COMMITTEE ON LEGAL AFFAIRS Brussels, 12 July 2021 - 16.45-17.45
Secretariat - CP/ie

VOTING LIST

Pharmaceutical strategy for Europe
(2021/2013(INI))

Rapporteur: Luisa Regimenti

Draft opinion: Fdr 1230727 - PE 692.709 v01-00
Amendments: (AMs 1 - 93) - Fdr 1233410 - PE 693.696 v02-00

Concerned text	AM	Tabled by	Remarks	Rapp	Vote
Paragraph 1	**CA 1**	Rapporteur, EPP, RE	**If adopted, 36, 2, 3, 4 and 5 fall**	+	
Paragraph 2 a (new)	36	Niebler	**Falls if CA 1 adopted**	+	
Paragraph 1a	**CA 2**	Rapporteur, EPP, RE	**If adopted, 7, 10, 16 and 2 fall**	+	
Paragraph 1 a (new)	7	Buxadé Villalba	**Falls if CA 2 adopted**	+	
Paragraph 1 a (new)	10	Buda	**Falls if CA 2 adopted**	+	
Paragraph 1 b (new)	16	Złotowski	**Falls if CA 2 adopted**	+	
Paragraph 1	2	Regimenti, Lebreton, Garraud	**Falls if CA 1 or CA 2 adopted**	+	
Paragraph 1	3	Niebler, Walsmann	**Falls if CA 1 or 2 adopted**	+	
Paragraph 1	4	Buda	**Falls if CA 1 or 3 adopted** *Compatible with AM 2*	+	
Paragraph 1 a (new)	8	Złotowski		+	
Paragraph 1 a (new)	9	Maurel		-	
Paragraph 1 b (new)	12	Toussaint		0	

Paragraph 1 b (new)	13	Maurel		+	
Paragraph 1b	**CA 3**	Rapporteur, EPP, RE	**If adopted, 14, 17, 26 Part 1 and 26 Part 2 fall**	+	
Paragraph 1 b (new)	14	Toom, Vázquez Lázara	**Falls if CA 3 adopted**	-	
Paragraph 1 b (new)	17	Niebler, Walsmann	**Falls if CA 3 adopted**	+	
Paragraph 1 b (new)	15	Buxadé Villalba		0	
Paragraph 1c	**CA 4**	Rapporteur, EPP, RE	**If adopted, 1, 5, 19, 6 and 24 fall**	+	
Paragraph -1 (new)	1	Toom, Vázquez Lázara	**Falls if CA 4 adopted**	+	
Paragraph 1 a (new)	5	Toussaint	**Falls if CA 1 or CA 4 adopted**	0	
Paragraph 1 c (new)	19	Niebler	**Falls if CA 4 adopted**	+	
Paragraph 1 a (new)	6	Toom, Vázquez Lázara	**Falls if CA 4 adopted**	+	
Paragraph 1 g (new)	24	Niebler, Walsmann	**Falls if CA 4 or 6 adopted**	+	
Paragraph 1 d (new)	21	Toom, Vázquez Lázara	**Split vote (EPP)** **Part 1** *Underlines the important role played by public investments in R&D, and calls on the Commission and the Member States to establish full transparency on the results of publicly financed R&D*	+	
			Part 2 *so that patenting and licensing conditions guarantee a public health return on public investments;*	-	
Paragraph 2 and 2a	**CA 5**	Rapporteur, EPP, RE	**If adopted, 20, 25, 26 Part 1, 26 Part 2, 27, 28, 29, 30, 32, 84, 34, 37 Part 1, 37 Part 2 and 62 fall**	+	

Paragraph 1 d (new)	20	Niebler, Walsmann	**Falls if CA 5 adopted**	+	
Paragraph 2	25	Regimenti, Lebreton, Garraud	**Falls if CA 5 adopted**	+	
Paragraph 2	26	Toussaint	**Split vote (EPP)** **Part 1** **Falls if CA 3, 14 or CA 5 adopted** *Text without the words "an adapted"* *Compatible with AM 25*	+	
			Part 2 **Falls if CA 3, 14 or CA 5 adopted** *The words "an adapted"*	-	
Paragraph 2	27	Niebler	**Falls if CA 5, 26 Part 1 or 26 Part 2 adopted** *Compatible with AM 25*	-	
Paragraph 2	28	Toom	**Falls if CA 5, 26 Part 1 or 26 Part 2 adopted** *Compatible with AM 25, AM 27*	-	
Paragraph 2	29	Buda	**Falls if CA 5 or 27 adopted** *Compatible with AM 25, AM 26, AM 28*	+	
Paragraph 2	30	Buxadé Villalba	**Falls if CA 5, 26 Part 1, 26 Part 2, 27, 28 or 29 adopted** *Compatible with AM 25*	+	
Paragraph 2 b (new)	32	Regimenti, Lebreton, Garraud	**Falls if CA 5 adopted**	+	
Paragraph 6 b (new)	84	Buxadé Villalba	**Falls if CA 5 adopted**	-	
Paragraph 2 a (new)	34	Toom, Vázquez Lázara	**Falls if CA 5 or 25 adopted**	-	
Paragraph 2 c (new)	39	Toom, Vázquez Lázara		-	
Paragraph 2 d (new)	40	Toom		-	
Paragraph 3	**CA 6**	Rapporteur, EPP, RE	**If adopted, 11, 18, 45, 46 Part 1, 46 Part 2, 47, 48 and 49 fall**	+	

Paragraph 1 a (new)	11	Niebler, Walsmann	**Falls if CA 6 adopted**	+	
Paragraph 1 c (new)	18	Toom	**Falls if CA 6 adopted**	0	
Paragraph 3	45	Regimenti	**Falls if CA 6 adopted**	+	
Paragraph 3	46	Toussaint	**Split vote (EPP)** **Part 1** **Falls if CA 6 or 45 adopted** *From "Stresses the importance of supporting research" until "where commercial interest is low, such as orphan and paediatric drugs;"*	+	
			Part 2 **Falls if CA 6 or 45 adopted** *From "whereas high degree of transparency should apply" until "decision-making to investment and open science;"*	-	
Paragraph 3	47	Buxadé Villalba	**Falls if CA 6, 45, 46 Part 1 or 46 Part 2 adopted**	-	
Paragraph 3	48	Niebler, Walsmann	**Falls if CA 6, 46 Part 1 or 46 Part 2 adopted** *Compatible with AM 45, AM 47*	+	
Paragraph 3	49	Toom	**Falls if CA 6, 46 Part 1, 46 Part 2 or 48 adopted** *Compatible with AM 45, AM 47*	-	
Paragraph 3a and 3b	**CA 7**	Rapporteur, EPP, RE	**If adopted, 42, 43, 50 and 57 fall**	+	
Paragraph 2 f (new)	42	Toom, Vázquez Lázara	**Falls if CA 7 adopted**	+	
Paragraph 2 g (new)	43	Toom, Vázquez Lázara	**Falls if CA 7 adopted**	-	
Paragraph 3 a (new)	50	Regimenti, Lebreton, Garraud	**Falls if CA 7 or 43 adopted**	+	
Paragraph 3 d (new)	57	Toussaint	**Falls if CA 7 adopted**	0	
Paragraph 3 b (new)	51	Regimenti, Lebreton, Garraud	**No vote** **Inadmissible**		

Paragraph 3 a (new)	53	Toussaint		-	
Paragraph 3 a (new)	54	Niebler		+	
Paragraph 3 b (new)	55	Toussaint		-	
Paragraph 3 c (new)	56	Toussaint		-	
Paragraph 4	**CA 8**	Rapporteur, EPP, RE	**If adopted, 37 Part 1, 37 Part 2, 58, 61, 68 and 22 fall**	+	
Paragraph 2 b (new)	37	Toom	**Split vote (EPP)** **Part 1** **Falls if CA 5, 25 or CA 8 adopted** *From "Recalls that Regulation (EC) No 816/2006" until "to address public health problems;"*	+	
			Part 2 **Falls if CA 5, 25 or CA 8 adopted** *From "calls on the Commission to consider the possibility" until "TRIPS obligations"*	-	
Paragraph 4 a (new)	62	Toussaint	**Falls if CA 5, 25, 39, 37 Part 1 or 37 Part 2 adopted**	-	
Paragraph 4	58	Buxadé Villalba	**Fall if CA 8 adopted** **Identical** *Deletion*	-	
	59	Złotowski			
	60	Toussaint			
Paragraph 4	61	Buda	**Falls if CA 8 or 58 adopted**	+	
Paragraph 4 b (new)	68	Złotowski	**Falls if CA 8 adopted**	+	
Paragraph 1 e (new)	22	Niebler, Walsmann	**Falls if CA 8 adopted**	+	
Paragraph 2 a (new)	35	Złotowski	**Falls if 56 or 22 adopted**	-	
Paragraph 4a	**CA 9**	Rapporteur, EPP, RE	**If adopted, 31, 64 and 91 fall**	+	

Paragraph 2 a (new)	31	Regimenti, Lebreton, Garraud	**Falls if CA 9 adopted**	+	
Paragraph 4 a (new)	64	Niebler, Walsmann	**Falls if CA 9 adopted**	+	
Paragraph 6 f (new)	91	Buxadé Villalba	**Falls if CA 9 adopted**	+	
Paragraph 4 a (new)	65	Buda		+	
Paragraph 4 a (new)	66	Złotowski		+	
Paragraph 4 b (new)	67	Niebler, Walsmann		+	
Paragraph 4 c (new)	70	Niebler		+	
Paragraph 4 d (new)	71	Niebler		+	
Paragraph 5	**CA 10**	Rapporteur, EPP, RE	**If adopted, 23, 38, 73 and 86 fall**	+	
Paragraph 1 f (new)	23	Niebler, Walsmann	**Falls if CA 10 adopted**	+	
Paragraph 2 b (new)	38	Niebler	**Falls if CA 10 adopted**	+	
Paragraph 5	73	Regimenti, Lebreton, Garraud	**Falls if CA 10 adopted**	+	
Paragraph 6 c (new)	86	Niebler, Walsmann	**Falls if CA 10 adopted**	+	
Paragraph 5 a (new)	75	Maurel		-	
Paragraph 5 a (new)	76	Garraud, Beck, Lebreton		-	
Paragraph 5a	**CA 11**	Rapporteur, EPP, RE	**If adopted, 44, 74, 77, 85 and 92 fall**	+	
Paragraph 2 h (new)	44	Toom	**Falls if CA 11 adopted**	+	
Paragraph 5 a (new)	74	Buxadé Villalba	**Falls if CA 11 adopted**	+	
Paragraph 5 b (new)	77	Garraud, Beck, Lebreton, Regimenti	**Falls if CA 11 adopted**	+	

Paragraph 6 b (new)	85	Niebler, Walsmann	**Falls if CA 11 adopted**	+	
Paragraph 6 g (new)	92	Buxadé Villalba	**Falls if CA 11 adopted**	0	
Paragraph 5b	**CA 12**	Rapporteur, EPP, RE	**If adopted, 33, 78 and 83 fall**	+	
Paragraph 2 c (new)	33	Regimenti	**Falls if CA 12 adopted**	+	
Paragraph 5 b (new)	78	Buxadé Villalba	**Falls if CA 12 adopted**	+	
Paragraph 6 a (new)	83	Niebler, Walsmann	**Falls if CA 12 adopted**	0	
Paragraph 6	**CA 13**	Rapporteur, RE	**If adopted, 79, 80, 82 and 90 fall**	+	
Paragraph 6	79	Toom	**Falls if CA 13 adopted** *Deletion*	-	
Paragraph 6	80	Toussaint	**Falls if CA 13 or 79 adopted**	-	
Paragraph 6 a (new)	82	Buxadé Villalba	**Falls if CA 13 adopted**	0	
Paragraph 6 e (new)	90	Buxadé Villalba	**Falls if CA 13 or 82 adopted**	0	
Paragraph 6a	**CA 14**	Rapporteur, EPP, RE	**If adopted, 63, 41, 69, 72, 81 and 52 fall**	+	
Paragraph 4 a (new)	63	Garraud, Beck, Lebreton	**Falls if CA 14 adopted**	-	
Paragraph 2 e (new)	41	Toom	**Falls if CA 14 adopted**	0	
Paragraph 4 c (new)	69	Złotowski	**Falls if CA 14 or 41 adopted**	0	
Paragraph 4 e (new)	72	Niebler	**Falls if CA 14 or 69 adopted**	+	
Paragraph 6 a (new)	81	Złotowski	**Falls if CA 14 adopted**	+	
Paragraph 3 a (new)	52	Złotowski	**Falls if CA 14 adopted**	-	
Paragraph 6 c (new)	87	Buxadé Villalba	**Falls if 40 adopted**	+	

Paragraph 6 d (new)	88	Buxadé Villalba		-	
Paragraph 6 d (new)	89	Niebler, Walsmann		+	
Paragraph 6 h (new)	93	Buxadé Villalba		+	
Final vote – Draft as amended (Roll-call vote)					

COMPROMISE AMENDMENTS

COMP 1- paragraph 1

AM 2 (ID), AM 4 (EPP), AM 5 (Greens/EFA), AM 36 (EPP)

1. Stresses the ***need and*** importance of ***introducing*** a new EU pharmaceutical strategy, which is consistent with the Union's competences under the Treaties and with the principles of proportionality and subsidiarity, as a means of stimulating the development of European enterprises and making them competitive at global level, ***driving scientific progress****,* ***as well as*** guaranteeing better prevention and preparedness and ***a*** more ***efficient and rapid*** response to future health emergencies***; calls*** for ***decisions and policies to provide solutions that enable an industrial ecosystem in the pharmaceutical sector in which the balance between the various interests at stake is duly taken into account***; *calls on the Commission to carefully analyse what lessons should be learned from the challenges posed by the COVID-19 pandemic for the pharmaceutical strategy;***

COMP 2 - paragraph 1a

AM 2 (ID), AM 10 (EPP), AM 16 (ECR), AM 7 (ECR)

1a. Recalls that the European Union is aiming to ensure the well-being of European citizens by promoting healthy lifestyles, fair and equitable access to healthcare and the marketing of safe, effective and affordable medicines in the single market; stresses the need to draw up future European framework provisions for regulatory approval, access and incentives for innovation, accompanied by vigorous industrial policies, with attractiveness and predictable rules being regarded as the key to innovation, and to facilitate patients' access to medicines; welcomes the Commission's intention to assess and review the existing incentive framework; believes that the EU Pharmaceutical Strategy and legislative measures should support European developers and manufacturers in driving scientific progress and remaining globally competitive; recalls the need to develop intra-European production chains, through the development of a rational and compatible regulatory framework between Member States, with the aim of developing a medicine supply system that looks at the whole production chain; calls on the Commission to stimulate competition by creating an appropriate regulatory framework;

COMP 3 - paragraph 1b

AM 14 (Renew), AM 17 (EPP)

1b. stresses that support for the competitiveness and innovative capacity of the EU pharmaceutical industry is crucial; Calls, in this regard, on the Commission and the Member States to introduce fiscal and financial incentives, in order to encourage manufacturers to relocate the production of active ingredients and medicines of strategic importance for health care to Europe;

COMP 4 - paragraph 1c

AM 1 (Renew), AM 5 (Greens/EFA), AM 19 (EPP), AM 24 (EPP)

1c. Considers that the preparation to next global health crisis urges decision and policy making to bring solutions allowing long-term resilience in society, and in particular to design an industrial ecosystem in the pharmaceutical sector where the balance between the different interests at stake is duly considered in the light of the circumstances; Believes that the strategic autonomy of the EU has to be a key objective when addressing the shortage of medicines for a better access of patients to these; Recalls the European Commission's 'Updating the 2020 New Industrial Strategy: Building a stronger Single Market for Europe's recovery' of May 2021 which states that the EU is strategically dependent on third countries regarding pharmaceutical ingredients and other health related products, which could lead to vulnerabilities for the EU and affect the EU's core interests, and refers to the pharmaceutical strategy to address these issues;

COMP 5 - paragraph 2 and 2a

AM 20 (EPP), AM 30 (ECR), AM 32 (ID), AM 25 (ID), AM 84 (ECR)

2. Emphasises the key importance of intellectual property protection in the EU, ***as an*** essential ***element for*** the EU not to be dependent on third countries and for enhancing its strategic autonomy in the field of medicines; ***stresses that intellectual property rights promote accessibility, innovation and competitiveness in the sector and improve the safety of medicines and of patients***; ***notes that a balance should be struck between intellectual property protection, encouraging innovation, ensuring access to medicines and protecting public health;*** calls for ***the role of the Member States to be enhanced by improving communication and cooperation between*** the European institutions, ***national authorities***, health professionals, industry and stakeholders, with a view to identifying shared approaches, particularly to the challenges posed by the COVID-19 pandemic;

2a. ***Encourages the strengthening of the role of Member States through collaboration and the development of best practices to identify and address the root causes of shortfall of medicines on EU markets, in order to tackle remaining obstacles to timely and effective access for patients; points out that affordability of medicines remains a challenge for national healthcare systems; recalls that in health crisis or emergency situations, making changes to the intellectual property regime is insufficient to address short-term needs and that compulsory licensing should only be possible in exceptional cases where no other solution can be found and where a compulsory licence appears to be justified and necessary***

to effectively increase production capacity;

COMP 6 - paragraph 3

AM 11 (PPE), AM 45 (Rapporteur), AM 47 (ECR), AM 48 (PPE)

3. ***stresses that R&D is crucial for the development of innovative medicines, therapies and diagnostics;*** stresses the importance of ***investment and facilitated support for*** research in the EU to ***create a thriving EU pharmaceutical sector, and to be world market leader in improving existing and developing new medicines which could then lead to an*** increase ***of*** the number of patents filed in the Member States; stresses that one of the priorities should be to develop medicines in areas where needs have been met only inefficiently or not at all or where commercial interest is low; ***points out that public research should particularly focus on areas of low commercial interest*** such as ***orphan and paediatric medicines and medicines to respond to antimicrobial resistance (AMR); recalls, in this respect***, the key role played by AI and its potential as a driver of research and development in the health and pharmaceutical sector;

COMP 7 - Paragraph *3a and 3b*

AM 42 (Renew), AM 43 (Renew), AM 50 (ID), AM 51 (ID), AM 57 (Greens/EFA)

3a. emphasises that full enjoyment of the potential of new innovative technologies also depends on proper exploitation of and access to health data, which can help speed up the identification of potential active substances, and support the development of new medicines or therapies; notes that the current COVID-19 crisis has already demonstrated that data sharing has been useful in accelerating research and strengthening public health surveillance systems across the EU with the aim of saving lives;

3b. Believes that secure and open access to interoperable health data must be increased while fully respecting EU data protection rules, and encourages the development of platforms to monitor and provide information on the safety and efficacy of vaccines after the authorisation procedure;

COMP 8 - Paragraph 4

AM 22 (EPP), AM 37(RE), AM 61 (EPP), AM 68 (ECR)

4. Recalls that Regulation (EC) No 816/2006 harmonises the procedure for granting compulsory licences in relation to patents and supplementary protection certificates concerning the manufacture and sale of pharmaceutical products, when such products are intended for export to eligible importing countries in need of such products in order to address public health problems; draws attention to the existing differences between the Member States in terms of the validity of patents and supplementary protection certificates and supports in this regard the IP Action Plan proposal including improving the supplementary protection certificate (SPC) or patented medicinal products; recommends a

consistent EU application of the IP Enforcement Directive and stresses the importance of launching the unitary patent without delay in order to create a one-stop-shop for patent protection and enforcement across the EU and to ***eliminate*** the fragmentation of the patent market and the obstacle that may pose to research and innovation;

COMP 9 - Paragraph 4a

AM 31 (ID), AM 64 (EPP), AM 91 (ECR)

4a. emphasises that intellectual property plays a pivotal role in the expansion and growth of SMEs, which are penalised by a lack of knowledge of procedures and by the lack of, or inadequate, publicity about opportunities for them; calls for making the IP system more effective for SMEs, through measures to simplify IP registration procedures (e.g. reform of EU legislation on industrial designs), to improve access to strategic IP advice and to facilitate the use of IP as a lever to access funding; highlights the need to allocate more resources at European level to the fight against unfair and abusive practices on the market for medicines; stresses in this regard the need to create new funding lines to support the efforts of new start-ups and SMEs in the field of medical biotechnology;

COMP 10 - Paragraph 5

AM 23 (EPP), AM 38 (EPP), AM 73 (ID), AM 86 (EPP)

5. ***Recalls that it is essential to continue to develop, improve and update European frameworks for intellectual property to ensure that ideas and inventions can be developed effectively and brought to market, particularly by and for SMEs; emphasises the importance of a robust, efficient and balanced system of IP and trade secrets protection, as well as the need for a coherent overall strategy ensuring both protection of innovation and fair access to it;*** calls on the Commission to use all the means at its disposal to prevent counterfeit products from entering the market ***in order*** to protect intellectual property rights holders and European citizens, ***since such*** products are often of low quality and ***dangerous*** to health, ***and have a major economic impact, estimated at a loss of at least EUR 10 billion to the European pharmaceutical industry and 37 000 jobs***; ***notes that technical assistance to the Member States is necessary for the proper implementation of the EMVS system; stresses the need to ensure a smart use of IP and to better combat intellectual property theft, as smart policies in this area are essential to help companies grow, create jobs and protect and develop what makes them unique and competitive;***

COMP 11 - Paragraph *5a*

AM 44 (Renew), AM 74 (ECR), AM 77 (ID), AM 85 (EPP), AM 92 (ECR)

5a. regrets that the EU is less attractive than other countries in terms of research and development in the pharmaceutical sector; emphasises that the Union should focus on the development of adequate production capacities for active substances, raw materials and medicinal products, thus making it possible to reduce dependence on external sources; recalls the need to bring the production of the most essential medicines back to the EU; calls, therefore, on the Commission to prioritise pharmaceutical production of vaccines

within the EU and for Member States to be able to conclude public contracts with the various European pharmaceutical laboratories producing vaccines in order to avoid shortages of doses and ensure the safety of Europeans during such a crisis; ***encourages the simplification of procedures and the reduction of burdens in order to promote the proliferation of new products for the market; calls for measures to improve the cooperation of operations along the entire value chain and to generate strategic investment in research, development, manufacturing and distribution of medicines and medical devices within the EU;***

COMP 12 - Paragraph *5b*

AM 33 (Rapporteur), AM 83 (EPP), AM 78 (ECR)

5b. notes that most of the time radical innovations in the pharmaceutical sector are driven by SMEs; stresses the importance of building appropriate legal and operational frameworks that allow industry agility and flexibility to replenish stocks promptly, based on the needs of patients in each country and using regional supply strategies, and the need to establish regulatory solutions to facilitate flexible and scalable production and distribution strategies; highlights the need for a dialogue with the industry to find viable solutions that increase the joint capacity to prevent shortages; calls on the Commission to develop, at the lowest possible cost, a digital platform as a contact point between Member States that provides information and ensures communication and the provision of advice for Member States to participate in innovation projects at national and European level; in this regard, calls on Member States to share their practices to promote innovation;

COMP 13 - Paragraph 6

AM 80 (Greens), AM 82 (ECR)

6. Emphasises, lastly, the importance for European companies, in strategic sectors such as pharmaceuticals, of contractual freedom in the areas of licensing and of the protection and effective ***and balanced*** enforcement of intellectual property rights, including in third countries where they operate; calls on the Commission to develop and implement new measures and tools for this purpose and to improve existing ones, such as the Intellectual Property Helpdesk for SMEs; ***calls on the Commission to provide easy public access to the conditions governing the patent and licensing system, information on clinical and pre-clinical trials and public and private contributions;***

COMP 14 - Paragraph *6a*

AM 41 (Renew), AM 63 (ID), AM 72 (EPP), AM 81 (ECR)

6a. Suggests to the Commission to carefully observe the pharmaceutical market and the protection of pharmaceutical data, in particular with a view to improving access to generic and biosimilar medicines, offering affordable treatments to a large number of patients and achieving savings on healthcare expenditure through the positive price effect of competition; points out that producers of generic medicines are often regional companies with less

resilience to supply problems and market turbulence; urges the Commission to promote legal solutions that foster competitiveness in the field of generic medicine production, while maintaining an appropriate legal balance between generic and innovative medicines; supports greater generic and biosimilar competition combined with an appropriate market protection mechanism; stresses that a possible revision of the so-called 'Bolar' exemption, which allow for the conduct of trials on patented products to support generic and biosimilar marketing authorisation applications without being regarded as infringing patent rights or supplementary protection certificates for medicinal products, can only take place after a comprehensive impact assessment;