayer**

**Motion for a resolution**  
**Paragraph 17**

*Motion for a resolution*

17. Calls for EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, and to guarantee the sustainability of EU public health care systems;

*Amendment*

17. Calls for EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, and to guarantee the sustainability of ***public health care systems in EU Member States***;

Or. de

## **Amendment 373**

**Aldo Patriciello**

### **Motion for a resolution**

#### **Paragraph 17**

##### *Motion for a resolution*

17. Calls for EU-wide measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, and to guarantee the sustainability of EU public health care systems;

##### *Amendment*

17. Calls for EU-wide measures to guarantee the right of patients to universal, affordable, **equal**, effective, safe and timely access to essential and innovative therapies, and to guarantee the sustainability of EU public health care systems;

Or. it

## **Amendment 374**

**Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn**

### **Motion for a resolution**

#### **Paragraph 17**

##### *Motion for a resolution*

17. Calls for **EU-wide** measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, and to guarantee the sustainability of EU public health care systems;

##### *Amendment*

17. Calls for **Member States to take** measures to guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, and to guarantee the sustainability of EU public health care systems;

Or. fr

## **Amendment 375**

**Christofer Fjellner**

### **Motion for a resolution**

#### **Paragraph 17**

##### *Motion for a resolution*

17. Calls for **EU-wide** measures to

##### *Amendment*

17. Calls for measures to guarantee the



guarantee the right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, and to guarantee the sustainability of EU public health care systems;

right of patients to universal, affordable, effective, safe and timely access to essential and innovative therapies, and to guarantee the sustainability of EU public health care systems;

Or. en

#### **Amendment 376**

**Piernicola Pedicini, Eleonora Evi, Marco Affronte**

#### **Motion for a resolution**

#### **Paragraph 17a (new)**

*Motion for a resolution*

*Amendment*

***17a. Calls on the Commission to launch a public consultation open to all stakeholders aimed at considering the creation of a European Public Pharmaceutical Company, with the main minimum objective of remedying the absence of the private sector of the pharmaceuticals industry when it comes to conditions for which the market does not offer a sufficient economic return;***

Or. it

#### **Amendment 377**

**Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn**

#### **Motion for a resolution**

#### **Paragraph 17 a (new)**

*Motion for a resolution*

*Amendment*

***17a. Stresses that as a result of austerity and its consequences on health systems (including frequent pharmaceutical product reimbursement reversals), Europeans are increasingly often obliged to give up medical care and/or pharmaceutical treatments which***

*they need;*

Or. fr

**Amendment 378**  
**Nicola Caputo, Marc Tarabella**

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

*Motion for a resolution*

*Amendment*

**17a. Encourages Member States to evaluate healthcare pathways and policies with a view to improving patient outcomes and the financial sustainability of the system notably by fostering digital solutions to improve healthcare delivery to patients and identify waste of resources;**

Or. en

**Amendment 379**  
**Eva Kaili**

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

*Motion for a resolution*

*Amendment*

**17a. Highlights the role of the European Union in monitoring and providing guidance on economic policies within the framework of the European Semester and welcomes the production of country-specific recommendations in the field of healthcare sustainability;**

Or. en

**Amendment 380**  
**Piernicola Pedicini, Eleonora Evi, Marco Affronte**

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

*Motion for a resolution*

*Amendment*

**17b.** *Calls on the Commission and the Member States to take the first step towards creating a European Public Pharmaceutical Company, by creating a central European facility from which to buy medicines, starting with life-saving medicines, price differences for which cannot be tolerated within the EU;*

Or. it

**Amendment 381**  
**Margrete Auken**

**Motion for a resolution**  
**Paragraph 18**

*Motion for a resolution*

*Amendment*

18. *Calls for EU-wide measures on the pharmaceutical market to reinforce the negotiation capacities of Member States in order to achieve fair prices for medicines;*

18. *Calls on the Member States, in cooperation with the Commission, to join forces to reinforce the negotiation capacities of Member States in order to achieve availability and fair prices of medicines all across the EU;*

Or. en

**Amendment 382**  
**Christofer Fjellner**

**Motion for a resolution**  
**Paragraph 18**

*Motion for a resolution*

*Amendment*

18. *Calls for EU-wide measures on the pharmaceutical market to reinforce the negotiation capacities of Member States in order to achieve fair prices for medicines;*

18. *Calls for measures to facilitate negotiation capacities of Member States in order to ensure patient access to medicines;*

**Amendment 383**

**Elisabetta Gardini, Cristian-Silviu Buşoi, Alojz Peterle, Giovanni La Via, Aldo Patriciello, Alessandra Mussolini**

**Motion for a resolution**

**Paragraph 18**

*Motion for a resolution*

18. Calls for EU-wide measures on the pharmaceutical market to reinforce the negotiation capacities of Member States in order to *achieve fair prices for* medicines;

*Amendment*

18. Calls for EU-wide measures on the pharmaceutical market to reinforce the negotiation capacities of Member States in order to *ensure fast and equitable access to innovative* medicines;

Or. en

**Amendment 384**

**Eva Kaili**

**Motion for a resolution**

**Paragraph 18**

*Motion for a resolution*

18. Calls for EU-wide measures on the pharmaceutical market to reinforce the negotiation capacities of Member States in order to *achieve fair prices for* medicines;

*Amendment*

18. Calls for EU-wide measures on the pharmaceutical market to reinforce the negotiation capacities of Member States in order to *ensure fast and equitable access to innovative* medicines;

Or. en

**Amendment 385**

**Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn**

**Motion for a resolution**

**Paragraph 18**

*Motion for a resolution*

18. Calls for **EU-wide** measures on the pharmaceutical market **to** reinforce the negotiation capacities of Member States in order to achieve fair prices for medicines;

*Amendment*

18. Calls for **every Member State to adopt** measures on the pharmaceutical market; **stresses that they must** reinforce the negotiation capacities of Member States in order to achieve fair prices for medicines;

Or. fr

**Amendment 386**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 18**

*Motion for a resolution*

18. Calls for EU-wide measures on the pharmaceutical market to reinforce the negotiation capacities of Member States in order to achieve fair prices for medicines;

*Amendment*

18. Calls for EU-wide measures on the pharmaceutical market to reinforce the negotiation capacities of Member States in order to achieve fair prices for medicines, **health systems sustainability; to reach fair prices of medicines and to promote sustainable and qualitative innovation and research as well as the competitiveness on industry**

Or. en

**Amendment 387**  
**Karl-Heinz Florenz, Peter Liese, Andrey Kovatchev**

**Motion for a resolution**  
**Paragraph 18**

*Motion for a resolution*

18. Calls for EU-wide measures on the pharmaceutical market to reinforce the negotiation capacities of Member States in order to achieve fair prices for medicines;

*Amendment*

18. Calls for EU-wide measures on the pharmaceutical market to reinforce the negotiation capacities of Member States in order to achieve fair prices for medicines, **including by strengthening collaborations**

*in health technology assessment (HTA)  
and evaluating its relative effectiveness at  
EU level;*

Or. de

**Amendment 388**  
**György Hölvényi**

**Motion for a resolution**  
**Paragraph 18**

*Motion for a resolution*

18. Calls for EU-wide measures on the pharmaceutical market to reinforce the negotiation capacities of Member States in order to achieve fair prices for medicines;

*Amendment*

18. Calls for EU-wide ***and regional*** measures on the pharmaceutical market to reinforce the negotiation capacities of Member States in order to achieve fair prices for medicines;

Or. en

**Amendment 389**  
**Lieve Wierinck, Frédérique Ries, José Inácio Faria, Marian Harkin**

**Motion for a resolution**  
**Paragraph 18**

*Motion for a resolution*

18. Calls for EU-wide measures on the pharmaceutical market to reinforce the negotiation capacities of Member States in order to achieve fair prices for medicines;

*Amendment*

18. Calls for EU-wide measures on the pharmaceutical market to reinforce the negotiation capacities of Member States in order to achieve fair prices for medicines, ***such as the initiative of the Benelux countries and Austria on rare diseases;***

Or. en

**Amendment 390**  
**Glenis Willmott**

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

*Motion for a resolution*

*Amendment*

**18 a. Welcomes the Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines and calls on the Commission and on Member States to take steps to implement the recommendations made therein;**

Or. en

**Amendment 391**  
**Alberto Cirio**

**Motion for a resolution**  
**Paragraph 19**

*Motion for a resolution*

*Amendment*

**19. Calls on the Commission to promote R&D driven by patients' needs, while fostering social responsibility in the pharmaceutical sector, by setting up an EU public platform for R&D funded by contributions from profits made by the pharmaceutical industry through sales to public health systems; calls for transparency on the costs of R&D;**

*deleted*

Or. en

**Amendment 392**  
**Margrete Auken**

**Motion for a resolution**  
**Paragraph 19**

*Motion for a resolution*

*Amendment*

19. Calls on the Commission to promote R&D driven by patients' needs, while fostering social responsibility in the

19. Calls on the Commission to promote **transparency on the costs of R&D and to promote** R&D driven by

pharmaceutical sector, by setting up an EU public platform *for R&D funded by contributions from profits made by the pharmaceutical industry through sales to public health systems; calls for transparency on the costs of R&D;*

patients' needs, while fostering social responsibility in the pharmaceutical sector, by setting up an EU public platform *aiming at defining EU public health needs in a democratic and inclusive way based on:*

*- analysis of the sales volumes for each medicine and for each therapeutic indication, to the extent possible including off-label use*

*- analysis of the burden of each disease, taking social and geographical distribution into account*

*- analysis of national registries for diseases and syndromes*

*- consultations with the Council, the Parliament, EMA and ECDC*

*- consultations with all stakeholders in a public and transparent way, including first and foremost patients, carers and doctors, including those who work with alternative treatments to chemical ones;*

Or. en

### **Amendment 393**

**Elisabetta Gardini, Cristian-Silviu Buşoi, Alojz Peterle, Françoise Grossetête, Giovanni La Via, Aldo Patriciello, Alessandra Mussolini**

#### **Motion for a resolution**

##### **Paragraph 19**

###### *Motion for a resolution*

19. Calls on the Commission to *promote R&D driven by patients' needs, while fostering social responsibility in the pharmaceutical sector, by setting up an EU public platform for R&D funded by contributions from profits made by the pharmaceutical industry through sales to public health systems; calls for transparency on the costs of R&D;*

###### *Amendment*

19. Calls on the Commission to *involve patients and their organisations in the definition of research priorities of all its programmes related to health, to promote R&D driven by patients' need;*



**Amendment 394**

**Eva Kaili**

**Motion for a resolution**

**Paragraph 19**

*Motion for a resolution*

19. Calls on the Commission to ***promote R&D driven by patients' needs, while fostering social responsibility in the pharmaceutical sector, by setting up an EU public platform for R&D funded by contributions from profits made by the pharmaceutical industry through sales to public health systems; calls for transparency on the costs of R&D;***

*Amendment*

19. Calls on the Commission to ***involve patients and their organizations in the definition of research priorities of all its programs related to health, to promote R&D driven by patients' need;***

Or. en

**Amendment 395**

**Frédérique Ries, Gesine Meissner, Lieve Wierinck**

**Motion for a resolution**

**Paragraph 19**

*Motion for a resolution*

19. Calls on the Commission to promote R&D driven by patients' needs, ***while fostering social responsibility in the pharmaceutical sector, by setting up an EU public platform for R&D funded by contributions from profits made by the pharmaceutical industry through sales to public health systems; calls for transparency on the costs of R&D;***

*Amendment*

19. Calls on the Commission to promote R&D driven by patients' needs, by setting up an EU public ***fund to finance R&D oriented towards unmet medical needs, in particular in the field of rare diseases and paediatric diseases;*** calls for ***more*** transparency ***regarding*** the costs of R&D;

Or. en

**Amendment 396**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 19**

*Motion for a resolution*

19. Calls on the Commission *to promote* R&D driven by patients' needs, *while fostering social responsibility in the pharmaceutical sector, by setting up an EU public platform for R&D funded by contributions from profits made by the pharmaceutical industry through sales to public health systems; calls for transparency on the costs of R&D;*

*Amendment*

19. Calls on the Commission *and the Member States to foster* R&D driven by patients' *unmet* needs, *such as researching new antimicrobes, to coordinate public resources for healthcare research in an effective manner and to foster social responsibility in the pharmaceutical sector by creating a European research platform;*

Or. es

**Amendment 397**  
**Annie Schreijer-Pierik**

**Motion for a resolution**  
**Paragraph 19**

*Motion for a resolution*

19. Calls on the Commission to promote R&D driven by patients' needs, while fostering social responsibility in the pharmaceutical sector, by setting up an EU public platform for R&D funded by contributions from profits *made* by the pharmaceutical industry through sales to public health systems *only*; calls for transparency on the costs of R&D;

*Amendment*

19. Calls on the Commission to promote R&D driven by *national health requirements and* patients' needs, while fostering social responsibility in the pharmaceutical sector, by setting up an EU public platform for R&D funded by contributions from profits *earned* by the pharmaceutical industry through sales to public health systems; calls for *maximum* transparency on the costs of R&D, *taking the legitimate scientific, public and private interests of the relevant stakeholders into account;*

Or. nl

## **Amendment 398**

**Tibor Szanyi**

### **Motion for a resolution**

#### **Paragraph 19**

##### *Motion for a resolution*

19. Calls on the Commission to promote R&D driven by patients' needs, while fostering social responsibility in the pharmaceutical sector, by setting up an EU public platform for R&D funded by contributions from profits made by the pharmaceutical industry through sales to public health systems; calls for transparency on the costs of R&D;

##### *Amendment*

19. Calls on the Commission to promote R&D driven by **public health and** patients' needs, while fostering social responsibility in the pharmaceutical sector, by setting up an EU public platform for R&D funded by contributions from profits made by the pharmaceutical industry through sales to public health systems; calls for transparency on the costs of R&D;

Or. en

## **Amendment 399**

**Nessa Childers**

### **Motion for a resolution**

#### **Paragraph 19**

##### *Motion for a resolution*

19. Calls on the Commission to promote R&D driven by patients' needs, while fostering social responsibility in the pharmaceutical sector, by setting up an EU public platform for R&D funded by contributions from profits made by the pharmaceutical industry through sales to public health systems; calls for transparency on the costs of R&D;

##### *Amendment*

19. Calls on the Commission to promote R&D driven by **public health and** patients' needs, while fostering social responsibility in the pharmaceutical sector, by setting up an EU public platform for R&D funded by contributions from profits made by the pharmaceutical industry through sales to public health systems; calls for **full** transparency on the costs of R&D;

Or. en

## **Amendment 400**

**Daciana Octavia Sârbu**

## Motion for a resolution

### Paragraph 19

#### *Motion for a resolution*

19. Calls on the Commission to promote R&D driven by patients' needs, while fostering social responsibility in the pharmaceutical sector, by setting up an EU public platform for R&D funded by contributions from profits made by the pharmaceutical industry through sales to public health systems; calls for transparency on the costs of R&D;

#### *Amendment*

19. Calls on the Commission to promote R&D driven by patients' needs, while fostering social responsibility in the pharmaceutical sector, by setting up an EU public platform for R&D funded by contributions from profits made by the pharmaceutical industry through sales to public health systems; calls for **full** transparency on the costs of R&D;

Or. en

## Amendment 401

**Karin Kadenbach, Soledad Cabezón Ruiz**

## Motion for a resolution

### Paragraph 19

#### *Motion for a resolution*

19. Calls on the Commission to promote R&D driven by **patients'** needs, while fostering social responsibility in the pharmaceutical sector, by setting up an EU public platform for R&D funded by contributions from profits made by the pharmaceutical industry through sales to public health systems; calls for transparency on the costs of R&D;

#### *Amendment*

19. Calls on the Commission to promote R&D driven by **public health** needs, while fostering social responsibility in the pharmaceutical sector, by setting up an EU public platform for R&D funded by contributions from profits made by the pharmaceutical industry through sales to public health systems; calls for transparency on the costs of R&D;

Or. en

## Amendment 402

**Kateřina Konečná, Biljana Borzan**

## Motion for a resolution

### Paragraph 19 a (new)

*Motion for a resolution*

*Amendment*

**19a.** *Calls on the European Commission to promote EMA's initiative on the safe use of adaptive pathways where it is deemed appropriate, to reduce the time to bring to the market medicines that address unmet medical needs and to ensure that marketing authorization will be granted without compromising patient safety, and only if there is a positive balance of benefits and risks for a defined patient population;*

Or. en

**Amendment 403**

**José Inácio Faria**

**Motion for a resolution**

**Paragraph 19 a (new)**

*Motion for a resolution*

*Amendment*

**19a.** *Highlights the threat of growing antimicrobial resistance; calls on the Commission to put forward measures to promote R&D in the public and the private sector and to build a business case to incentivise the development and commercialisation of antibiotics of last resource to fight the lack of innovation in this area;*

Or. en

**Amendment 404**

**Elena Gentile, Massimo Paolucci**

**Motion for a resolution**

**Paragraph 19a (new)**

*Motion for a resolution*

*Amendment*

**19a.** *Calls on the Commission to promote initiatives for guiding public and private-sector research towards bringing out innovative medicines for curing childhood illnesses;*

Or. it

**Amendment 405**

**Elena Gentile, Massimo Paolucci**

**Motion for a resolution**

**Paragraph 19b (new)**

*Motion for a resolution*

*Amendment*

**19b.** *Calls on the Commission to promote public and private-sector research into medicines for female patients, to remedy gender inequality in research and development and allow all citizens to benefit from fairer access to medicines;*

Or. it

**Amendment 406**

**Frédérique Ries, Gesine Meissner, Lieve Wierinck**

**Motion for a resolution**

**Paragraph 20**

*Motion for a resolution*

*Amendment*

20. *Calls on* the Commission to ***analyse*** the overall impact of IP in promoting innovation, especially the impact of supplementary protection certificates (SPCs), data exclusivity or market exclusivity on competitiveness and quality of innovation, and ***to set strict limits on*** these practices;

20. *Notes the Council Conclusions of 17 June 2016 inviting* the Commission to ***conduct a fact- and evidence-based analysis on*** the overall impact of IP in promoting innovation, especially the impact of supplementary protection certificates (SPCs), data exclusivity or market exclusivity on competitiveness and

quality of innovation, and *where necessary, to regulate* these practices;

Or. en

**Amendment 407**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 20**

*Motion for a resolution*

20. Calls on the Commission to analyse the overall impact of IP in promoting innovation, especially the impact of supplementary protection certificates (SPCs), data exclusivity or market exclusivity on competitiveness and quality of innovation, and to set strict limits on these practices;

*Amendment*

20. Calls on the Commission to analyse the overall impact of IP in promoting innovation, *as also requested by the Council in its Council Conclusions on 17 June 2016*, especially the impact of supplementary protection certificates (SPCs), data exclusivity or market exclusivity on competitiveness and quality of innovation, and to set strict limits on these practices;

Or. en

**Amendment 408**  
**Nessa Childers**

**Motion for a resolution**  
**Paragraph 20**

*Motion for a resolution*

20. Calls on the Commission to analyse the overall impact of IP in promoting innovation, especially the impact of supplementary protection certificates (SPCs), data exclusivity *or* market exclusivity on competitiveness and quality of innovation, and to *set strict limits on these practices*;

*Amendment*

20. Calls on the Commission to analyse the overall impact of IP in promoting *needs-driven* innovation, *affordability and commensurably improved therapeutic outcomes* especially the impact of supplementary protection certificates (SPCs), data exclusivity *and* market exclusivity on competitiveness and quality of innovation, and to *amend legislation accordingly*;

**Amendment 409**

**Damiano Zoffoli, Soledad Cabezón Ruiz**

**Motion for a resolution**

**Paragraph 20**

*Motion for a resolution*

20. Calls on the Commission to analyse the overall impact of IP in promoting innovation, especially the impact of supplementary protection certificates (SPCs), data exclusivity or market exclusivity on competitiveness and quality of innovation, and to set strict limits on these practices;

*Amendment*

20. Calls on the Commission to analyse ***through a deep, objective and unbiased study*** the overall impact of IP in promoting innovation ***and on patient access***, especially the impact of supplementary protection certificates (SPCs), data exclusivity or market exclusivity on competitiveness and quality of innovation, and to set strict limits on these practices;

Or. en

**Amendment 410**

**Annie Schreijer-Pierik**

**Motion for a resolution**

**Paragraph 20**

*Motion for a resolution*

20. Calls on the Commission to analyse the overall impact of IP in promoting innovation, especially the impact of supplementary protection certificates (SPCs), data exclusivity or market exclusivity on competitiveness and quality of innovation, and to set strict limits on these practices;

*Amendment*

20. Calls on the Commission to analyse the overall impact of IP in promoting innovation ***and patients' access to drugs***, especially the impact of supplementary protection certificates (SPCs), data exclusivity or market exclusivity on competitiveness and quality of innovation, and to set strict limits on these practices;

Or. nl

**Amendment 411**

**Soledad Cabezón Ruiz**



**Motion for a resolution**  
**Paragraph 20**

*Motion for a resolution*

20. Calls on the Commission to analyse the overall impact of IP in promoting innovation, especially the impact of supplementary protection certificates (SPCs), data exclusivity or market exclusivity on competitiveness and quality of innovation, **and to set strict limits on these practices;**

*Amendment*

20. Calls on the Commission to analyse the overall impact of IP in promoting innovation, **with regard, in particular, to the quality of innovations,** especially the impact of supplementary protection certificates (SPCs), data exclusivity or market exclusivity on competitiveness and quality of innovation, **along with the impact on access to the medicines;**

Or. es

**Amendment 412**  
**Christofer Fjellner**

**Motion for a resolution**  
**Paragraph 20**

*Motion for a resolution*

20. Calls on the Commission to **analyse the overall impact of IP in promoting** innovation, especially the impact of supplementary protection certificates (SPCs), data exclusivity or market exclusivity on competitiveness and quality of innovation, **and to set strict limits on these practices;**

*Amendment*

20. Calls on the Commission to **analyse how to best promote** innovation, especially the impact of supplementary protection certificates (SPCs), data exclusivity or market exclusivity on competitiveness and quality of innovation;

Or. en

**Amendment 413**  
**Karin Kadenbach, Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 20**

*Motion for a resolution*

20. Calls on the Commission to analyse the overall impact of IP in promoting innovation, especially the impact of supplementary protection certificates (SPCs), data exclusivity or market exclusivity on competitiveness and quality of innovation, and to set strict limits on these practices;

*Amendment*

20. Calls on the Commission to analyse the overall impact of IP in promoting innovation **and on patient access**, especially the impact of supplementary protection certificates (SPCs), data exclusivity or market exclusivity on competitiveness and quality of innovation, and to set strict limits on these practices;

Or. en

**Amendment 414**  
**Biljana Borzan**

**Motion for a resolution**  
**Paragraph 20**

*Motion for a resolution*

20. Calls on the Commission to analyse the overall impact of IP in promoting innovation, especially the impact of supplementary protection certificates (SPCs), data exclusivity or market exclusivity on competitiveness and quality of innovation, and to set strict limits on these practices;

*Amendment*

20. Calls on the Commission to analyse the overall impact of IP in promoting innovation **and patient access**, especially the impact of supplementary protection certificates (SPCs), data exclusivity or market exclusivity on competitiveness and quality of innovation, and to set strict limits on these practices;

Or. en

**Amendment 415**  
**Margrete Auken**

**Motion for a resolution**  
**Paragraph 20**

*Motion for a resolution*

20. Calls on the Commission to analyse the overall impact of IP in **promoting** innovation, especially the impact of supplementary protection certificates

*Amendment*

20. Calls on the Commission to analyse the overall impact of IP in **delaying access to** innovation, especially the impact of supplementary protection certificates

(SPCs), data exclusivity or market exclusivity on competitiveness and quality of innovation, and to set strict limits on these practices;

(SPCs), data exclusivity or market exclusivity on competitiveness and quality of innovation, and to set strict limits on these practices;

Or. en

#### **Amendment 416**

**Karl-Heinz Florenz, Peter Liese, Andrey Kovatchev**

#### **Motion for a resolution**

##### **Paragraph 20**

###### *Motion for a resolution*

20. Calls on the Commission to analyse the overall impact of IP in promoting innovation, especially the impact of supplementary protection certificates (SPCs), data exclusivity or market exclusivity on competitiveness and quality of innovation, ***and to set strict limits on these practices;***

###### *Amendment*

20. Calls on the Commission to analyse the overall impact of IP in promoting innovation ***with a neutral, fact-based and comprehensive approach,*** especially the impact of supplementary protection certificates (SPCs), data exclusivity or market exclusivity on competitiveness and quality of innovation;

Or. de

#### **Amendment 417**

**Nicola Caputo, Marc Tarabella, Soledad Cabezón Ruiz**

#### **Motion for a resolution**

##### **Paragraph 20 a (new)**

###### *Motion for a resolution*

###### *Amendment*

***20a. Invites the Commission to prepare, as soon as possible and with the close involvement of the Member States, an overview of the current EU legislative instruments and related incentives that aim to facilitate the investment in the development of medicinal products and the marketing authorization of medicinal products given to the holders of a marketing authorisation as implemented within the EU: Supplementary Protection***

*Certificates (Regulation EC 469/2009), medicinal products for human use (Directive 2001/83/EC and Regulation EC 726/2004), orphan medicinal products (Regulation EC 141/2000) and paediatrics (Regulation EC 1901/2006); invites also the Commission to prepare an evidence based analysis of the impact of the incentives in these EU legislative instruments, as implemented, on innovation, as well as on the availability, in particular supply shortages and deferred or missed market launches, and accessibility of medicinal products, including high priced essential medicinal products for conditions that pose a high burden for patients and health systems as well as availability of generic medicinal products; calls on the Commission to prepare in the coming months a timetable and methodology for conducting the analysis as mentioned in this paragraph;*

Or. en

**Amendment 418**  
**Cristian-Silviu Buşoi**

**Motion for a resolution**  
**Paragraph 20 a (new)**

*Motion for a resolution*

*Amendment*

**20a. *Recalls that maintaining incentives is important to attract R&D in Europe and deliver quality innovative treatments to patients, therefore encourages the Commission not to revise incentive frameworks that have proven successful in delivering the intended results, such as the Regulation on orphan medicinal products, and calls on the Commission to perform, when the case, evidence-based analysis of the impact of incentives provided by the EU legislative framework based on an objective, balanced and scientifically sound***

*methodology;*

Or. en

**Amendment 419**

**Andrey Kovatchev, Cristian-Silviu Buşoi, Kateřina Konečná, Biljana Borzan, Karl-Heinz Florenz, Karin Kadenbach**

**Motion for a resolution**

**Paragraph 20 a (new)**

*Motion for a resolution*

*Amendment*

**20a. Calls on the Commission to adopt a targeted SPC manufacturing waiver for export purposes to allow EU-based manufacturers of generic and biosimilar medicines to compete on equal footing with competitors from non-EU countries, thus avoiding the outsourcing of production and helping to maintain and create additional jobs and growth in the EU;**

Or. en

**Amendment 420**

**José Inácio Faria, Frédérique Ries, Marian Harkin, Yana Toom**

**Motion for a resolution**

**Paragraph 20 a (new)**

*Motion for a resolution*

*Amendment*

**20a. Acknowledges that the incentives put forward by the Paediatric Regulation have not proved effective to drive innovation in medicines for children, namely in the fields of oncology and neonatology; calls on the Commission to examine existing obstacles and propose measures to promote advancement in this area;**

Or. en

**Amendment 421**

**Elisabetta Gardini, Alojz Peterle, Giovanni La Via, Aldo Patriciello, Alessandra Mussolini**

**Motion for a resolution**

**Paragraph 20 a (new)**

*Motion for a resolution*

*Amendment*

**20a. Calls on EU Member States and the pharmaceutical industry to increase transparency on the process of pricing and reimbursement of pharmaceutical products, including the costs of R&D;**

Or. en

**Amendment 422**

**Eva Kaili**

**Motion for a resolution**

**Paragraph 20 a (new)**

*Motion for a resolution*

*Amendment*

**20a. Calls on the EU Member states and the pharmaceutical industry to increase transparency on the process of pricing and reimbursement of pharmaceutical products, including the costs of R&D;**

Or. en

**Amendment 423**

**José Inácio Faria**

**Motion for a resolution**

**Paragraph 20 b (new)**

*Motion for a resolution*

*Amendment*

**20b. Recognises that off-label use of**

*medicines can bring benefits to patients when approved alternatives are absent; Notes with concern that patients are subject to increased risks due to the lack of a solid evidence-base proving safety and efficacy of off-label use, to the lack of informed consent and to increased difficulty in monitoring adverse events; underlines that certain population sub-groups are particularly exposed to this practice such as children and the elderly;*

Or. en

**Amendment 424**  
**José Inácio Faria**

**Motion for a resolution**  
**Paragraph 20 c (new)**

*Motion for a resolution*

*Amendment*

*20c. Calls on the Commission, the European Medicines Agency and Member States to promote Good Off-Label Use Guidelines in order to reduce patients' risk associated with this clinical practice; Calls on the Commission to analyse the drivers of off-label use and to propose measures that mitigate the need for this clinical practice, by promoting access to all patients' groups to licensed indications, for example through adequate incentives for drug repurposing and new indication licensing;*

Or. en

**Amendment 425**  
**José Inácio Faria**

**Motion for a resolution**  
**Paragraph 20 d (new)**

*Motion for a resolution*

*Amendment*

**20d. Calls on the Commission to collaborate with the European Medicines Agency and with stakeholders with a view to introduce a Code of Practice for mandatory reporting of adverse events and of outcomes for off-label use of medicines and to ensure patients' registries in order to strengthen the evidence base and mitigate risks for patients;**

Or. en

**Amendment 426**

**José Inácio Faria, Marian Harkin**

**Motion for a resolution**

**Paragraph 20 e (new)**

*Motion for a resolution*

*Amendment*

**20e. Acknowledges the significant development of medicinal products with the orphan designation following the incentives put in place by the current legislative framework on orphan medicinal products; notes that such medicines are also used off-label, or repurposed and authorised for additional indications allowing increased sales and returns; calls on the Commission to examine these occurrences and to monitor the volume of sales of such medicines to ensure balanced incentives without discouraging innovation in this area;**

Or. en

**Amendment 427**

**José Inácio Faria**



**Motion for a resolution**  
**Paragraph 20 f (new)**

*Motion for a resolution*

*Amendment*

**20f.** *Notes that the repurposing of existing drugs for new indications can be accompanied by a price increase; asks the Commission to collect and analyse data on price increases in cases of drug repurposing and to report back to the European Parliament and the Council on the balance and proportionality of the incentives that encourage industry to invest in drug repurposing;*

Or. en

**Amendment 428**  
**José Inácio Faria**

**Motion for a resolution**  
**Paragraph 20 g (new)**

*Motion for a resolution*

*Amendment*

**20g.** *Recognises the need to ensure the continued supply of medicines with proven added value for patients and health systems; Calls on the Commission to monitor and to propose measures, when appropriate, on the withdrawal of old molecules from the market for commercial reasons, including its re-authorization for a new indication at a much higher price;*

Or. en

**Amendment 429**  
**Christofer Fjellner**

**Motion for a resolution**  
**Paragraph 21**

*Motion for a resolution*

21. Calls on the Commission to promote open data *in private research, especially* where public funding is involved, *and to establish conditions such as affordable pricing and non-exclusivity, or co-ownership of IP for projects funded by EU public grants such as Horizon 2020;*

*Amendment*

21. Calls on the Commission to promote open data where public funding is involved;

Or. en

**Amendment 430**

**Nessa Childers**

**Motion for a resolution**

**Paragraph 21**

*Motion for a resolution*

21. Calls on the Commission to promote open data in private research, especially where public funding is involved, and to *establish* conditions such as affordable pricing and non-exclusivity, or co-ownership of IP for projects funded by EU public grants such as Horizon 2020;

*Amendment*

21. Calls on the Commission to promote open data in private research, especially where public funding is involved, and to *require* conditions *to ensure a public health return on investment in biomedical research*, such as affordable pricing and non-exclusivity, or co-ownership of IP for projects funded by EU public grants such as Horizon 2020;

Or. en

**Amendment 431**

**Frédérique Ries, Gesine Meissner, Lieve Wierinck**

**Motion for a resolution**

**Paragraph 21**

*Motion for a resolution*

21. Calls on the Commission to promote open data *in private research, especially where* public funding is

*Amendment*

21. Calls on the Commission to promote *as far as possible* open data *where a significant amount of* public funding is

involved, and to **establish** conditions such as affordable pricing and non-exclusivity, or co-ownership of IP for projects funded by EU public grants such as Horizon 2020;

involved, and to **encourage** conditions such as affordable pricing and non-exclusivity, or co-ownership of IP for projects funded by EU public grants such as Horizon 2020;

Or. en

## **Amendment 432** **Margrete Auken**

### **Motion for a resolution** **Paragraph 21**

#### *Motion for a resolution*

21. Calls on the Commission to promote open data in **private** research, **especially where public funding is involved**, and to establish conditions such as affordable pricing and non-exclusivity, or co-ownership of IP for projects funded by EU public grants such as Horizon 2020;

#### *Amendment*

21. Calls on the Commission to promote open data in research **on public health**, and to establish conditions such as affordable pricing and non-exclusivity, or co-ownership of IP for projects funded by EU public grants such as Horizon 2020 **and IMI**;

Or. en

## **Amendment 433** **Krzysztof Hetman**

### **Motion for a resolution** **Paragraph 21**

#### *Motion for a resolution*

21. Calls on the Commission to promote open data in private research, **especially** where public funding is involved, and to establish conditions such as affordable pricing and non-exclusivity, or co-ownership of IP for projects funded by EU public grants such as Horizon 2020;

#### *Amendment*

21. Calls on the Commission to promote open data in private research, where public funding is involved, and to establish conditions such as affordable pricing and non-exclusivity, or co-ownership of IP for projects funded by EU public grants such as Horizon 2020;

Or. en

**Amendment 434**  
**Piernicola Pedicini, Eleonora Evi, Marco Affronte**

**Motion for a resolution**  
**Paragraph 21a (new)**

*Motion for a resolution*

*Amendment*

**21a. Urges the Commission to adopt a strategic plan aimed at preventing the spread of HCV and eradicating the Hepatitis C epidemic through the use of new and old medicines, to be administered to all patients diagnosed with hepatic fibroses caused by Hepatitis C starting from at least stage F2, when damage to the fibrocytic tissue can be considered significant, up to stage F3 when sclerocytic damage is severe, and stage F4 when the patient is considered cirrhotic or pre-cirrhotic;**

Or. it

**Amendment 435**  
**Nicola Caputo, Marc Tarabella, Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 21 a (new)**

*Motion for a resolution*

*Amendment*

**21a. Stresses that both public and private investments are essential for the research and development of innovative medicinal products; notes that in those cases where public investment has played a major role in the development of certain innovative medicinal products, a fair share of the return on investment in such products should preferably be used for further innovative research in the public health interest for example through agreements made on benefit sharing during the research phase;**

Or. en

**Amendment 436**  
**Peter Liese, Karl-Heinz Florenz**

**Motion for a resolution**  
**Paragraph 21 a (new)**

*Motion for a resolution*

*Amendment*

**21a.** *Calls for the framework conditions in the areas of research and medicine policy to be established in a way that promotes innovation, particularly against diseases such as cancer, which cannot yet be treated to a satisfactory degree;*

Or. de

**Amendment 437**  
**Margrete Auken**

**Motion for a resolution**  
**Paragraph 21 a (new)**

*Motion for a resolution*

*Amendment*

**21a.** *Calls on the Commission, when engaged in bilateral trade and investment partnerships to ensure that these agreements do not include provisions that interfere with the obligations of Member States to fulfil the right to health;*

Or. en

**Amendment 438**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 22**

*Motion for a resolution*

*Amendment*

22. Calls on the Commission to ***review***

22. Calls on the Commission to

*the* regulatory framework for orphan medicines, to define clearly the concept of unmet medical needs, to assess the impact of incentives to develop effective, safe and affordable drugs compared to the best available alternative and to promote the European register of rare diseases and reference centres;

*streamline the implementation of the current* regulatory framework for orphan medicines, *and if necessary review it in order to ensure on the one hand the development of medicines for rare diseases and on the other hand the correct application of the current rules and incentives*, to define clearly the concept of unmet medical needs, to assess the impact of incentives to develop effective, safe and affordable drugs compared to the best available alternative and to promote the European register of rare diseases and reference centres;

Or. en

#### **Amendment 439**

**Karl-Heinz Florenz, Peter Liese, Andrey Kovatchev**

#### **Motion for a resolution**

##### **Paragraph 22**

###### *Motion for a resolution*

22. Calls on the Commission *to review the regulatory framework* for orphan medicines, *to define clearly the concept of unmet medical needs, to assess the impact of incentives to develop effective, safe and affordable drugs compared to the best available alternative* and to promote the European register of rare diseases and reference centres;

###### *Amendment*

22. Calls on the Commission *to analyse the implementation of the regulatory framework* for orphan medicines *and subsequently decide whether it needs to be revised*, and to promote the European register of rare diseases and reference centres;

Or. de

#### **Amendment 440**

**Christel Schaldemose**

#### **Motion for a resolution**

##### **Paragraph 22**

*Motion for a resolution*

22. Calls on the Commission to review the regulatory framework for orphan medicines, to define clearly the concept of unmet medical needs, to assess the impact of incentives to develop effective, safe and affordable drugs compared to the best available alternative **and** to promote the European register of rare diseases and reference centres;

*Amendment*

22. Calls on the Commission to review the regulatory framework for orphan medicines, to define clearly the concept of unmet medical needs, to ***better determine the level of new development***, to assess the impact of incentives to develop effective, safe and affordable drugs compared to the best available alternative, to promote the European register of rare diseases and reference centres ***and to ensure the correct implementation of the legislation***;

Or. en

**Amendment 441**

**Piernicola Pedicini, Eleonora Evi, Marco Affronte**

**Motion for a resolution**

**Paragraph 22**

*Motion for a resolution*

22. Calls on the Commission to review the regulatory framework for orphan medicines, to define clearly the concept of unmet medical needs, to assess the impact of incentives to develop effective, safe and affordable drugs compared to the best available alternative and to promote the European register of rare diseases and reference centres;

*Amendment*

22. Calls on the Commission to review the regulatory framework for orphan medicines, to define clearly the concept of unmet medical needs, to assess the impact of incentives to develop effective, safe and affordable drugs compared to the best available alternative and to promote the ***principle of simultaneous introduction of orphan medicines in all Member States, as well as the*** European register of rare diseases and reference centres;

Or. it

**Amendment 442**

**Elisabetta Gardini, Cristian-Silviu Buşoi, Alojz Peterle, Giovanni La Via, Aldo Patriciello, Alessandra Mussolini**

**Motion for a resolution**

**Paragraph 22**

*Motion for a resolution*

22. Calls on the Commission to **review** the regulatory framework for orphan medicines, to **define clearly the concept of** unmet medical needs, **to assess the impact of incentives to develop** effective, safe and affordable drugs compared to the best available alternative and to promote the European register of rare diseases and reference centres;

*Amendment*

22. Calls on the Commission to **update** the regulatory framework for orphan medicines, to **provide guidance on priority** unmet medical needs, **and to review existing incentives schemes to facilitate the development of** effective, safe and affordable drugs **for rare diseases, including rare cancers**, compared to the best available alternative and to promote the European register of rare diseases and reference centres;

Or. en

**Amendment 443**

**Eva Kaili**

**Motion for a resolution**

**Paragraph 22**

*Motion for a resolution*

22. Calls on the Commission to **review** the regulatory framework for orphan medicines, to **define clearly the concept of** unmet medical needs, **to assess the impact of incentives to develop** effective, safe and affordable drugs compared to the best available alternative and to promote the European register of rare diseases and reference centres;

*Amendment*

22. Calls on the Commission to **update** the regulatory framework for orphan medicines, to **provide guidance on priority** unmet medical needs, **and to review existing incentive schemes to facilitate the development of** effective, safe and affordable drugs **for rare diseases, including rare cancers**, compared to the best available alternative and to promote the European register of rare diseases and reference centres;

Or. en

**Amendment 444**

**Nessa Childers**

**Motion for a resolution**

**Paragraph 22**



*Motion for a resolution*

22. Calls on the Commission to review the regulatory framework for orphan medicines, to define clearly the concept of unmet medical needs, to assess the impact of incentives to develop effective, safe and affordable drugs compared to the best available alternative and to promote the European register of rare diseases and reference centres;

*Amendment*

22. Calls on the Commission to **fully and comprehensively** review the regulatory framework for orphan medicines, to define clearly the concept of unmet medical needs, to assess the impact of incentives to develop effective, safe and affordable drugs compared to the best available alternative and to promote the European register of rare diseases and reference centres;

Or. en

**Amendment 445**

**Aldo Patriciello**

**Motion for a resolution**

**Paragraph 22**

*Motion for a resolution*

22. Calls on the Commission to review the regulatory framework for orphan medicines, to define clearly the concept of unmet medical needs, to assess the impact of incentives to develop effective, safe and affordable drugs compared to the best available alternative and to **promote** the European register of rare diseases and reference centres;

*Amendment*

22. Calls on the Commission to review the regulatory framework for orphan medicines, to define clearly the concept of unmet medical needs, to assess the impact of incentives to develop effective, safe and affordable drugs compared to the best available alternative and to **redraft, as a priority**, the European register of rare diseases and reference centres;

Or. it

**Amendment 446**

**Lieve Wierinck, Gesine Meissner, José Inácio Faria, Marian Harkin, Jasenko Selimovic**

**Motion for a resolution**

**Paragraph 22**

*Motion for a resolution*

22. Calls on the Commission to **review**

*Amendment*

22. Calls on the Commission to

the regulatory framework for orphan medicines, to define clearly the concept of unmet medical needs, to assess the impact of incentives to develop effective, safe and affordable drugs compared to the best available alternative and to promote the European register of rare diseases and reference centres;

*evaluate* the regulatory framework for orphan medicines, to define clearly the concept of unmet medical needs, to assess the impact of incentives to develop effective, safe and affordable drugs compared to the best available alternative and to promote the European register of rare diseases and reference centres;

Or. en

#### **Amendment 447**

**Françoise Grossetête, Angélique Delahaye**

#### **Motion for a resolution**

#### **Paragraph 22**

##### *Motion for a resolution*

22. *Calls on the Commission to review the regulatory framework for orphan medicines, to define clearly the concept of unmet medical needs, to assess the impact of incentives to develop effective, safe and affordable drugs compared to the best available alternative and to promote the European register of rare diseases and reference centres;*

##### *Amendment*

22. *Highlights the success of Regulation (EC) No 141/2000 on orphan medicinal products, which enabled a number of innovative products for misdiagnosed patients or patients deprived of treatment to be placed on the market; calls on the Commission to promote the European register of rare diseases and reference centres;*

Or. fr

#### **Amendment 448**

**Soledad Cabezón Ruiz**

#### **Motion for a resolution**

#### **Paragraph 22 a (new)**

##### *Motion for a resolution*

22a. *Calls on the Commission and the Member States to establish European registers of rare diseases, national reference centres with experts such as doctors that prescribe drugs and monitoring centres to improve evidence;*

*to place emphasis on transparency in pricing and reimbursement, improving the authorisation procedure on the basis of the best evidence bought and transparency in study and cost data, particularly when public financing exists follow-up monitoring by way of high-quality trials after placing on the market on the basis of safety and optimum benefit for the patient; to push for the revision of the definition of unmet medical needs, the definition of 'no satisfactory treatment' and 'additional benefits to the existing alternatives', the criterion for measuring the effectiveness of rare disease treatments;*

Or. es

**Amendment 449**  
**Glenis Willmott**

**Motion for a resolution**  
**Paragraph 22 a (new)**

*Motion for a resolution*

*Amendment*

*22a. Calls on the Commission to immediately begin work on the report required under Article 50 of the Paediatric Medicines Regulation and to amend the legislation to address the lack of innovation in paediatric oncology treatments by revising the criteria for allowing a Paediatric Investigation Plan (PIP) waiver and to ensure that PIPs are implemented early in a drug's development so that children are not waiting longer than necessary for access to innovative new treatments;*

Or. en

**Amendment 450**  
**Andrey Kovatchev, Cristian-Silviu Buşoi, Kateřina Konečná, Biljana Borzan, Karin**

**Kadenbach**

**Motion for a resolution**  
**Paragraph 22 a (new)**

*Motion for a resolution*

*Amendment*

**22a.** *Calls on the Commission to analyse the adequacy of the legislative framework to the current situation with the parallel export and re-export of medicines, and underlines the need to strike the right balance between public health and economic considerations;*

Or. en

**Amendment 451**  
**Elisabetta Gardini**

**Motion for a resolution**  
**Paragraph 22 a (new)**

*Motion for a resolution*

*Amendment*

**22a.** *Calls on the Commission for further actions to foster the development and the patients access to ATMPs, with a particular focus on the lack of harmonisation regarding the conditions required by Member States for the application of the Hospital Exemption;*

Or. en

**Amendment 452**  
**Damiano Zoffoli, Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 22 a (new)**

*Motion for a resolution*

*Amendment*

**22a.** *Stress the importance to clearly demonstrate the added value in terms of*

*R&I in marketing authorisation of so called orphan drugs.*

Or. en

**Amendment 453**

**Karl-Heinz Florenz, Peter Liese, Andrey Kovatchev**

**Motion for a resolution**

**Paragraph 22 a (new)**

*Motion for a resolution*

*Amendment*

*22a. Calls on the Commission to clearly define the concept of unmet medical needs;*

Or. de

**Amendment 454**

**Soledad Cabezón Ruiz**

**Motion for a resolution**

**Paragraph 22 b (new)**

*Motion for a resolution*

*Amendment*

*22b. Calls on the Commission to revise the clinical and socioeconomic impact of the incentives for researching less prevalent areas such as rare diseases, paediatrics and advanced therapies;*

Or. es

**Amendment 455**

**Karin Kadenbach, Soledad Cabezón Ruiz**

**Motion for a resolution**

**Paragraph 23**

*Motion for a resolution*

23. Calls on the Commission to **guarantee** safety and efficacy in any fast-track approval process and to **introduce the concept of conditional authorisation based on effectiveness**;

*Amendment*

23. Calls on the Commission to **maintain and set up if necessary strong rules aimed at guaranteeing** safety and efficacy in any fast-track approval process and to **ensure that such approvals are made possible only in exceptional circumstances where a clear unmet medical need has been identified**;

Or. en

**Amendment 456**

**Eva Kaili**

**Motion for a resolution**

**Paragraph 23**

*Motion for a resolution*

23. Calls on the Commission to **guarantee safety and efficacy in any fast-track approval process** and to introduce **the concept of conditional authorisation based on effectiveness**;

*Amendment*

23. Calls on the Commission to **promote fast-track approval processes for unmet medical needs** and to introduce **transparent and accountable processes to monitor safety and effectiveness**;

Or. en

**Amendment 457**

**Elisabetta Gardini, Cristian-Silviu Buşoi, Françoise Grossetête, Giovanni La Via, Aldo Patriciello, Alessandra Mussolini**

**Motion for a resolution**

**Paragraph 23**

*Motion for a resolution*

23. Calls on the Commission **to guarantee safety and efficacy in any fast-track approval process** and to introduce **the concept of conditional authorisation based on effectiveness**;

*Amendment*

23. Calls on the Commission **promote fast-track approval processes for unmet medical needs**, and to introduce **transparent and accountable process to monitor safety and effectiveness**;

**Amendment 458**  
**Karl-Heinz Florenz**

**Motion for a resolution**  
**Paragraph 23**

*Motion for a resolution*

23. Calls on the Commission to **guarantee** safety and efficacy in any fast-track approval process and to introduce **the concept of conditional authorisation based on effectiveness**;

*Amendment*

23. Calls on the Commission to **ensure a thorough assessment of quality**, safety and efficacy in any fast-track approval process and to introduce **the systematic monitoring of the conditions and sanctions as regards non-compliance**;

Or. de

**Amendment 459**  
**Damiano Zoffoli, Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 23**

*Motion for a resolution*

23. Calls on the Commission to guarantee safety and efficacy in any fast-track approval process and to **introduce the concept of conditional authorisation based on effectiveness**;

*Amendment*

23. Calls on the Commission to guarantee safety and efficacy in any fast-track approval process and to **guarantee that the existing schemes of early marketing authorization are restricted to a limited range of medicines addressing "unmet medical need" and when there is no other available alternative**;

Or. en

**Amendment 460**  
**José Inácio Faria, Jasenko Selimovic, Frédérique Ries, Marian Harkin, Lieve Wierinck, Yana Toom**

**Motion for a resolution**  
**Paragraph 23**

*Motion for a resolution*

23. Calls on the Commission to guarantee safety and efficacy in any fast-track approval process and to ***introduce the concept of conditional authorisation based on effectiveness***;

*Amendment*

23. Calls on the Commission to guarantee safety and efficacy in any fast-track approval process and to ***ensure that such approvals are admissible in exceptional circumstances where a high unmet medical need has been identified***;

Or. en

**Amendment 461**  
**Margrete Auken**

**Motion for a resolution**  
**Paragraph 23**

*Motion for a resolution*

23. Calls on the Commission to guarantee safety and efficacy in any ***fast-track approval*** process and to introduce the concept of conditional authorisation based on effectiveness;

*Amendment*

23. Calls on the Commission to ***only allow fast-track approval in exceptional and duly justified urgencies***, to guarantee safety and efficacy in any process and to introduce the concept of conditional authorisation based on effectiveness;

Or. en

**Amendment 462**  
**Piernicola Pedicini, Eleonora Evi, Marco Affronte**

**Motion for a resolution**  
**Paragraph 23**

*Motion for a resolution*

23. Calls on the Commission to guarantee safety and efficacy in any fast-track approval process and to introduce the concept of conditional authorisation based on ***effectiveness***;

*Amendment*

23. Calls on the Commission to guarantee safety and efficacy in any fast-track approval process and to introduce the concept of conditional authorisation based on ***clinical trial data that demonstrate an advance over existing treatment options***



*for patients and clinically-relevant outcomes;*

Or. en

**Amendment 463**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 23**

*Motion for a resolution*

23. Calls on the Commission to guarantee safety and efficacy in any fast-track approval process and **to** introduce the concept of conditional authorisation based on effectiveness;

*Amendment*

23. Calls on the Commission to guarantee safety, **quality** and efficacy in any fast-track approval process and **calls on the Commission and the Member States to explore synergies between regulatory bodies, HTA bodies and payers for facilitation timely patient's access to innovative technologies as well as for defining conditions and eventual exit strategies for products that enter the market through such approval processes to** introduce the concept of conditional authorisation based on effectiveness;

Or. en

**Amendment 464**  
**György Hölvényi, Alojz Peterle, Miroslav Mikolášik**

**Motion for a resolution**  
**Paragraph 23**

*Motion for a resolution*

23. Calls on the Commission to guarantee safety and efficacy in any fast-track approval process and to introduce the concept of conditional authorisation based on effectiveness;

*Amendment*

23. Calls on the Commission to **take a very cautious approach and** guarantee safety and efficacy in any fast-track approval process and to introduce the concept of conditional authorisation based on effectiveness; **in this respect, calls on the Commission to take into consideration the opinion of non-industry related**

*stakeholders;*

Or. en

**Amendment 465**

**Cristian-Silviu Buşoi, Andrey Kovatchev**

**Motion for a resolution**

**Paragraph 23**

*Motion for a resolution*

23. Calls on the Commission to guarantee safety and efficacy in any fast-track approval process and to ***introduce the concept of conditional authorisation based on effectiveness;***

*Amendment*

23. Calls on the Commission to guarantee safety and efficacy in any fast-track approval process and to ***ensure that such approvals are made possible only in exceptional circumstances where a clear unmet medical need has been identified;***

Or. en

**Amendment 466**

**Nessa Childers**

**Motion for a resolution**

**Paragraph 23**

*Motion for a resolution*

23. Calls on the Commission to guarantee safety and efficacy in any fast-track approval process and to introduce the concept of conditional authorisation based on effectiveness;

*Amendment*

23. Calls on the Commission to guarantee safety and efficacy in any fast-track approval process and to introduce the concept of conditional authorisation based on effectiveness, ***within the scope of the circumstances identified in Regulation EC/507/2006;***

Or. en

**Amendment 467**

**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 23 a (new)**

*Motion for a resolution*

*Amendment*

**23a.** *Calls on the Commission to ensure that the fast access procedures respond to solid evidence in favour of potential health benefits and a real need for treating owing to an absence of effective alternatives without reducing patient safety or quality or effectiveness of treatment and in application of the evidence-based medicine criteria; calls for the transparency of each procedure and of clinical data to be guaranteed, including pharmacovigilance information, information on how citizens can obtain compensation and their right thereto following harm; calls on the Commission to ensure that all stakeholders, including HTA agencies, payers, patients and the European Parliament, participate in the study launched by the EMA in 2014 on adaptive licensing, given the potential importance of the new research and authorisation models;*

Or. es

**Amendment 468**  
**Piernicola Pedicini, Eleonora Evi, Marco Affronte**

**Motion for a resolution**  
**Paragraph 23 a (new)**

*Motion for a resolution*

*Amendment*

**23a.** *Calls on the Commission to guarantee the independence of drug regulatory agencies from corporate influence and funding;*

Or. en

**Amendment 469**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 23 b (new)**

*Motion for a resolution*

*Amendment*

**23b. Calls on the Commission to work on new advances in the monitoring and pharmacovigilance of drugs by means of post-authorisation assessments on their effectiveness and adverse effects, and by means of a register for all adverse effects with closer collaboration between Member States' agencies, and patients and doctors should have access to that register, which should be published every year; calls for the revision and harmonisation of the drugs labelling systems with a view to improving patient safety and enabling drugs to be traced in the EU;**

Or. es

**Amendment 470**  
**Piernicola Pedicini, Eleonora Evi, Marco Affronte**

**Motion for a resolution**  
**Paragraph 23 b (new)**

*Motion for a resolution*

*Amendment*

**23b. Calls on the Commission to ensure rigorous and proactive pharmacovigilance requirements, including the application of dissuasive sanctions if post-marketing requirements are not complied with;**

Or. en

**Amendment 471**  
**Christofer Fjellner**

**Motion for a resolution**  
**Paragraph 24**

*Motion for a resolution*

24. Calls on the Commission to ***set up a framework to promote, guarantee and reinforce*** the competitiveness of generic medicines, ***guaranteeing their faster entry onto the market and*** monitoring unfair practices in accordance with Articles 101 and 102 of the TFEU, ***and to present a biannual report in this regard;***

*Amendment*

24. Calls on the Commission to ***improve*** the competitiveness of generic medicines ***by*** monitoring unfair practices in accordance with Articles 101 and 102 of the TFEU;

Or. en

**Amendment 472**  
**Karin Kadenbach, Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 24**

*Motion for a resolution*

24. Calls on the Commission to set up a framework to promote, guarantee and reinforce the competitiveness of generic medicines, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles ***101 and 102*** of the TFEU, and to present a biannual report in this regard;

*Amendment*

24. Calls on the Commission to set up a framework to promote, guarantee and reinforce the competitiveness ***and use*** of generic ***and biosimilar*** medicines ***in sustainable market conditions***, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles ***101 and 102*** of the TFEU, and to present a biannual report in this regard;

Or. en

**Amendment 473**  
**Nikolay Barekov, Bolesław G. Piecha**

**Motion for a resolution**  
**Paragraph 24**

*Motion for a resolution*

24. Calls on the Commission to set up a framework to promote, guarantee and reinforce the competitiveness of generic medicines, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles 101 and 102 of the TFEU, and to present a biannual report in this regard;

*Amendment*

24. Calls on the Commission to set up a framework to promote, guarantee and reinforce the competitiveness **and use** of generic **and biosimilar** medicines **in sustainable market conditions**, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles 101 and 102 of the TFEU, and to present a biannual report in this regard;

Or. en

**Amendment 474**

**György Hölvényi, Alojz Peterle**

**Motion for a resolution**

**Paragraph 24**

*Motion for a resolution*

24. Calls on the Commission to set up a framework to promote, guarantee and reinforce the competitiveness of generic medicines, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles 101 and 102 of the TFEU, and to present a biannual report in this regard;

*Amendment*

24. Calls on the Commission to set up a framework to promote, guarantee and reinforce the competitiveness of generic **and biosimilar** medicines **in sustainable market conditions**, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles 101 and 102 of the TFEU, and to present a biannual report in this regard;

Or. en

**Amendment 475**

**Piernicola Pedicini, Marco Affronte, Eleonora Evi**

**Motion for a resolution**

**Paragraph 24**

*Motion for a resolution*

24. Calls on the Commission to set up a

*Amendment*

24. Calls on the Commission to set up a

framework to promote, guarantee and reinforce the competitiveness of generic medicines, guaranteeing their faster entry onto the market **and monitoring** unfair practices in accordance with Articles 101 and 102 of the TFEU, and to present a biannual report in this regard;

framework to promote, guarantee and reinforce the competitiveness of generic **and biosimilar** medicines, guaranteeing their faster entry onto the market **and sustainable conditions, and to monitor** unfair practices in accordance with Articles 101 and 102 of the TFEU, and to present a biannual report in this regard;

Or. it

**Amendment 476**  
**Nicola Caputo**

**Motion for a resolution**  
**Paragraph 24**

*Motion for a resolution*

24. Calls on the Commission to set up a framework to promote, guarantee and reinforce the competitiveness of generic medicines, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles 101 and 102 of the TFEU, and to present a biannual report in this regard;

*Amendment*

24. Calls on the Commission to set up a framework to promote, guarantee and reinforce the competitiveness of generic medicines, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles 101 and 102 of the TFEU, and to present a biannual report in this regard; **also calls on the Commission to promote and coordinate a clear and transparent IT system so that consumers are able to compare various equivalent medicines to the original and choose which product they want on the basis of the active ingredient and the bulking agents used in the medicine;**

Or. it

**Amendment 477**  
**Nessa Childers**

**Motion for a resolution**  
**Paragraph 24**

*Motion for a resolution*

24. Calls on the Commission to set up a framework to promote, guarantee and reinforce the competitiveness of generic medicines, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles 101 and 102 of the TFEU, and to present a biannual report in this regard;

*Amendment*

24. Calls on the Commission to set up a framework to promote, guarantee and reinforce the competitiveness of generic **and biosimilar** medicines, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles 101 and 102 of the TFEU, and to present a biannual report in this regard;

Or. en

**Amendment 478**  
**Biljana Borzan**

**Motion for a resolution**  
**Paragraph 24**

*Motion for a resolution*

24. Calls on the Commission to set up a framework to promote, guarantee and reinforce the competitiveness of generic medicines, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles 101 and 102 of the TFEU, and to present a biannual report in this regard;

*Amendment*

24. Calls on the Commission to set up a framework to promote, guarantee and reinforce the competitiveness of generic **and biosimilar** medicines, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles 101 and 102 of the TFEU, and to present a biannual report in this regard;

Or. en

**Amendment 479**  
**Nicola Caputo, Marc Tarabella**

**Motion for a resolution**  
**Paragraph 24**

*Motion for a resolution*

24. Calls on the Commission to set up a framework to promote, guarantee and

*Amendment*

24. Calls on the Commission to set up a framework to promote, guarantee and



reinforce the competitiveness of generic medicines, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles 101 and 102 of the TFEU, and to present a biannual report in this regard;

reinforce the competitiveness of generic **and biosimilar** medicines, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles 101 and 102 of the TFEU, and to present a biannual report in this regard;

Or. en

#### **Amendment 480**

**José Inácio Faria, Jasenko Selimovic, Frédérique Ries, Marian Harkin, Lieve Wierinck**

#### **Motion for a resolution**

##### **Paragraph 24**

###### *Motion for a resolution*

24. Calls on the Commission to set up a framework to promote, guarantee and reinforce the competitiveness of generic medicines, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles 101 and 102 of the TFEU, and to present a biannual report in this regard;

###### *Amendment*

24. Calls on the Commission to set up a framework to promote, guarantee and reinforce the competitiveness of generic **and biosimilar** medicines, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles 101 and 102 of the TFEU, and to present a biannual report in this regard;

Or. en

#### **Amendment 481**

**Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn**

#### **Motion for a resolution**

##### **Paragraph 24**

###### *Motion for a resolution*

24. Calls on the Commission **to set up a framework** to promote, guarantee and reinforce the competitiveness of generic medicines, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles 101 and 102 of the TFEU, and to present a

###### *Amendment*

24. Calls on the Commission to promote, guarantee and reinforce the competitiveness of generic medicines, guaranteeing their faster entry onto the market and monitoring unfair practices in accordance with Articles 101 and 102 of the TFEU, and to present a biannual report

biannual report in this regard;

in this regard;

Or. fr

**Amendment 482**  
**Kateřina Konečná**

**Motion for a resolution**  
**Paragraph 24 a (new)**

*Motion for a resolution*

*Amendment*

**24a. Calls on the Commission to analyse the impact of the existing rules outlined in Directive 2001/83/EC governing the marketing authorisation procedures of non-prescription homeopathic medicinal products on patients' choice, therapeutic freedom and ultimately access to medicines intended at self-medication;**

Or. en

**Amendment 483**  
**Karl-Heinz Florenz, Peter Liese, Andrey Kovatchev**

**Motion for a resolution**  
**Paragraph 24 a (new)**

*Motion for a resolution*

*Amendment*

**24a. Stresses that health technology assessments (HTA) are an important and effective instrument that contributes to the sustainability of national healthcare systems and creates incentives for innovations by rewarding them with high added value;**

Or. de

**Amendment 484**  
**Nicola Caputo, Marc Tarabella**

**Motion for a resolution**  
**Paragraph 24 a (new)**

*Motion for a resolution*

*Amendment*

**24a.** *Underlines the importance of timely availability of generics and biosimilars in order to facilitate patients' access to pharmaceutical therapies and to improve the sustainability of national health systems;*

Or. en

**Amendment 485**  
**Andrey Kovatchev, Cristian-Silviu Buşoi, Kateřina Konečná, Biljana Borzan, Karl-Heinz Florenz, Karin Kadenbach**

**Motion for a resolution**  
**Paragraph 24 a (new)**

*Motion for a resolution*

*Amendment*

**24a.** *Reiterates that European collaboration on HTA allows Member States to pool their expertise and use their resources more effectively, thus helping them to better meet the increasing demand for assessments;*

Or. en

**Amendment 486**  
**Cristian-Silviu Buşoi**

**Motion for a resolution**  
**Paragraph 24 a (new)**

*Motion for a resolution*

*Amendment*

**24a.** *calls on the Commission and encourages Member States to develop a*

*strategy to stimulate new use of old drugs with the objective to ultimately fight against suboptimal use of current treatments and to tackle related inefficiencies impacting patient's life and the sustainability of the healthcare systems;*

Or. en

**Amendment 487**  
**Christel Schaldemose**

**Motion for a resolution**  
**Paragraph 24 a (new)**

*Motion for a resolution*

*Amendment*

**24a. Calls on the Commission to observe and reinforce the EU competition legislation and its competencies on the pharmaceutical market to counter abuse and to promote fair prices for patients;**

Or. en

**Amendment 488**  
**Kateřina Konečn, Biljana Borzan**

**Motion for a resolution**  
**Paragraph 24 b (new)**

*Motion for a resolution*

*Amendment*

**24b. Calls on the European Commission to enhance dialogue on unmet medical needs between all relevant stakeholders, patients, healthcare professionals, regulators, HTA bodies, payers and developers throughout the life span of medicines.**

Or. en

**Amendment 489**  
**Cristian-Silviu Buşoi**

**Motion for a resolution**  
**Paragraph 25**

*Motion for a resolution*

25. Calls on the Commission to ***propose legislation on a European system for health technology assessment as soon as possible, and to assess added-value medicines compared with the best available alternative; also calls on the Commission to harmonise pricing and reimbursement criteria to take into account the level of innovation and the social and economic cost-benefit analysis, and to put in place a European classification on the added value level of medicines;***

*Amendment*

25. Calls on the Commission to ***continue supporting cooperation between MS on HTA through the HTA Network and EUnetHTA and to continue to investigate the feasibility and added value of further streamlining national health technology assessments, taking into account the specificities of national pricing and reimbursement systems;***

Or. en

**Amendment 490**  
**Margrete Auken**

**Motion for a resolution**  
**Paragraph 25**

*Motion for a resolution*

25. Calls on the Commission to ***propose legislation on a European system for health technology assessment as soon as possible, and to assess added-value medicines compared with the best available alternative; also calls on the Commission to harmonise pricing and reimbursement criteria to take into account the level of innovation and the social and economic cost-benefit analysis, and to put in place a European classification on the added value level of medicines;***

*Amendment*

25. Calls on the Commission to ***produce a report analysing the current different national systems for classification on the added value level of medicines in the EU and beyond;***

Or. en

## **Amendment 491**

**Elisabetta Gardini, Giovanni La Via, Aldo Patriciello, Alessandra Mussolini**

### **Motion for a resolution**

#### **Paragraph 25**

##### *Motion for a resolution*

25. Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible, ***and to assess added-value medicines compared with the best available alternative; also calls on the Commission to harmonise pricing and reimbursement criteria to take into account the level of innovation and the social and economic cost-benefit analysis, and to put in place a European classification on the added value level of medicines;***

##### *Amendment*

25. Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible;

Or. en

## **Amendment 492**

**Eva Kaili**

### **Motion for a resolution**

#### **Paragraph 25**

##### *Motion for a resolution*

25. Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible, ***and to assess added-value medicines compared with the best available alternative; also calls on the Commission to harmonise pricing and reimbursement criteria to take into account the level of innovation and the social and economic cost-benefit analysis, and to put in place a European classification on the added value level of medicines;***

##### *Amendment*

25. Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible;

**Amendment 493**  
**Mireille D'Ornano**

**Motion for a resolution**  
**Paragraph 25**

*Motion for a resolution*

25. Calls on the Commission to ***propose legislation on a European system for health technology assessment as soon as possible, and to assess added-value*** medicines compared with the best available alternative; also calls on the Commission to ***harmonise pricing and reimbursement criteria to take into account the level of innovation and the social and economic cost-benefit analysis, and to put in place*** a European classification on the added value level of medicines;

*Amendment*

25. Calls on the Commission to ***press for the added value of*** medicines ***to be factored in when they are*** compared with the best available alternative; also calls on the Commission to ***support*** a European classification on the added value level of medicines;

Or. fr

**Amendment 494**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 25**

*Motion for a resolution*

25. Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible, ***and to assess added-value medicines*** compared with the best available alternative; ***also calls on the Commission to harmonise pricing and reimbursement criteria to take into account the level of innovation and the social and economic cost-benefit analysis,*** ***and*** to put in place a European classification on the added value level of

*Amendment*

25. Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible, ***to facilitate assessment of*** compared with the best available alternative; ***such legislation shall ensure that HTA output jointly produced at EU level is user in national decision making process. It shall reflect the differences between pharmaceuticals and other medical technologies and procedures. It shall foresee joint Rapid Relative***

medicines;

*Effectiveness Assessment for pharmaceutical, strengthen early dialogues. it should consider a coordination mechanisms based on an independent body, which could foster cooperation between national HTA bodies and at the same time ensuring that expertise on HTA remains within national (and regional) HTA bodies. Could be helpful* to put in place a European Classification on the added value level of medicines;

Or. en

#### **Amendment 495**

**Karl-Heinz Florenz, Peter Liese, Andrey Kovatchev**

#### **Motion for a resolution**

#### **Paragraph 25**

##### *Motion for a resolution*

25. Calls on the Commission to propose legislation on a European system for health technology assessment *as soon as possible*, and to assess added-value medicines compared with the best available alternative; also calls on the Commission *to harmonise pricing and reimbursement criteria to take into account the level of innovation and the social and economic cost-benefit analysis*, and to put in place a European classification on the added value level of medicines;

##### *Amendment*

25. Calls on the Commission to propose legislation on a European system for health technology assessment and to assess added-value medicines compared with the best available alternative; also calls on the Commission *to promote early dialogue with companies that develop new health technologies, introduce compulsory relative effectiveness assessments at EU level as a first step for new medicines, ensure that joint HTA information at national level can be reused to harmonise processes and methods to prevent unnecessary overlaps, and address any financing and organisational issues with regard to this new system; also calls on the Commission to take into account the degree of innovation* and to put in place a European classification on the added value level of medicines;

Or. de



**Amendment 496**  
**Christofer Fjellner**

**Motion for a resolution**  
**Paragraph 25**

*Motion for a resolution*

25. Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible, and to assess added-value medicines compared with the best available alternative; ***also calls on the Commission to harmonise pricing and reimbursement criteria to take into account the level of innovation and the social and economic cost-benefit analysis***, and to put in place a European classification on the added value level of medicines;

*Amendment*

25. Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible, and to assess added-value medicines compared with the best available alternative; and to put in place a European classification on the added value level of medicines;

Or. en

**Amendment 497**  
**Monica Macovei**

**Motion for a resolution**  
**Paragraph 25**

*Motion for a resolution*

25. Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible, and to assess added-value medicines compared with the best available alternative; also calls on the Commission to harmonise pricing and reimbursement criteria to take into account the level of innovation and the social and economic cost-benefit analysis, and to put in place a European classification on the added value level of medicines;

*Amendment*

25. Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible, and to assess added-value medicines compared with the best available alternative; also calls on the Commission to harmonise pricing and reimbursement criteria ***throughout the EU*** to take into account the level of innovation and the social and economic cost-benefit analysis, and to put in place a European classification on the added value level of medicines; ***calls for simplifying the reimbursement criteria and process of the***

*medicals costs in another country than their own*

Or. en

**Amendment 498**

**Nikolay Barekov, Boleslaw G. Piecha**

**Motion for a resolution**

**Paragraph 25**

*Motion for a resolution*

25. Calls on the Commission to **propose** legislation on **a European system for** health technology assessment **as soon as possible, and to** assess added-value medicines compared with the best available alternative; also calls on the Commission to **harmonise** pricing and reimbursement criteria **to take** into account the level of innovation and the social and economic cost-benefit analysis, and to put in place a European classification on the added value level of medicines;

*Amendment*

25. Calls on the Commission to **consider proposing** legislation on **these aspects of the** health technology assessment **which are relevant for the EU, in particular clinical evaluation, to better** assess added-value medicines compared with the best available alternative; also calls on the Commission to **work towards** pricing and reimbursement criteria **taking** into account the level of innovation and the social and economic cost-benefit analysis **for all the Member States**, and to put in place a European classification on the added value level of medicines;

Or. en

**Amendment 499**

**György Hölvényi, Alojz Peterle**

**Motion for a resolution**

**Paragraph 25**

*Motion for a resolution*

25. Calls on the Commission to **propose legislation** on a European system for health technology assessment as soon as possible, and to assess added-value medicines compared with the best available alternative; **also calls on the Commission to harmonise pricing and reimbursement**

*Amendment*

25. Calls on the Commission to **carry out an impact assessment** on a European system for health technology assessment as soon as possible, and to assess added-value medicines compared with the best available alternative; and to put in place a European classification on the added value level of

*criteria to take into account the level of innovation and the social and economic cost-benefit analysis, and to put in place a European classification on the added value level of medicines;*

medicines;

Or. en

#### **Amendment 500**

**Françoise Grossetête, Angélique Delahaye**

#### **Motion for a resolution**

#### **Paragraph 25**

##### *Motion for a resolution*

25. *Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible, and to assess added-value medicines compared with the best available alternative; also calls on the Commission to harmonise pricing and reimbursement criteria to take into account the level of innovation and the social and economic cost-benefit analysis, and to put in place a European classification on the added value level of medicines;*

##### *Amendment*

25. *Welcomes the HTA multi-annual work programme 2016-2020 and recognises the added value of European cooperation when it comes to assessing health technology; calls on the Commission to propose legislation on establishing a system for health technology assessment as soon as possible; calls for that system to be developed in close collaboration with the European Medicines Agency.*

Or. fr

#### **Amendment 501**

**Krzysztof Hetman**

#### **Motion for a resolution**

#### **Paragraph 25**

##### *Motion for a resolution*

25. *Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible, and to assess added-value medicines compared with the best available*

##### *Amendment*

25. *Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible, and to assess added-value medicines compared with the best available*

alternative; also calls on the Commission to harmonise pricing and reimbursement criteria to take into account the level of innovation and the social and economic cost-benefit analysis, and to put in place a European classification on the added value level of medicines;

alternative; also calls on the Commission to harmonise pricing *procedure* and reimbursement criteria to take into account the level of innovation and the social and economic cost-benefit analysis, and to put in place a European classification on the added value level of medicines;

Or. en

## **Amendment 502** **Biljana Borzan**

### **Motion for a resolution** **Paragraph 25**

#### *Motion for a resolution*

25. Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible, and to assess added-value medicines compared with the best available alternative; also calls on the Commission to harmonise *pricing and reimbursement* criteria to take into account the level of innovation and the social and economic cost-benefit analysis, and to put in place a European classification on the added value level of medicines;

#### *Amendment*

25. Calls on the Commission to propose legislation on a European system for health technology assessment as soon as possible, and to assess added-value medicines compared with the best available alternative; also calls on the Commission to harmonise *HTA* criteria to take into account the level of innovation, *value for patients*, and the social and economic cost-benefit analysis, and to put in place a European classification on the added value level of medicines;

Or. en

## **Amendment 503** **Kateřina Konečná**

### **Motion for a resolution** **Paragraph 25 a (new)**

#### *Motion for a resolution*

#### *Amendment*

***25a. Calls on the Commission and the Member States to identify and/or develop frameworks, structures and methodologies in order to meaningfully***

*incorporate patient evidence at all stages of the medicines R&D cycle, from early dialogue to regulatory approval, Health Technology Assessment, relative effectiveness assessments, and pricing and reimbursement decision-making with the involvement of patients and their representative organisations.*

Or. en

**Amendment 504**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 25 a (new)**

*Motion for a resolution*

*Amendment*

**25a.** *Calls on the Commission and the Member States to identify and develop frameworks, structures and methodologies in order to meaningfully incorporate patient evidence at all stages of the medicines R&D cycle, from early dialogue to regulatory approval, Health Technology Assessment, relative effectiveness assessments, and pricing and reimbursement decision-making with the involvement of patients and their representative organisations;*

Or. en

**Amendment 505**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 25 a (new)**

*Motion for a resolution*

*Amendment*

**25a.** *Calls on the Commission to analyse the economic, social and ethical criteria which some Member States'*

*HTAs already apply and to establish common principles or guidelines in that regard on the basis of the usefulness of those criteria with regarding to pricing and reimbursement, then to decide whether the innovation quality is important to establishing its economic value, but not important enough to guarantee an appropriate cost-effectiveness relationship;*

Or. es

**Amendment 506**

**Elisabetta Gardini, Alojz Peterle, Giovanni La Via, Aldo Patriciello, Alessandra Mussolini**

**Motion for a resolution**

**Paragraph 25 a (new)**

*Motion for a resolution*

*Amendment*

*25a. Calls on the European Medicines Agency to assess added-value medicines compared with the best available alternative; also calls on the Commission to harmonise pricing and reimbursement criteria to take into account the level of innovation and the social and economic cost-benefit analysis, and to put in place a European classification on the added value level of medicines;*

Or. en

**Amendment 507**

**Nicola Caputo, Marc Tarabella, Soledad Cabezón Ruiz**

**Motion for a resolution**

**Paragraph 25 a (new)**

*Motion for a resolution*

*Amendment*

*25a. Calls on the Commission to establish a permanent and single*

*mechanism assessing relative efficacy of new medicinal products at EU level based on harmonized data requirements, so as to enhance patient access to new treatments and avoid duplications in drug assessments;*

Or. en

**Amendment 508**  
**Sirpa Pietikäinen**

**Motion for a resolution**  
**Paragraph 25 a (new)**

*Motion for a resolution*

*Amendment*

**25a.** *Calls on the Commission to establish a permanent and single mechanism assessing relative efficacy of new medicinal products at EU level based on harmonized data requirements, so as to enhance patient access to new treatments and avoid duplications in drug assessments;*

Or. en

**Amendment 509**  
**Notis Marias**

**Motion for a resolution**  
**Paragraph 26**

*Motion for a resolution*

*Amendment*

26. Calls on the Commission and the Member States to promote major publicly funded investment in research based on medical needs, and to introduce conditional funding based on affordable end pricing and non-exclusive licencing;

26. Calls on the Commission and the Member States to promote major publicly funded investment in research based on medical needs, and to introduce conditional funding based on affordable end pricing and non-exclusive licencing; *at the same time, given that the violent economic adjustment imposed by the EU does not permit each Member State to tackle the*

*deficits observed in the health system,  
considers that the Union should take  
immediate steps to cover these deficits;*

Or. el

**Amendment 510**

**Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn**

**Motion for a resolution**

**Paragraph 26**

*Motion for a resolution*

26. Calls on the Commission and the Member States to promote major publicly funded investment in research based on medical needs, *and to introduce conditional funding based on affordable end pricing and non-exclusive licencing;*

*Amendment*

26. Calls on the Commission and the Member States to promote major publicly funded investment in research based on medical needs;

Or. fr

**Amendment 511**

**Piernicola Pedicini, Eleonora Evi, Marco Affronte**

**Motion for a resolution**

**Paragraph 26**

*Motion for a resolution*

26. Calls on the Commission and the Member States to promote major publicly funded investment in research based on medical needs, and to introduce conditional funding based on affordable end pricing *and non-exclusive licencing;*

*Amendment*

26. Calls on the Commission and the Member States to promote major publicly funded investment in research based on medical needs, and to introduce conditional funding based on affordable end pricing, non-exclusive licencing, *and results yielded by biomedical research in the form of suitable and affordable medicines;*

Or. it



**Amendment 512**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 26**

*Motion for a resolution*

26. Calls on the Commission and the Member States to promote major publicly funded investment in research based on medical needs, and to introduce conditional funding based on affordable end pricing and non-exclusive licencing;

*Amendment*

26. Calls on the Commission and the Member States to promote major publicly funded investment in research based on *unmet* medical needs, and to introduce conditional funding based on affordable end pricing and non-exclusive licencing;

Or. en

**Amendment 513**  
**Cristian-Silviu Buşoi**

**Motion for a resolution**  
**Paragraph 26**

*Motion for a resolution*

26. Calls on the Commission and the Member States to promote major publicly funded investment in research based on medical needs, *and to introduce conditional funding based on affordable end pricing and non-exclusive licencing;*

*Amendment*

26. Calls on the Commission and the Member States to promote major publicly funded investment in research based on medical needs; *further encourages Member States to ensure that their pricing and reimbursement frameworks guide private investment towards those innovations which they expect to deliver the desired benefits and patient outcomes;*

Or. en

**Amendment 514**  
**Cristian-Silviu Buşoi**

**Motion for a resolution**  
**Paragraph 26 a (new)**

*Motion for a resolution*

*Amendment*

**26a.** *Calls on Member States to ensure that their pricing and reimbursement systems and pharmaceutical policies effectively convey a long term policy vision, therefore creating a more predictable operating environment for all actors of the healthcare system, including pharmaceutical companies, ultimately supporting patient access to medicines throughout the whole lifecycle of molecules and incentivizing innovation;*

Or. en

**Amendment 515**

**Eva Kaili**

**Motion for a resolution**

**Paragraph 26 a (new)**

*Motion for a resolution*

*Amendment*

**26a.** *Calls on the European Medicines Agency to assess added-value medicines compared with the best available alternative; also calls on the European Commission to harmonize pricing and reimbursement criteria, to take into account the level of innovation as well as the social and economic cost-benefit analysis, and to put in place a European classification on the added value of medicines;*

Or. en

**Amendment 516**

**Annie Schreijer-Pierik**

**Motion for a resolution**

**Paragraph 26 a (new)**

*Motion for a resolution*

*Amendment*

**26a.** *calls on the Commission to take measures to promote the development of drugs for preventative and curative geriatrics, and access to innovative drugs for patients suffering from mesothelioma and amyotrophic lateral sclerosis (ALS);*

Or. nl

**Amendment 517**

**Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn**

**Motion for a resolution**

**Paragraph 27**

*Motion for a resolution*

*Amendment*

27. Calls on the Council to increase cooperation between the Member States as regards price-setting procedures, ***in order to share information about prices, reimbursement, negotiation agreements and good practices and to avoid unnecessary administrative requirements and delays;***

27. Calls on the Council to increase cooperation between the Member States as regards price-setting procedures; ***emphasises that the European Medicines Agency would benefit from developing the assessment of the 'medical service delivered' by medicines on the basis of several satisfaction levels and the 'improvement of the medical service delivered' with a view to comparing the latter with the treatments that already existed, as the French Health Authority already does;***

Or. fr

**Amendment 518**

**Alberto Cirio**

**Motion for a resolution**

**Paragraph 27**

*Motion for a resolution*

*Amendment*

27. Calls on the Council to ***increase***

27. Calls on the Council to ***support the***

*cooperation between the Member States as regards price-setting procedures, in order to share information about prices, reimbursement, negotiation agreements and good practices and to avoid unnecessary administrative requirements and delays;*

*exchange of good practices between Member States on those aspects where cooperation can lead to broader and faster patient access, while also preserving necessary incentives for innovation;*

Or. en

### **Amendment 519**

**José Inácio Faria, Jasenko Selimovic, Anneli Jäätteenmäki, Yana Toom**

#### **Motion for a resolution**

##### **Paragraph 27**

###### *Motion for a resolution*

27. Calls on the Council *to increase* cooperation between the Member States as regards price-setting procedures, in order to share information about prices, reimbursement, negotiation agreements and good practices and to avoid unnecessary administrative requirements and delays;

###### *Amendment*

27. Calls on the Council *and the Commission to promote increased* cooperation between the Member States as regards price-setting procedures, in order to share information about prices, reimbursement, negotiation agreements and good practices and to avoid unnecessary administrative requirements and delays;

Or. en

### **Amendment 520**

**Nikolay Barekov, Bolesław G. Piecha**

#### **Motion for a resolution**

##### **Paragraph 27**

###### *Motion for a resolution*

27. Calls on the Council to increase cooperation between the Member States as regards price-setting procedures, in order to share information about prices, reimbursement, *negotiation agreements* and good practices and to avoid unnecessary administrative requirements

###### *Amendment*

27. Calls on the Council to increase cooperation between the Member States as regards price-setting procedures, in order to share information about prices, reimbursement and good practices and to avoid unnecessary administrative requirements and delays;

and delays;

Or. en

#### **Amendment 521**

**Lieve Wierinck, Gesine Meissner, Frédérique Ries, José Inácio Faria, Anneli Jäätteenmäki, Marian Harkin, Yana Toom, Jasenko Selimovic**

#### **Motion for a resolution**

##### **Paragraph 27**

###### *Motion for a resolution*

27. Calls on the Council to increase cooperation between the Member States as regards price-setting procedures, in order to share information about prices, reimbursement, negotiation agreements and good practices and to avoid unnecessary administrative requirements and delays;

###### *Amendment*

27. Calls on the Council to increase cooperation between the Member States as regards price-setting procedures, in order to share information about prices, reimbursement, negotiation agreements and good practices and to avoid unnecessary administrative requirements and delays, ***ensuring faster patient access to innovative medicines***;

Or. en

#### **Amendment 522**

**Elisabetta Gardini, Alojz Peterle, Giovanni La Via, Aldo Patriciello, Alessandra Mussolini**

#### **Motion for a resolution**

##### **Paragraph 27**

###### *Motion for a resolution*

27. Calls on the Council to increase cooperation between the Member States as regards price-setting procedures, in order to share information about prices, reimbursement, negotiation agreements and good practices and to avoid unnecessary administrative requirements and delays;

###### *Amendment*

27. Calls on the Council to increase cooperation between the Member States as regards price-setting procedures, in order to share information about prices, reimbursement, negotiation agreements and good practices and to avoid unnecessary administrative requirements and delays, ***based also on the work of the EURIPID project and existing bilateral and multilateral collaborations***;

**Amendment 523**

**Eva Kaili**

**Motion for a resolution**

**Paragraph 27**

*Motion for a resolution*

27. Calls on the Council to increase cooperation between the Member States as regards price-setting procedures, in order to share information about prices, reimbursement, negotiation agreements and good practices and to avoid unnecessary administrative requirements and delays;

*Amendment*

27. Calls on the Council to increase cooperation between the Member States as regards price-setting procedures, in order to share information about prices, reimbursement, negotiation agreements and good practices and to avoid unnecessary administrative requirements and delays, ***based also on the work of EURIPID project and existing bilateral and multilateral collaborations;***

Or. en

**Amendment 524**

**Soledad Cabezón Ruiz**

**Motion for a resolution**

**Paragraph 27**

*Motion for a resolution*

27. Calls on the Council to increase cooperation between the Member States as regards price-setting procedures, in order to share information about prices, reimbursement, negotiation agreements and good practices and to avoid unnecessary administrative requirements and delays;

*Amendment*

27. Calls on the Council to increase cooperation between the Member States as regards price-setting procedures, in order to share information about prices, reimbursement, negotiation agreements and good practices and to avoid unnecessary administrative requirements and delays; ***also calls on the Council to ensure that Member States make greater use of the mutual recognition of authorisations;***

Or. es

**Amendment 525**

**Karl-Heinz Florenz, Peter Liese, Andrey Kovatchev**

**Motion for a resolution**

**Paragraph 27**

*Motion for a resolution*

27. Calls on the Council to **increase cooperation** between the Member States as regards price-setting procedures, in order to share information about prices, reimbursement, negotiation agreements and good practices and to avoid unnecessary administrative requirements and delays;

*Amendment*

27. Calls on the Council to **improve communication** between the Member States as regards price-setting procedures, in order to share information about prices, reimbursement, negotiation agreements and good practices and to avoid unnecessary administrative requirements and delays;

Or. de

**Amendment 526**

**Monica Macovei**

**Motion for a resolution**

**Paragraph 27**

*Motion for a resolution*

27. Calls on the Council to increase cooperation between the Member States as regards price-setting procedures, in order to share information about prices, reimbursement, negotiation agreements and good practices and to avoid unnecessary administrative requirements and delays;

*Amendment*

27. Calls on the Council to increase cooperation **and dialogue** between the Member States as regards price-setting procedures, in order to share information about prices, reimbursement, negotiation agreements and good practices and to avoid unnecessary administrative requirements and delays;

Or. en

**Amendment 527**

**Nicola Caputo, Marc Tarabella, Soledad Cabezón Ruiz**

**Motion for a resolution**

**Paragraph 27 a (new)**

*Motion for a resolution*

*Amendment*

**27a.** *Invites the Member States to explore possible strategies on voluntary cooperation to jointly work on relative efficacy assessments of medicines, on common horizon scanning tools to allow for better budgetary planning and on measures enabling joint price negotiations in coalitions of Member States, that have expressed interest to do so;*

Or. en

**Amendment 528**  
**Christel Schaldemose**

**Motion for a resolution**  
**Paragraph 27 a (new)**

*Motion for a resolution*

*Amendment*

**27a.** *Calls on the Commission to consider a model in which a maximum price for a pharmaceutical product is set when approved for the European Market by EMA in accordance with Directive 2001/83/EC and Regulation 2004/726/EC; this maximum price should be based on the cost of research, development and production with a fair profit margin;*

Or. en

**Amendment 529**  
**Margrete Auken, Michèle Rivasi**

**Motion for a resolution**  
**Paragraph 27 a (new)**

*Motion for a resolution*

*Amendment*

**27a.** *Calls on the EPO and the Member*



*States to grant patents on health products that strictly fulfil the patentability requirements of novelty, inventive step and industrial applicability; a mere discovery of a new form of a known substance that does not improve efficacy should not be patentable;*

Or. en

**Amendment 530**

**Nicola Caputo, Marc Tarabella, Soledad Cabezón Ruiz**

**Motion for a resolution**

**Paragraph 27 b (new)**

*Motion for a resolution*

*Amendment*

*27b. Invites the Member States to consider organising during each EU Presidency an informal meeting of relevant high level representatives from the Member States responsible for pharmaceutical policy (e.g. national directors of pharmaceutical policy), encouraging strategic reflection and discussion on current and future developments in the pharmaceutical system in the EU and its Member States; notes that these discussions could be used, where relevant, as an input for further reflection in the appropriate EU fora, in particular the Working Party on Pharmaceuticals and Medical Devices;*

Or. en

**Amendment 531**

**Damiano Zoffoli**

**Motion for a resolution**

**Paragraph 28**

*Motion for a resolution*

28. Calls on the Council to promote rational use of medicines across the EU;

*Amendment*

28. Calls on the Council to promote *a more* rational use of medicines across the EU, *and to promote campaigns and educational programmes aimed at making citizens aware of how to use medicines responsibly and on the collection of medicines that have not yet expired, the latter representing a precious asset to the poor, a huge waste and a serious financial loss for national health systems, without forgetting the negative consequences of disposal on the environment;*

Or. it

**Amendment 532**

**Mireille D'Ornano, Sylvie Goddyn, Jean-François Jalkh**

**Motion for a resolution**

**Paragraph 28**

*Motion for a resolution*

28. Calls on the Council to promote rational use of medicines across the EU;

*Amendment*

28. Calls on the Council to promote rational use of medicines across the EU, *including by limiting wastage through excessive use of medicines or prescriptions which are inappropriate to patients' illnesses; in fact, this challenge amounts to several millions of euros which could be put to better use elsewhere;*

Or. fr

**Amendment 533**

**Nessa Childers**

**Motion for a resolution**

**Paragraph 28**

*Motion for a resolution*

28. Calls on the Council to promote rational use of medicines across the EU;

*Amendment*

28. Calls on the Council to promote rational use of medicines across the EU, ***including a better use of pharmacist expertise in procurement and patient advice;***

Or. en

**Amendment 534**

**Lieve Wierinck, Frédérique Ries, Gesine Meissner, José Inácio Faria, Anneli Jäätteenmäki, Marian Harkin, Yana Toom, Jasenko Selimovic**

**Motion for a resolution  
Paragraph 28**

*Motion for a resolution*

28. Calls on the Council to promote rational use of medicines across the EU;

*Amendment*

28. Calls on the Council to promote rational use of medicines across the EU, ***such as avoiding overconsumption of medicines, in particular antibiotics;***

Or. en

**Amendment 535**

**Biljana Borzan**

**Motion for a resolution  
Paragraph 28**

*Motion for a resolution*

28. Calls on the Council to promote rational use of medicines across the EU;

*Amendment*

28. Calls on the Council to promote rational use of medicines, ***and especially antimicrobials,*** across the EU;

Or. en

**Amendment 536**

**Karl-Heinz Florenz, Peter Liese, Françoise Grossetête, Norbert Lins, Andrey Kovatchev**

**Motion for a resolution**  
**Paragraph 28 a (new)**

*Motion for a resolution*

*Amendment*

**28a. Stresses that antimicrobial resistance has become a serious problem that needs to be urgently tackled; therefore calls on the Commission and the Member States to tackle the key scientific, regulatory and economic challenges facing the development of antimicrobial agents, particularly by creating incentives for investments in research and development as well as new financing models to address the most urgent needs of the public healthcare sector and at the same time safeguard the sustainability of public healthcare systems in order to improve and ensure future access to suitable antimicrobial agents;**

Or. de

**Amendment 537**  
**Margrete Auken**

**Motion for a resolution**  
**Paragraph 28 a (new)**

*Motion for a resolution*

*Amendment*

**28a. Calls on the Member States, where the private sector fails to deliver on availability and/or affordability of medicines listed on the WHO list of essential medicines, to cooperate in setting up public facilities for medicines production, while those medicines should be produced and sold in the EU at a price not exceeding the cost of production;**

Or. en

**Amendment 538**

**Yana Toom, Ilhan Kyuchyuk, Marian Harkin**

**Motion for a resolution**

**Paragraph 28 a (new)**

*Motion for a resolution*

*Amendment*

**28a. Call on the Member States to ensure accessibility of pharmacies, including their density in both urban and rural areas, professional staff number, appropriate opening hours, qualitative advice and counselling service;**

Or. en

**Amendment 539**

**Piernicola Pedicini, Eleonora Evi, Marco Affronte**

**Motion for a resolution**

**Paragraph 28 a (new)**

*Motion for a resolution*

*Amendment*

**28a. Calls on the Commission, the Council and the Member States to operationalize funding for R&D through delinkage innovation models with a view to addressing antimicrobial resistance and the related challenges;**

Or. en

**Amendment 540**

**José Inácio Faria, Jasenko Selimovic, Anneli Jäätteenmäki, Frédérique Ries, Marian Harkin, Lieve Wierinck, Yana Toom**

**Motion for a resolution**

**Paragraph 28 a (new)**

*Motion for a resolution*

*Amendment*

**28a. Calls on the Commission and on Member States to ensure full**

*implementation of the pharmacovigilance legislation;*

Or. en

**Amendment 541**

**Yana Toom, Ilhan Kyuchyuk, Marian Harkin**

**Motion for a resolution**

**Paragraph 28 b (new)**

*Motion for a resolution*

*Amendment*

**28b.** *Call on the Member States to ensure that for the protection of health and life and in the interests of consumer protection information notes accompanying medicines are provided by retailers in widely used languages of a particular Member State in addition to official language or languages;*

Or. en

**Amendment 542**

**Andrey Kovatchev, Cristian-Silviu Buşoi, Kateřina Konečná, Biljana Borzan, Karin Kadenbach**

**Motion for a resolution**

**Paragraph 29**

*Motion for a resolution*

*Amendment*

29. Calls on the Commission and the Council to *explore new measures to control prices*, such as *horizontal* scanning and coordinating joint procurements;

29. Calls on the Commission and the Council to *develop a framework for ensuring "fair access" that maximises patient access and societal benefit whilst avoiding unacceptable impact on healthcare budgets; including exploration of different measures*, such as *horizon* scanning, *early dialogue*, *innovative pricing models*, *mechanisms for systematic collection of real-world data*, and coordinating joint procurements;

**Amendment 543**

**Karl-Heinz Florenz, Ivo Belet**

**Motion for a resolution**

**Paragraph 29**

*Motion for a resolution*

29. Calls on the Commission and the Council to explore new *measures to control prices*, such as horizontal scanning and *coordinating joint* procurements;

*Amendment*

29. Calls on the Commission and the Council to explore new *initiatives that predict developments in the pharmaceutical market and prices*, such as horizontal scanning and *voluntary cooperation in price negotiations and joint* procurements, *as is the case in the initiative between the Benelux countries and Austria*;

Or. de

**Amendment 544**

**Soledad Cabezón Ruiz**

**Motion for a resolution**

**Paragraph 29**

*Motion for a resolution*

29. Calls on the Commission and the Council to explore new measures to *control prices*, such as *horizontal* scanning and coordinating joint procurements;

*Amendment*

29. Calls on the Commission and the Council to explore new measures to *address uncertainty on the expected budget impact ant to make sure that products are available in the markets*, such as *horizon* scanning and coordinating joint procurements;

Or. en

**Amendment 545**

**Carlos Zorrinho**

**Motion for a resolution**  
**Paragraph 29**

*Motion for a resolution*

29. Calls on the Commission and the Council to explore new measures to control prices, such as horizontal scanning **and** coordinating joint procurements;

*Amendment*

29. Calls on the Commission and the Council to explore new measures to control prices, such as horizontal scanning, coordinating joint procurements **and the evolution of healthcare public expenditures**;

Or. en

**Amendment 546**  
**Christofer Fjellner**

**Motion for a resolution**  
**Paragraph 29**

*Motion for a resolution*

29. Calls on the Commission and the Council to explore new measures to control **prices**, such as horizontal scanning and coordinating joint procurements;

*Amendment*

29. Calls on the Commission and the Council to explore new measures to control **public expenditure on health care**, such as horizontal scanning and coordinating joint procurements;

Or. en

**Amendment 547**  
**Krzysztof Hetman**

**Motion for a resolution**  
**Paragraph 29**

*Motion for a resolution*

29. Calls on the Commission and the Council to explore new measures to control prices, such as horizontal scanning and coordinating joint procurements;

*Amendment*

29. Calls on the Commission and the Council to explore **in justified cases** new measures to control prices, such as horizontal scanning and coordinating joint procurements;

Or. en



**Amendment 548**

**Notis Marias**

**Motion for a resolution**

**Paragraph 29**

*Motion for a resolution*

29. Calls on the Commission and the Council to explore new measures to control prices, such as horizontal scanning and coordinating joint procurements;

*Amendment*

29. Calls on the Commission and the Council to explore new **improved** measures to control prices, such as horizontal scanning and coordinating joint procurements;

Or. el

**Amendment 549**

**Nikolay Barekov, Boleslaw G. Piecha**

**Motion for a resolution**

**Paragraph 29**

*Motion for a resolution*

29. Calls on the Commission and the **Council** to explore new measures to control prices, such as horizontal scanning and **coordinating** joint procurements;

*Amendment*

29. Calls on the Commission and the **Member States** to explore new measures to control prices, such as horizontal scanning and **facilitating** joint procurements;

Or. en

**Amendment 550**

**Cristian-Silviu Buşoi**

**Motion for a resolution**

**Paragraph 29 a (new)**

*Motion for a resolution*

*Amendment*

**29a. calls on the Commission to define with all relevant stakeholders how best the most advantageous economic tender (MEAT) criterion, as described in the**

*Public Procurement Directive, and which does not imply only the lower cost criteria, could apply to medicines tenders in hospitals at national level, in order to enable sustainable and responsible supply of medicines; encourages Member States to best transpose the most economic advantageous tender criterion for medicinal products in their national legislation;*

Or. en

**Amendment 551**

**Lieve Wierinck, Frédérique Ries, Gesine Meissner, José Inácio Faria, Marian Harkin, Ulrike Müller, Yana Toom, Jasenko Selimovic**

**Motion for a resolution**

**Paragraph 29 a (new)**

*Motion for a resolution*

*Amendment*

*29a. Calls on the Member States to enter into dialogue with all the relevant stakeholders, such as patient organisations, paying agencies, healthcare professionals and industry, with the aim of establishing short-, medium- and long term holistic strategies for access to medicines, ensuring the sustainability of healthcare systems and a competitive pharmaceutical industry, leading to faster access for patients and affordable prices;*

Or. en

**Amendment 552**

**Françoise Grossetête**

**Motion for a resolution**

**Paragraph 29 a (new)**

*Motion for a resolution*

*Amendment*

**29a.** *Calls on the Commission to launch a new high-level European strategic dialogue for the pharmaceutical sector that brings together representatives of the Commission, the European Parliament and the Member States, along with key stakeholders from the healthcare world: payers, patients, representatives from the academic and scientific world and manufacturers, including SMEs;*

Or. fr

**Amendment 553**  
**Monica Macovei**

**Motion for a resolution**  
**Paragraph 30**

*Motion for a resolution*

30. Calls on the Commission and the Council to define clear rules on incompatibility, conflicts of interest and transparency in the EU institutions and for experts involved in issues related to medicines;

*Amendment*

30. Calls on the Commission and the Council to define clear rules on incompatibility, conflicts of interest and transparency in the EU institutions and for experts involved in issues related to medicines; ***calls on the experts involved in the authorisation process to publish their CVs and to sign a declaration of absence of conflict of interest;***

Or. en

**Amendment 554**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 30 a (new)**

*Motion for a resolution*

*Amendment*

**30a.** *Calls on the Member States, under*

*the supervision of the Commission, to enact the regulation on clinical trials in the scope of transparency and to study open access to those trials once they have been authorised for the market, and to push for the publication of all of the clinical trial results, including negative data, with a view to fostering research and economic growth;*

Or. es

**Amendment 555**

**Piernicola Pedicini, Eleonora Evi, Marco Affronte**

**Motion for a resolution**

**Paragraph 30a (new)**

*Motion for a resolution*

*Amendment*

**30a. Calls on the Commission and national antitrust authorities to monitor unfair practices to protect consumers from artificially high prices of medicines;**

Or. it

**Amendment 556**

**György Hölvényi**

**Motion for a resolution**

**Paragraph 31**

*Motion for a resolution*

*Amendment*

**31. Calls on the Commission to propose a new directive on transparency of price-setting procedures and reimbursement systems, taking into account the challenges of the market;**

*deleted*

Or. en

### **Amendment 557**

**Piernicola Pedicini, Marco Affronte, Eleonora Evi**

#### **Motion for a resolution**

##### **Paragraph 31**

###### *Motion for a resolution*

31. Calls on the Commission to propose a new directive on transparency *of price-setting procedures and reimbursement systems, taking into account the challenges of the market;*

###### *Amendment*

31. Calls on the Commission to propose a new directive on transparency *containing measures to regulate the setting of prices of speciality medicines for human consumption and their inclusion in national health insurance regimes, to guarantee full transparency and effective controls over all procedures used to establish prices and the reimbursement of medicines in the Member States of the EU;*

Or. it

### **Amendment 558**

**Elisabetta Gardini, Giovanni La Via, Aldo Patriciello, Alessandra Mussolini**

#### **Motion for a resolution**

##### **Paragraph 31**

###### *Motion for a resolution*

31. Calls on the Commission to *propose a new directive on transparency of price-setting procedures and reimbursement systems, taking into account the challenges of the market;*

###### *Amendment*

31. Calls on the Commission to *review the existing EU Directive 89/105/EEC, and in particular to put in place more solid implementing measures to ensure that Member States abide to the limit of 180 days imposed to them to fix the price of new medicines approved by EMA (Article 6);*

Or. en

### **Amendment 559**

**Eva Kaili**

**Motion for a resolution**  
**Paragraph 31**

*Motion for a resolution*

31. Calls on the Commission to **propose a new directive on transparency of price-setting procedures and reimbursement systems, taking into account the challenges of the market;**

*Amendment*

31. Calls on the Commission to **review the existing EU Directive 89/105/EEC and in particular to put in place more solid implementing measures to ensure that Member states abide to the limit of 180 days imposed to them to fix the price of new medicines approved by EMA (Article 6);**

Or. en

**Amendment 560**  
**Karin Kadenbach, Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 31**

*Motion for a resolution*

31. Calls on the Commission to propose a new directive on transparency of price-setting procedures and reimbursement systems, taking into account the challenges of the market;

*Amendment*

31. Calls on the Commission to propose a new directive on transparency of price-setting procedures and reimbursement systems, **with a view to extending transparency to the market authorisation holder, and** taking into account the challenges of the market.

Or. en

**Amendment 561**  
**Biljana Borzan**

**Motion for a resolution**  
**Paragraph 31**

*Motion for a resolution*

31. Calls on the Commission to propose a new directive on transparency of price-setting procedures and

*Amendment*

31. Calls on the Commission to propose a new directive on transparency of price-setting procedures and

reimbursement systems, taking into account the challenges of the market;

reimbursement systems, *with a view to extending transparency to the market authorisation holder, and* taking into account the challenges of the market;

Or. en

## **Amendment 562**

**Nikolay Barekov, Bolesław G. Piecha**

### **Motion for a resolution**

#### **Paragraph 31**

##### *Motion for a resolution*

31. Calls on the Commission to propose a new directive on transparency of price-setting procedures and reimbursement systems, taking into account the challenges of the market;

##### *Amendment*

31. Calls on the Commission to propose a new directive on transparency of price-setting procedures and reimbursement systems, taking into account the challenges of the market *and the division of competences between the EU and its Member States*;

Or. en

## **Amendment 563**

**Margrete Auken**

### **Motion for a resolution**

#### **Paragraph 31**

##### *Motion for a resolution*

31. Calls on the Commission to propose a new directive on transparency of price-setting procedures and reimbursement systems, taking into account the challenges of the market;

##### *Amendment*

31. Calls on the Commission to propose a new directive on transparency of price-setting procedures, *of real costs of R&D and marketing* and reimbursement systems, taking into account the challenges *of public budgets and* of the market;

Or. en

**Amendment 564**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 31**

*Motion for a resolution*

31. Calls on the Commission to propose a new directive on transparency of price-setting procedures and reimbursement systems, taking into account the **challenges** of the market;

*Amendment*

31. Calls on the Commission to propose a new directive on transparency of price-setting procedures and reimbursement systems, taking into account the **changes** of the market;

Or. en

**Amendment 565**  
**Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn**

**Motion for a resolution**  
**Paragraph 31**

*Motion for a resolution*

31. Calls on the Commission to **propose a new directive on** transparency of price-setting procedures and reimbursement systems, taking into account the challenges of the market;

*Amendment*

31. Calls on the Commission to **support** transparency of price-setting procedures and reimbursement systems, taking into account the challenges of the market;

Or. fr

**Amendment 566**  
**Monica Macovei**

**Motion for a resolution**  
**Paragraph 32**

*Motion for a resolution*

32. Calls on the Commission and the Court of Justice of the European Union to clarify, in accordance with Article 102 of the TFEU, what constitutes an abuse of a dominant position due to high prices;

*Amendment*

32. Calls on the Commission and the Court of Justice of the European Union to clarify, in accordance with Article 102 of the TFEU, what constitutes an abuse of a dominant position due to high prices **and to**



*limit the parallel trade of pharmaceuticals as it leads to shortages;*

Or. en

**Amendment 567**  
**Margrete Auken**

**Motion for a resolution**  
**Paragraph 32**

*Motion for a resolution*

32. Calls on the Commission and the Court of Justice of the European Union to clarify, in accordance with Article 102 of the TFEU, what constitutes an abuse of a dominant position due to high prices;

*Amendment*

32. Calls on the Commission and the Court of Justice of the European Union to clarify, in accordance with Article 102 of the TFEU, what constitutes an abuse of a dominant position due to high prices *in the case of the Peyona orphan drug;*

Or. en

**Amendment 568**  
**Christel Schaldemose**

**Motion for a resolution**  
**Paragraph 32 a (new)**

*Motion for a resolution*

*32a. Calls on the Commission to continue and where possible intensify the monitoring, and investigation of potential cases of market abuse including so called "pay for delay", excessive pricing as well as other market restrictions specifically relevant to the pharmaceutical companies operating within the EU, in accordance with Articles 101 and 102 of the Treaty on Functioning of the European Union;*

Or. en

**Amendment 569**  
**Piernicola Pedicini, Eleonora Evi, Marco Affronte**

**Motion for a resolution**  
**Paragraph 32a (new)**

*Motion for a resolution*

*Amendment*

**32a. Calls on the Commission and the Member States to stop concluding free-trade agreements that could seriously damage health systems and compromise the principle of universal access to medicines, along with the principle of universal access to health services;**

Or. it

**Amendment 570**  
**Andrey Kovatchev, Cristian-Silviu Buşoi, Kateřina Konečná**

**Motion for a resolution**  
**Paragraph 32 a (new)**

*Motion for a resolution*

*Amendment*

**32a. Calls on the Commission to take note of the scale of the problem with parallel export of pharmaceuticals within the EU, as well as of the margin of discretion of the Member States when justifying measures on public health grounds;**

Or. en

**Amendment 571**  
**Piernicola Pedicini, Marco Affronte, Eleonora Evi**

**Motion for a resolution**  
**Paragraph 33**

*Motion for a resolution*

*Amendment*

**33. Calls on the Commission and the**

**33. Strongly supports Member States**

Member States *to make use of the flexibilities* under the WTO TRIPS Agreement *and to coordinate and clarify their use when necessary*;

*that intend to use the safeguard and flexibility clauses* under the WTO TRIPS Agreement *to protect and promote public health, and calls on the Commission to coordinate efforts in this regard; calls on the EU to stop discriminating against countries such as India that have implemented progressive IP policies that promote access to medicines in the interest of the health of their citizens, through its watch-list of ‘priority countries’*;

Or. it

**Amendment 572**  
**Margrete Auken**

**Motion for a resolution**  
**Paragraph 33**

*Motion for a resolution*

33. Calls on the Commission and the Member States to make use of the flexibilities under the WTO TRIPS Agreement and to coordinate and clarify their use when necessary;

*Amendment*

33. Calls on the Commission and the Member States to make use of the flexibilities under the WTO TRIPS Agreement and to coordinate and clarify their use when necessary; *recalls that no undue political and economic pressures should be used to dissuade governments from using the flexibilities that could protect public health*;

Or. en

**Amendment 573**  
**Nessa Childers**

**Motion for a resolution**  
**Paragraph 33 a (new)**

*Motion for a resolution*

*Amendment*

**33a. Calls on the Council and the Commission to safeguard access to**

*clinical trial and pharmacovigilance data from any trade secret or commercial confidentiality provisions in international trade negotiations, as well as information exchanged between parties' national authorities as regards matters of safety and overriding public interest;*

Or. en

**Amendment 574**  
**Nessa Childers**

**Motion for a resolution**  
**Paragraph 33 b (new)**

*Motion for a resolution*

*Amendment*

**33b. Calls on the Council and the Commission to exclude any provisions concerning price and reimbursement criteria or procedures from international trade negotiations;**

Or. en

**Amendment 575**  
**Nessa Childers**

**Motion for a resolution**  
**Paragraph 33 c (new)**

*Motion for a resolution*

*Amendment*

**33c. Calls on the Council and the Commission to fully safeguard the practicability of biomedical innovation models other than patent-based intellectual property regimes in international trade negotiations;**

Or. en

**Amendment 576**  
**György Hölvényi**

**Motion for a resolution**  
**Paragraph 34**

*Motion for a resolution*

*Amendment*

**34. Calls on the Commission to examine and compare the prices of medicines in the EU and to present an annual report to Parliament in this regard;**

*deleted*

Or. en

**Amendment 577**  
**Cristian-Silviu Buşoi**

**Motion for a resolution**  
**Paragraph 34**

*Motion for a resolution*

*Amendment*

34. Calls on the Commission to examine and compare the **prices of** medicines in the EU and to present an annual report to Parliament in this regard;

34. Calls on the Commission to examine and compare the **access to** medicines in the EU and to present an annual report to Parliament in this regard;

Or. en

**Amendment 578**  
**José Inácio Faria, Jasenko Selimovic, Marian Harkin, Yana Toom**

**Motion for a resolution**  
**Paragraph 34**

*Motion for a resolution*

*Amendment*

34. Calls on the Commission to examine and compare the prices of medicines in the EU and to present an annual report to Parliament in this regard;

34. Calls on the Commission to examine and compare the **actual** prices of medicines in the EU and to present an annual report to **the Council and to the European** Parliament in this regard;

**Amendment 579**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 34**

*Motion for a resolution*

34. Calls on the Commission to examine and compare the prices of medicines in the EU and to present an annual report to Parliament in this regard;

*Amendment*

34. Calls on the Commission to examine and compare the prices of medicines in the EU, ***together with access to medicines***, and to present an annual report to Parliament in this regard;

Or. es

**Amendment 580**  
**Nikolay Barekov, Bolesław G. Piecha**

**Motion for a resolution**  
**Paragraph 34**

*Motion for a resolution*

34. Calls on the Commission to examine and compare the prices of medicines in the EU and to present an annual report to Parliament in this regard;

*Amendment*

34. Calls on the Commission to examine and compare, ***to the extent possible***, the prices of medicines in the EU and to present an annual report to Parliament in this regard;

Or. en

**Amendment 581**  
**Karin Kadenbach**

**Motion for a resolution**  
**Paragraph 34**

*Motion for a resolution*

34. Calls on the Commission to

*Amendment*

34. Calls on the Commission to

examine and compare the prices of medicines in the EU and to present an annual report to Parliament in this regard;

examine and compare the *actual* prices of medicines in the EU and to present an annual report to Parliament in this regard;

Or. en

#### **Amendment 582**

**Andrey Kovatchev, Cristian-Silviu Buşoi, Kateřina Konečná**

#### **Motion for a resolution**

##### **Paragraph 34**

###### *Motion for a resolution*

34. Calls on the Commission to examine and compare *the prices of* medicines in the EU and to present an annual report to Parliament in this regard;

###### *Amendment*

34. Calls on the Commission to examine and compare *access to* medicines in the EU and to present an annual report to Parliament in this regard;

Or. en

#### **Amendment 583**

**Karl-Heinz Florenz, Peter Liese, Andrey Kovatchev**

#### **Motion for a resolution**

##### **Paragraph 35**

###### *Motion for a resolution*

35. *Calls for the creation of a European Parliament task force to monitor the prices of medicines;*

###### *Amendment*

*deleted*

Or. de

#### **Amendment 584**

**Nikolay Barekov, Bolesław G. Piecha**

#### **Motion for a resolution**

##### **Paragraph 35**

*Motion for a resolution*

*Amendment*

**35. Calls for the creation of a European Parliament task force to monitor the prices of medicines;**

*deleted*

Or. en

**Amendment 585  
Margrete Auken**

**Motion for a resolution  
Paragraph 35**

*Motion for a resolution*

*Amendment*

**35. Calls for the creation of a European Parliament task force to monitor the prices of medicines;**

*deleted*

Or. en

**Amendment 586  
Christofer Fjellner**

**Motion for a resolution  
Paragraph 35**

*Motion for a resolution*

*Amendment*

**35. Calls for the creation of a European Parliament task force to monitor the prices of medicines;**

*deleted*

Or. en

**Amendment 587  
José Inácio Faria**

**Motion for a resolution  
Paragraph 35**



*Motion for a resolution*

*Amendment*

**35. Calls for the creation of a European Parliament task force to monitor the prices of medicines;**

**deleted**

Or. en

**Amendment 588**  
**Cristian-Silviu Buşoi**

**Motion for a resolution**  
**Paragraph 35**

*Motion for a resolution*

*Amendment*

35. Calls for the creation of a European Parliament task force to monitor the *prices of medicines*;

35. Calls for the creation of a European Parliament task force to monitor the *access to medicines*;

Or. en

**Amendment 589**  
**Peter Liese, Karl-Heinz Florenz**

**Motion for a resolution**  
**Paragraph 35 a (new)**

*Motion for a resolution*

*Amendment*

**35a. Calls on the Commission to recommend measures to improve the rate of approval of novel therapies and their supply to patients;**

Or. de

**Amendment 590**  
**Nessa Childers**

**Motion for a resolution**  
**Paragraph 36**

*Motion for a resolution*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, **and** to promote the supply of generics;

*Amendment*

36. Calls on the Commission to ***better define the concept, and*** analyse the causes of, ***medicines*** shortages, ***from the perspective of timely patient access,*** to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, ***which are to be reported on by the Commission on an annual basis,*** to promote the supply of generics, ***and to seek solutions to secure the continued availability of effective but commercially discontinued medicines;***

Or. en

**Amendment 591**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 36**

*Motion for a resolution*

36. Calls on the Commission to analyse the causes ***of shortages,*** to establish a list of essential medicines ***and*** monitor compliance with Article 81 of Directive ***2001/83/EU*** on shortages of supply, and to promote the supply of generics;

*Amendment*

36. Calls on the Commission to ***define ‘shortage’ and to*** analyse the causes ***of the shortages in the EU,*** to establish a ***European*** list of essential medicines ***which uses as a reference the WHO’s list of essential medicines and a database on the medicines handled by the EMA,*** to monitor compliance with Article 81 of Directive ***2001/83/EC*** on shortages of supply, and to promote the supply of generics, ***and to draw up a report in that respect on an annual basis;***

Or. es

**Amendment 592**  
**José Inácio Faria, Jasenko Selimovic, Anneli Jäätteenmäki, Marian Harkin, Yana Toom**

**Motion for a resolution**  
**Paragraph 36**

*Motion for a resolution*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of generics;

*Amendment*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, *to explore mechanisms to address the withdrawal of effective medicines from the market purely for commercial reasons, such as remarketing for new indications*, and to promote the supply of generics;

Or. en

**Amendment 593**

**Biljana Borzan**

**Motion for a resolution**

**Paragraph 36**

*Motion for a resolution*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of generics;

*Amendment*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, *to explore mechanisms to address the withdrawal of effective medicines from the market purely for commercial reasons*, and to promote the supply of generics;

Or. en

**Amendment 594**

**Annie Schreijer-Pierik**

**Motion for a resolution**

**Paragraph 36**

*Motion for a resolution*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on *shortages of supply*, and to promote the supply of generics;

*Amendment*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on *drug shortages and the withdrawal from the market of efficient drugs for purely commercial reasons*, and to promote the supply of generics;

Or. nl

**Amendment 595**  
**Kateřina Konečná**

**Motion for a resolution**  
**Paragraph 36**

*Motion for a resolution*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of generics;

*Amendment*

36. Calls on the Commission to analyse the causes of shortages, to establish *and update together with Member States, EMA and relevant stakeholders* a list of essential medicines *under short of supply* and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of generics;

Or. en

**Amendment 596**  
**Monica Macovei**

**Motion for a resolution**  
**Paragraph 36**

*Motion for a resolution*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to

*Amendment*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to

promote the supply of generics;

promote the supply of generics *after providing a cost-benefit report on the access on generic medicines*;

Or. en

#### **Amendment 597**

**Andrey Kovatchev, Cristian-Silviu Buşoi, Kateřina Konečná**

#### **Motion for a resolution**

##### **Paragraph 36**

###### *Motion for a resolution*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of generics;

###### *Amendment*

36. Calls on the Commission to analyse the causes of shortages, *particularly the specific impact of parallel trade of medicines*, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of generics;

Or. en

#### **Amendment 598**

**Notis Marias**

#### **Motion for a resolution**

##### **Paragraph 36**

###### *Motion for a resolution*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of generics;

###### *Amendment*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to *take action to deal with these shortages and to* promote the supply of generics;

Or. el

#### **Amendment 599**

**Karl-Heinz Florenz**

**Motion for a resolution**  
**Paragraph 36**

*Motion for a resolution*

36. Calls on the Commission to analyse the causes of shortages, to **establish** a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of generics;

*Amendment*

36. Calls on the Commission to analyse the causes of shortages, to **check the practicality and purpose of** a list of essential medicines and monitor **the Member States'** compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of generics;

Or. de

**Amendment 600**  
**Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn**

**Motion for a resolution**  
**Paragraph 36**

*Motion for a resolution*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of generics;

*Amendment*

36. Calls on the Commission, **by way of independent studies**, to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of generics;

Or. fr

**Amendment 601**  
**György Hölvényi, Alojz Peterle**

**Motion for a resolution**  
**Paragraph 36**

*Motion for a resolution*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and **monitor compliance with** Article 81 of Directive 2001/83/EU on shortages of supply, and to

*Amendment*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and **submit a proposal to further specify** Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of **generic and**

promote the supply of *generics*;

*biosimilar medicines*;

Or. en

#### **Amendment 602**

**Nikolay Barekov, Bolesław G. Piecha**

#### **Motion for a resolution**

##### **Paragraph 36**

###### *Motion for a resolution*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of *generics*;

###### *Amendment*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of *generic and biosimilar medicines*;

Or. en

#### **Amendment 603**

**Karin Kadenbach, Soledad Cabezón Ruiz**

#### **Motion for a resolution**

##### **Paragraph 36**

###### *Motion for a resolution*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of *generics*;

###### *Amendment*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of *generic and biosimilar medicines*;

Or. en

#### **Amendment 604**

**Piernicola Pedicini, Marco Affronte, Eleonora Evi**

**Motion for a resolution**  
**Paragraph 36**

*Motion for a resolution*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of *generics*;

*Amendment*

36. Calls on the Commission to analyse the causes of shortages, to establish a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of *generic and biosimilar medicines*;

Or. it

**Amendment 605**  
**Cristian-Silviu Buşoi, Mairead McGuinness**

**Motion for a resolution**  
**Paragraph 36**

*Motion for a resolution*

36. Calls on the Commission to analyse the causes of shortages, *to establish* a list of essential medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of generics;

*Amendment*

36. calls on the Commission to analyse the causes of shortages, *especially due the impact of parallel trade, to address effectively parallel trade consequences by establishing* a list of essential *medicines and a mechanism to enable stable supply of these* medicines and monitor compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of generics;

Or. en

**Amendment 606**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 36**

*Motion for a resolution*

36. Calls on the Commission to analyse the causes of *shortages*, to establish a list of essential medicines and monitor

*Amendment*

36. Calls on the Commission to analyse the causes of *medicines*, to establish a list of essential medicines and monitor



compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of generics;

compliance with Article 81 of Directive 2001/83/EU on shortages of supply, and to promote the supply of generics;

Or. en

**Amendment 607**

**Eva Kaili**

**Motion for a resolution**

**Paragraph 36 a (new)**

*Motion for a resolution*

*Amendment*

**36a. Calls on the European Commission to assess the impact of parallel trade in hampering access to treatments and creates significant shortages in certain Member States, in view of producing a legislative proposal to control and decrease the phenomenon of parallel trade;**

Or. en

**Amendment 608**

**Soledad Cabezón Ruiz**

**Motion for a resolution**

**Paragraph 36 a (new)**

*Motion for a resolution*

*Amendment*

**36a. Notes the fragmentation of systems within the EU is presently very high and leads to duplication of efforts and misallocation of resources within the EU for Member States and industry. The lack of predictability has also an adverse impact;**

Or. en

**Amendment 609**

**Elisabetta Gardini, Giovanni La Via, Aldo Patriciello, Alessandra Mussolini**

**Motion for a resolution**

**Paragraph 36 a (new)**

*Motion for a resolution*

*Amendment*

**36a. Calls on the European Commission to assess the impact of parallel trade in hampering access to treatments, in view of producing a legislative proposal to control and decrease the phenomenon of parallel trade;**

Or. en

**Amendment 610**

**Christel Schaldemose**

**Motion for a resolution**

**Paragraph 36 a (new)**

*Motion for a resolution*

*Amendment*

**36a. Calls on the Commission to put forward, with wide stakeholder input, a set of clear definitions for medicines shortages and to enhance a policy dialogue on the topic;**

Or. en

**Amendment 611**

**Monica Macovei**

**Motion for a resolution**

**Paragraph 36 a (new)**

*Motion for a resolution*

*Amendment*

**36a. Calls on the Commission to promote the importance of having the same medicine composition across the**

*EU;*

Or. en

**Amendment 612**  
**Cristian-Silviu Buşoi**

**Motion for a resolution**  
**Paragraph 36 a (new)**

*Motion for a resolution*

*Amendment*

**36a. Calls on the Commission and Member States to develop a single eHealth and mHealth road map including notably the development and valorisation of pilots projects at national level, the modernisation of the reimbursement models stimulating a shift towards health outcomes driven healthcare systems, the definition of incentives to stimulate the healthcare community to engage in this digital revolution, and to enhance education of healthcare professionals, patients, and all relevant stakeholders to enable their empowerment;**

Or. en

**Amendment 613**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 36 b (new)**

*Motion for a resolution*

*Amendment*

**36b. Calls to the Commission and Member States to coordinate a possible European joint procurement in the context of an European plan to eradicate hepatitis C;**

Or. en

**Amendment 614**

**Cristian-Silviu Buşoi, Mairead McGuinness, Andrey Kovatchev**

**Motion for a resolution**

**Paragraph 36 b (new)**

*Motion for a resolution*

*Amendment*

**36b. Calls on the Commission and Council to establish a mechanism whereby medicine shortages across the EU can be reported upon on an annual basis;**

Or. en

**Amendment 615**

**Cristian-Silviu Buşoi, Mairead McGuinness, Andrey Kovatchev**

**Motion for a resolution**

**Paragraph 36 c (new)**

*Motion for a resolution*

*Amendment*

**36c. Calls on the Commission and Council to review the statutory basis of the European Medicines Agency, and give consideration to enhancing its remit to coordinate pan-European activity aiming at tackling medicines shortages in EU Member States;**

Or. en

**Amendment 616**

**Christel Schaldemose**

**Motion for a resolution**

**Paragraph 36 b (new)**

*Motion for a resolution*

*Amendment*

**36b. Calls on the Commission to**

*conduct an annual report on the status of medicines shortages across the EU;*

Or. en

**Amendment 617**  
**Soledad Cabezón Ruiz**

**Motion for a resolution**  
**Paragraph 37 a (new)**

*Motion for a resolution*

*Amendment*

*37a. Calls the urgency of the Threats of AMR recognised by the UN recently, call the commission to increases its actions to combat antimicrobial resistance and to present a new and comprehensive EU Action Plan based on the "One Health" approach, is crucial to include concert legislative on top on the three regulation;*

Or. en