MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

on a pharmaceutical strategy for Europe (2021/2013 (INI))

AMENDMENTS

In view of the adoption of the European Parliament's own initiative report of the European Parliament on the Pharmaceutical Strategy for Europe, the Access to Medicines (A2M) Task Force of the Association of European Cancer Leagues (ECL), suggested several amendments to protect public health interest.

In the table below,we report our proposed amendments to the European Parliament's draft of May 2021 and the final text issued on 24 November 2021.

For more information, please do not hesitate to contact: ecl@cancer.eu.

Proposed Amendments	**Final text**
Amendment 1 **Added recitals**	
– having regard to the ongoing Commission revision of the Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products[1] **– having regard to the ongoing Commission revision of the Regulation** (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use[2]	**– having regard to Regulation** (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products[7], **– having regard to Regulation** (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use[10], 22. Calls on the Commission to **revise Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006**

[1] OJ L 18, 22.1.2000
[2] OJ L 378, 27.12.2006

Justification & result: *ECL suggested including a reference to the ongoing revision of two key, relevant regulations on paediatric and orphan medicinal products. The European Parliament added the two legislations to the recitals in point 22.*

Amendment 2 **Paragraph 1**	
Stresses that **sustainable and future-proofed** investment in research into and the development of innovative medicines and treatments, as well as access to safe, effective and high-quality medicines, are essential for making progress in the prevention, **diagnosis,** treatment of diseases, **and quality of life of patients;**	8. Stresses that **public and private** investment in research into and the development of innovative diagnostics, as well as access to safe, affordable, effective and high-quality medicines and treatments, are essential for making progress in the prevention, **diagnosis** and treatment of diseases **and the quality of life of patients;**
Justification & result*:* *ECL suggested specifying the type of investment and adding "diagnosis" and "and quality of life of patients" to a sentence that only mentioned prevention and treatment. "Sustainable and future-proofed" was not added to the recitals; whereas references to "diagnosis" and "and quality of life of patients" were adopted.*	

Amendment 3 **Paragraph 2**	
Considers that investment **coming both from public and private sources** in research have not been **neither effective nor** sufficient to meet the therapeutic needs of patients with rare diseases, paediatric **diseases, in particular paediatric** cancers, and neurodegenerative diseases or to deal with antimicrobial resistance (AMR);	9. Recalls **that public and private investments should be aligned with** the necessary regulatory and legislative measures in order to meet the therapeutic and diagnostic needs of patients, including for rare and chronic diseases, rare adult cancers **and paediatric cancers**, and neurodegenerative diseases, and tackle antimicrobial resistance (AMR);

Justification & result: *ECL wished to stress the paucity and ineffectiveness of investment from both the public and private sources. The reference to "public and private" funding has been adopted, while "neither effective" was somewhat conveyed as "should be aligned with". The final text refers to "paediatric cancers" instead of "paediatric cancers". However, there exist many paediatric diseases with high unmet needs that are not cancers.*

Amendment 4 **Added paragraph**	
Stresses that public and private investments should aim at addressing and meeting public health and patients' needs, with particular attention to cancer and rare cancers with low survival;	9. Recalls that public and private investments should be aligned with the necessary regulatory and legislative measures in order to **meet the therapeutic and diagnostic needs of patients**, including for **rare and chronic diseases, rare adult cancers and paediatric cancers**, and neurodegenerative diseases, and tackle antimicrobial resistance (AMR);
Justification & result: *ECL suggested highlighting the importance of addressing public health and patients' needs with special attention for (rare) cancers. ECL's suggested paragraph was not used in its entirety but the overall idea is reflected in point 9.*	
Amendment 5 **Added paragraph**	
Calls on the Commission to set an unambiguous and clear definition for the term 'unmet medical needs' (UMN), based on transparent and objective criteria. The definition should include but not be limited to the following: incidence[3], survival rates, existing alternative treatments, mortality, and severity of the disease. Patient-centredness and participatory decision-	6. Calls on the Commission to **start the process of defining unmet medical needs, under the coordination of the European Medicines Agency (EMA), in order to establish a commonly accepted definition** that would help to better orientate research needs and prevent the use of various definitions for unmet medical needs which, at an early stage,

[3] See Gatta, G. et al (2017) 'Burden and centralised treatment in Europe of rare tumours: results of RARECAREnet - a population-based study'. Lancet Oncology, 18 (8), 1022-1039. Available here: https://doi.org/10.1016/S1470-2045(17)30445-X

making should be at the heart of defining UMN;	lead to exorbitant pricing in the marketing of medicines; 39. Stresses the importance of striking the right balance between, on the one hand, **offering incentives in medicine development, particularly where no treatment alternatives exist,** and, on the other, safeguarding the public interest by preventing the distortion of competition and unintended effects and ensuring the affordability and availability of medicinal products;
***Justification & result**:* *ECL advocated for the inclusion of an unambiguous and clear definition for the term 'unmet medical needs' in the text and listed several aspects to be included in such a definition. Point 6 ended up referring to a common definition of unmet medical needs, but our suggested aspects were not included. ECL also stressed the importance of addressing areas where there is no treatment; a point which was included and this point have been included in point 39.*	

Amendment 6 **Paragraph 4**	
Calls on the Commission to incorporate new criteria into the system of incentives for research into and the development of new medicines for unmet therapeutic needs, prioritising **public health research projects** combating rare diseases, paediatric cancers, neurodegenerative diseases and AMR, with the aim of finding more therapeutic **options with proven added value**, and meeting the needs of patients and health systems; Calls on the Commission to promote the creation of an EU framework to guide and **regularly monitor and evaluate** the implementation of national plans to fight	16. Calls on the Commission to assess, and revise where appropriate, the system of incentives to promote research into and the development of new medicines for unmet diagnostic and therapeutic needs**, prioritising public interests and patient safety when assessing projects promoted by the pharmaceutical industry** to combat cancers, including paediatric cancers, in particular to incentivise first-in-child development of paediatric anticancer medicines, rare diseases, neurodegenerative and mental illnesses, and AMR, with the aim of finding more therapeutic options and meeting the

these diseases;	needs of patients and health systems 17. Calls on the Commission to **promote the creation of an EU framework to guide and regularly evaluate** the implementation of national plans to fight these diseases, and calls on the Member States to support R&D that focuses on unmet medical needs; stresses that a system based solely on research incentives will not achieve the necessary objectives in the fight against rare diseases;
***Justification & result**:* *By adding "public health research projects", ECL wished to emphasise that the ultimate objective of research projects should be serving public health needs. Point 16 "prioritising public interests and patient safety when assessing projects promoted by the pharmaceutical industry" built on ECL's proposal but also highlighted how the industry continues to have a prominent role in research, according to MEPs. "Proven added value" did not feature in the text; whereas "added value" was mentioned a few times. "Regularly monitor and evaluate" was adopted as "regularly evaluate".*	
Amendment 7 **Added paragraph**	
Calls on the Commission to create a system of rewards and obligations to cover knowledge gaps in basic research to address neglected diseases, guarantee the supply of medicines, and steer accessibility;	63. Underlines the potential of big data to complement the evidence from clinical trials and fill **knowledge gaps on medicines, as well as to help to better characterise diseases, treatments and the performance of medicines in individual healthcare systems**; 10. Stresses that the revision of the system of **legal incentives and obligations that supports innovation, access and affordability of medicines** across the EU has recognised the relationship with IP rights;

Justification & result:
ECL wished to link "the supply of medicines" to rewards and obligations. Point 63 acknowledged that there are "knowledge gaps", but instead of considering these in the framework of rewards and obligations, the challenge seems to be solved with big data. "Legal incentives and obligations" mentioned in point 10 were linked to IP rights.

Amendment 8 **Added paragraph**	
Calls on the Commission to discourage the creation of artificial subsets of common diseases ('salami-slicing') just to receive for each of them the orphan disease designation and the related incentives and benefits.	N. whereas many innovations in the pharmaceutical industry do not really offer breakthrough improvements for patients, but are **either so-called 'me-too'** pharmaceuticals, which are simply another substance used for the same therapeutic purposes but without major benefits, or only offer minor improvements at a significantly higher cost; **whereas it would be beneficial for patients if the framework for the pharmaceutical industry in Europe were to better incentivise real breakthrough innovations;** 21. Calls on the Commission, in dialogue with the Member States, to **work on a framework for pharmaceutical legislation and a reimbursement system that favours meaningful innovation for patients and incentivises fewer 'me-too' pharmaceuticals which have no added value** or highly expensive pharmaceuticals that offer only minor improvements for patients;

Justification & result:
ECL's suggestion to refer to the practice of "salami-slicing" made it into the final text with a few references to "me-too drugs". While ECL's proposal referred to diseases, the European Parliament addressed the medicines that treat those diseases. MEPs recognised the need to better incentivise 'real breakthrough innovations'.

Amendment 9 Added paragraph	
Stresses the need for targeted incentives to support early-stage medicine development and ensure medicines with proven added value and medicines in areas where there currently are no treatments. To this end, digitalization can be of great help. Real-Word Data (RWD) and Real-World Evidence (RWE) can play a major role when it comes to clinical trials with a limited number of patients (e.g., rare cancers) and therefore little evidence of the safety, efficacy, and real added value of new health technologies;	19. Stresses the importance of continuous innovation, including in the off-patent segment, to address patients' unmet needs; calls on the Commission to design a fit-for-purpose regulatory framework that will enable the **development of value-added medicines, as well as recognise this category of affordable innovation, through appropriate incentives, for its value for healthcare system**s; 63. Highlights the potential of AI-based solutions in strengthening the resilience and sustainability of the EU's healthcare systems, **while offering innovative therapies and better diagnosis using real-world data and keeping meaningful human control**; insists that AI-based solutions must include safeguards to prevent any form of racial, social or gender bias; **underlines the potential of big data to complement the evidence from clinical trials and fill knowledge gaps on medicines, as well as to help to better characterise diseases**, treatments and the performance of medicines in individual healthcare systems. 136. Welcomes the initiative of building interoperable digital infrastructure for the European Health Data Space, which will **collate real-world data, to leverage the full potential of real-world data and access to rare therapies and to ensure fair, transparent and non-discriminatory access to data throughout Europe**; underlines that the consistent application and enforcement of the General Data

	Protection Regulation[20] (GDPR) in all Member States is the foundation for such initiatives;
***Justification & result**:* *"Appropriate incentives" for value-added medicines were mentioned in the final text. The text acknowledged that real-world data and real-world evidence are complementary to clinical trials and to fill knowledge gaps. "Clinical trials" are mentioned 10 times in the text. A specific subsection is dedicated to clinical trials (points 103 to 106).*	

Amendment 10 **Paragraph 5**	
Calls on the Commission to promote dialogue with the Member States, **HTA bodies,** and stakeholders to assess new criteria for national pricing, such as whether a product **has a positive impact on the quality of life of patients, moving beyond the assessment of the risks limited to toxicity and effectiveness of the new treatments.**	33. Calls on the Commission to **promote dialogue with the Member States and all relevant stakeholders to promote 'Made in Europe' pharmaceuticals** by strengthening manufacturing and supply resilience, **by assessing additional criteria for national pricing,** at no additional cost to patients and without prejudice to the sustainability of the health system; stresses that these criteria should include high environmental manufacturing standards, robust supply chain management and investment in innovation and research; 108. Points out that **new health technologies should demonstrate their clinical added value and cost-effectiveness compared to what is already available on the market; emphasises that health technology assessment is a tool to support this analysis but that it is currently highly fragmented within the Union, although it can enable cooperation on clinical evidence requirements and**

	clinical trial design and therefore support Member States' timely and evidence-based decision making on patient access to new medicines; reiterates that the Commission and Member States implement the regulation expeditiously in accordance with the agreed timeframe;
Justification & result: *Health Technology Assessment has its own subsection in the final report (points 107-108). The subsection focuses on fostering greater convergence between Member States on the evaluation of health technologies, which reflects ECL's suggestion to include the HTA bodies.* *ECL's input on quality of life improvement beyond effectiveness was not adopted, but cooperation on clinical evidence and clinical added value are highlighted. This can demonstrate that the idea of considering patient's health beyond mere treatment is still not mainstreamed.*	
Amendment 11 **Added paragraph**	
Calls on the Commission to apply the Health Technology Assessment (HTA) framework to streamline the evaluation of medicines and equip the HTA bodies with adequate resources and tools, such as access to data. The HTA is of critical importance given its impact on the identification of unmet medical needs.	107. Welcomes the agreement reached by Parliament and the Council on the forthcoming regulation on health technology assessment and calls for its swift adoption and thorough implementation so as to **foster greater convergence between Member States on the evaluation of health technologies** and to facilitate rapid access to innovative treatments for patients; 136. Welcomes the initiative of building interoperable digital infrastructure for the European Health Data Space, which will collate real-world data, to leverage the full potential of real-world data and access to rare therapies and to **ensure fair, transparent and non discriminatory access to data throughout Europe;**
Justification & result: *ECL's suggested paragraph focused on the importance of streamlining the evaluation of medicines. This idea was emphasised several times throughout the final text. ECL proposed to*	

add "adequate resources and tools" whilst the final text stresses the importance of ensuring fair, transparent and non-discriminatory access to data throughout Europe.

Amendment 12 **Added paragraph**	
Calls on the Commission to assess the impact of the incentives already granted before extending the market exclusivity period. This could be done by looking at (i) the real added value brought by the new health technology applying a European Health Technology Assessment, and (ii) the impact of the new product into the market on pharmaceutical expenditure, and on health expenditures more broadly;	19. Stresses the importance of continuous innovation, including in the off-patent segment, to address patients' unmet needs; calls on the Commission to design a fit-for-purpose regulatory framework that will enable the **development of value-added medicines, as well as recognise this category of affordable innovation, through appropriate incentives, for its value for healthcare system**s;
Justification & result: *ECL suggested starting by revising the existing system of incentives rather than jumping into new and additional incentives on top of those already existing. The European Union has the longest period of market exclusivity in the world and yet it is often compared to other jurisdictions where, despite the shorter period of market exclusivity, the number of innovative medicines is higher. ECL flagged HTA as a tool for evidence-based decisions on incentives and the sustainability of the healthcare system. This latter point has been adopted in the text as "value for healthcare systems".*	

Amendment 13 **Added paragraph**	
Calls on the Commission to investigate and address the withdrawing of off-patent drugs and reintroduction similar medicines with new indications and	39. Stresses the importance of striking the right balance between, on the one hand, offering **incentives in medicine development, particularly where no treatment alternatives exist**, and, on

higher prices[4]**.**	the other, safeguarding the public interest by **preventing the distortion of competition** and unintended effects and **ensuring the affordability and availability of medicinal products;**
Justification & result: *ECL highlighted that one of the causes of high prices of medicines is the withdrawal of off-patent drugs to substitute them with similar medicines considered as "innovative". This market tactic distorts competition and undermines the affordability and availability of medicinal products, as reported in the final text.*	

Amendment 14 **Paragraph 7**	
Stresses that generic and biosimilar medicines are accessible and affordable treatments and contribute greatly to the budgetary sustainability of healthcare systems; calls on the Commission to introduce measures to support a greater market presence of these medicines and to harmonise at EU level the interpretation of the so-called Bolar provision concerning possible exemptions from the legal framework for the Unitary Patent system for generic drug manufacturers; further calls on the Commission to design rules **[<u>for the industry</u>]** that promote research, development and the production of generic and biosimilar medicines in the EU and to propose EU protocols for the interchangeability of biosimilar medicines;	43. Points out that generic and biosimilar medicines increase patients' access to effective and safe treatment options, increase competition, offer accessible and affordable treatments and contribute greatly to the budgetary sustainability of healthcare systems, generating costs savings, while maintaining the high quality of healthcare; 45. Calls on the Commission to take measures to support the greater market presence of these medicines, and to harmonise at EU level the interpretation of the Bolar provision concerning possible exemptions from the legal framework for the Unitary Patent system for generic drug manufacturers; 46. Calls on the Commission to take action that promotes research, development and the production of generic and biosimilar medicines in the EU and to propose EU protocols for the interchangeability of biosimilar

[4] See the Pharmaceutical Sector Inquiry by the European Commission.

	medicines, as defined by the EMA, with respect for individual patient needs and clinicians' freedom to prescribe the best treatment for each patient, while always keeping the patient informed and at the centre of all decision making;
***Justification & result**:* *ECL wished to point out that research and development are not carried out by industry only. The final text still includes "for the industry". This idea is reiterated in 3 points in the final text (43, 45, 46).*	
Amendment 15 **Paragraph 8**	
Stresses the need to **address the reasons why the medicine approval time is so heterogeneous across the EU** and align them with European Medicines Agency (EMA) times, in order to ensure rapid and equal access to medicines for everyone in the EU;	52. Stresses the need to **reduce medicine approval times,** setting, where appropriate, a time limit for market access, and to align them with EMA decision-making times, in order to ensure **rapid and equal access to medicines for everyone in the EU and prevent discrimination between EU citizens**; recalls that MAH and distributors could also play a key role in the availability of medicinal products across the EU by avoiding the discontinuation of products and delays to arrival on the market due only to commercial factors;
***Justification & result**:* *ECL wished to stress that, once drugs are approved by the EMA, patient access to that medicine still differs greatly across the EU because 1) MAH decides when and where to launch the product and 2) price and reimbursement decisions have different durations in the EU. This disparity was reported in the final text as discrimination between EU citizens in line with ECL's suggestion.*	
Amendment 16 **Paragraph 9**	

Highlights the benefits **and risks** of public-private partnership tenders for national health systems in funding research into and the production of **new added-valued** medicines;	53. Highlights **the benefits of public-private partnership tenders** for national health systems in funding research into and **the production of innovative medicines** and research into medicine repurposing, and that academia-pharma cooperation is essential for the exchange of knowledge and information for the benefit of all patients across the Union;
Justification & result: *ECL wished to underline that benefits and opportunities come with risks and possible unforeseen undesirable consequences. Yet "risks'' does not appear in the final text. ECL suggested "new added-value" but the final text included "innovative".*	

Amendment 17 **Paragraph 10**	
Stresses the importance of new joint EU public procurement contracts by the Commission and the Member States, especially for emergency medicines, **unaffordable and innovative medicines medicines, and those that are launched in a limited number of Member States;**	31. Calls on the Commission and the Member States to encourage **cross-country cooperation to promote joint negotiations on the pricing of medicines and/or joint health technology assessments (HTAs);** 61. Stresses the importance of new joint EU public procurement contracts by the Commission and the Member States, especially for, **but not limited to,** emergency medicines **and unmet therapeutic needs to improve their affordability and access to them at EU level; calls for exploration of such practices in areas such as rare diseases and cancer** through clearly outlined milestones, objectives and commitments agreed by all parties involved; **highlights the need to ensure high levels of transparency in these initiatives** and to apply lessons learned from the joint procurement of COVID-19 products; stresses that joint

	procurement must not risk having a negative impact on supply flows by increasing the risk of shortages in the EU.
Justification & result: *ECL called on extending joint procurement to medicines beyond emergency use in order to facilitate patient access to medicines with high prices. The final text adopted by the European Parliament outlined that cross-country cooperation systems should aim to improve affordability. It also specifically mentioned the disease areas where this practice should start from: rare diseases and cancer. The final text goes even beyond and calls for more transparency "in these initiatives", possibly referring to contracts.*	
Amendment 18 **Paragraph 11**	
Is concerned that the **accessibility and** affordability of medicines remains a challenge for national health systems, and that innovative medicines are expensive **or products are not even launched in Member States for commercial reasons;** welcomes the Commission's intention to review pharmaceutical legislation to promote robust **and fair** competition and to **support fair** national drug pricing systems;	68. Is concerned that the **accessibility and** affordability of medicines remain a challenge for national health systems, and that innovative medicines are expensive or **in certain Member States not even brought to the market for commercial reasons;** 70. Welcomes the Commission's intention to review pharmaceutical legislation to promote robust **and fair** competition, to support the Member States in stabilising and balancing national drug pricing systems, to **promote fair** national drug pricing systems and to ensure equal access to medicines and medical products across the Member States; highlights that decisions on the pricing of medicines and reimbursement of the cost of medicines are the purview of Member States;
Justification: *All ECL's suggestions were taken into account.*	

Amendment 19 **Paragraph 12**	
Insists that a competitive EU pharmaceutical industry is strategic and more responsive to patients' needs; points out that the industry needs a stable, flexible and agile regulatory environment; believes that it can thrive globally with a clear, robust and efficient intellectual property system; welcomes the initiative to build interoperable digital infrastructure for the European Health Data Space **that can bring to the light the real value of medicines in the long term and in wider population size;**	136. Welcomes the initiative of building interoperable digital infrastructure for the European Health Data Space, **which will collate real-world data, to leverage the full potential of real-world data** and access to rare therapies and to ensure fair, transparent and non discriminatory access to data throughout Europe;
Justification & result: *ECL wanted to emphasise the role of the European Health Data Space (EHDS), a new tool which will help collect more information and evidence about the real value of medicines, especially those that receive marketing authorization with limited proof but high expectations. The EHDS could be a game changer for centralised post-marketing studies' results, as acknowledged by the MEPs.*	
Amendment 20 **Added paragraph**	
Insists that practices that extend market exclusivity should be discouraged such as prolonging intellectual property protection with incremental patenting of existing products ("ever-greening" strategies) and consequent competition distortion and profit maximization;	55. Acknowledges that policy which incentivises medical innovation is in the interest of patients and society at large; underlines the need to ensure a smart use of IP; **recalls that IP rights allow an extensive period of exclusivity that needs to be regulated, monitored and implemented carefully and effectively by the competent authorities so that IP rights do not limit accessibility and availability of medicines or conflict with the fundamental human right to health**; 163. Notes that **patent protection is a key incentive for companies to invest in innovation and produce new**

	medicines; notes, at the same time, that the exclusionary effect of patents may lead to limited market supply and reduced access to medicines and pharmaceutical products; stresses that a balance should be struck between encouraging innovation through the exclusionary effect of patents and ensuring access to medicines and protecting public health; **recalls that a company that markets a medicine can enjoy data exclusivity for a period of eight years as of the first marketing authorisation pursuant to Article 14(11) of Regulation (EC) No 726/2004** [...]
Justification & result: *"market exclusivity" and its length are addressed in the report which points out that the "data exclusivity"duration is 8 years. ECL's suggestion to carefully monitor intellectual property protection was featured in the final text. However, the report did not mention discouraging market exclusivity period extensions.*	
Amendment 21 **Added paragraph**	
Calls on the Commission to promote generic competition for off-patent rare disease drugs. To this end, advanced market commitments and subsidies for non-for-profit manufacturers should be considered;	10. Welcomes the Commission's intention to assess and review the existing incentive framework; calls on the Commission to stimulate competition by adapting its regulatory framework and **stimulating investments in off-patent orphan and paediatric medicines, including for oncology, paediatric cancers** and neurological diseases;
Justification: *ECL called for increasing market competition by 1) promoting generic medicines for off-patent orphan medicinal products 2) investing in non-for-profit manufacturers. The final text included only the first suggestion. Non-profit entities were not considered by the European Parliament.*	
Amendment 22 **Paragraph 15**	

Highlights the fact that gene and cell therapies, personalised medicine, nanotechnology, next-generation vaccines, e-health and the 'Million plus genomes' initiative can bring enormous benefits in relation to the prevention, diagnosis, treatment and post-treatment of all diseases **if they prove their added value compared to existing health technologies before and after the marketing authorisation phase;** Urges the Commission to develop appropriate regulatory frameworks, to guide new business models, and to run information campaigns to raise awareness and encourage the use of these innovations **once they prove they positive risk-benefit and improve overall the quality of life of patients;**	97. Highlights the fact that gene and cell therapies, personalised medicine, radionuclide therapy, nanotechnology, next-generation vaccines, including tmRNA derivatives, e health and the '1+ Million Genomes' initiative can bring enormous benefits in relation to the prevention, diagnosis, treatment and post-treatment of all diseases **if they prove their added value compared to existing health technologies**; underlines the **transformative potential** of these novel therapies and technologies **for patients as well as societies at large**, for example by enabling a shift from chronic management and care to one-time treatment, thereby contributing to reducing costs for health systems, and strengthening their efficacy, sustainability and resilience; urges the Commission to promote sufficient expertise, develop appropriate regulatory frameworks, guide new business models, consistently ensure high standards for safe products, and run information campaigns to raise awareness and ensure the uptake of these innovations; urges the Commission to propose adequate resources for the EMA to meet these objectives effectively;
Justification & result: *ECL's suggestion to include "prove their added value compared to existing health technologies" was adopted. The specification that comparison should be performed both before and after marketing authorisation was adopted. ECL noted that the assessment should go beyond the risk-benefit assessment but should improve the overall quality of life of patients. The final text, instead, mentions only the fact that therapies have "transformative potential [...] for patients as well as societies at large", hence without even questioning the long-term effect of these new therapies and technologies and their cost-effectiveness.*	

Amendment 23 **Paragraph 17**	
Urges the Commission, based on the experience with the authorisation of COVID-19 vaccines, to work with the EMA to consider extending the application of rolling reviews to other emergency medicines; further calls on the Commission to work with the EMA to develop the use of electronic product information for all medicines in the EU **which should not however substitute the traditional leaflet on paper;**	109. Urges the Commission, based on the experience of the authorisation of COVID-19 vaccines, to work with the EMA to consider extending the application of rolling reviews to other emergency medicines and evaluate if further regulatory flexibilities could contribute to a more efficient authorisation system, while safeguarding a high level of safety, quality and effectiveness; 67. Stresses the importance of ensuring the protection of personal data while harnessing the benefits of digital technologies in the pharmaceutical and health sector; **stresses that electronic product information should complement, but not replace, the package information leaflet;**
Justification & result: *ECL added a reference to keeping the traditional paper leaflet. Our suggestion was adopted.*	
Amendment 24 **Paragraph 18**	
Calls on the Commission to reassess the system which leads from conditional marketing authorisation to standard marketing authorisation or to the exceptional renewal of the authorisation **based on mid-point evaluations**; calls on the EMA to thoroughly carry out the final evaluation and ensure the strict compliance by producers with all of the requirements for each medicine under conditional marketing authorisation in order to ensure the efficacy and safety of such medicine;	112. Calls on the Commission to reassess the system which leads from conditional marketing authorisation to standard marketing authorisation or to the exceptional renewal of the authorisation, **on the basis of robust clinical data**; calls on the EMA to thoroughly carry out the final evaluation and ensure the strict compliance by producers with all of the requirements for each medicine under conditional marketing authorisation in

asks for the time before the final evaluation to be reduced from five to three years;	order to ensure the efficacy and safety of such medicine; asks for the time before the final evaluation to be reduced from five to three years where such measures are supported by sufficient clinical data;
Justification & result: *The final text of the report is comprehensive and calls for "robust clinical data".*	
Amendment 25 **Added paragraph**	
Calls on the Commission to establish clear criteria and a common European definition of 'medicine shortages', no matter the cause. This is an essential action in order to establish a coordinated approach for reporting and managing shortages.; calls on the Commission to request to marketing authorisation holders mandatory prevention plans to avoid shortages along with the mitigation plans should a shortage occur;	135. Calls on the Commission to **draft a harmonised definition of 'shortages' and to standardise reporting requirements across Member States** in order to enable closer cooperation and enhanced data exchange across Europe; 120. [...] calls on the Commission, moreover, to increase public-private collaboration and **to monitor the obligation on the part of all relevant supply stakeholders to provide early and transparent information on the availability of medicines, demand for medicines, parallel trade activities, export bans and market distortions**, without undue regulatory and administrative burdens;
Justification & result: *ECL called for a EU-wide definition of "medicine shortages" as well as a coordinated approach for reporting them. Our suggestion was adopted in the final text. ECL also pointed out the importance of preventing medicine shortages, besides managing them. The final text of the European Parliament reports "obligation on the part of all relevant supply stakeholders to provide early and transparent information" on a series of elements that would ultimately prevent shortages. Hence, ECL's suggested amendment was included in the final text.*	
Amendment 26 **Paragraph 19**	

Recalls that the EU's open strategic autonomy is linked to the constant and sufficient availability of medicines in all Member States; calls on the Commission to develop an early warning system for drug shortages **that involve all stakeholders**, based on a European information network on supply problems, to increase public-private collaboration and to monitor the obligation on the part of industry to provide early and transparent information on the availability of medicines; calls on the Commission to develop a mechanism to safeguard transparency in production and supply chains in the event of emergencies;	120. Recalls that the EU's open strategic autonomy is linked to the constant and sufficient availability of medicines in all Member States; **reiterates, in this regard, the recommendations stated in its resolution of 17 September 2020 on the shortage of medicines;** calls on the Commission, the Member States and the EMA to develop an **early warning system for medicine shortages, based on a European innovative, user friendly, transparent and centralised digital platform to exchange information and data on shortages and focusing on supply problems**; considers that such a system should be capable of determining the volume of existing medicine stock and demand and provide data capable of detecting, predicting and preventing shortages of medicinal products; calls on the Commission, moreover, to increase public-private collaboration and to **monitor the obligation on the part of all relevant supply stakeholders to provide early and transparent information on the availability of medicines**, demand for medicines, parallel trade activities, export bans and market distortions, without undue regulatory and administrative burdens;
Justification & result: *The final text included various ECL suggestions and calls already included elsewhere.*	
Amendment 27 **Added paragraph**	
Calls on the Commission to consider medicine shortages as a cross-border health threat as it puts national health systems under pressure and poses risks to patient's	A. **whereas the problem of shortages of medicines in the EU is long-standing and the number of incidents relating to shortages of**

health and may lead to non-treatment, under-treatment, and possible medication errors from attempts to substitute missing medicines[5];	**medicines has been growing in the Member States in recent years**; whereas an effective pharmaceutical strategy should include measures designed not only to mitigate the impact of medicine shortages, but also to prevent them, by looking at their root causes; whereas the EU's open strategic autonomy and security of supply should be ensured by, among other things, the diversification of supply chains for essential medicines and medicinal products, including European manufacturing sites and public procurement;
Justification & result: *Even though ECL's suggested amendment was not included, MEPs acknowledged that the problem of medicine shortages is a longstanding issue that existed before the pandemic and that COVID-19 only amplified its magnitude. ECL's reflections on the topic can be found here: https://www.cancer.eu/wp-content/uploads/ECL-Reflections-medicine-shortages_June_2021.pdf*	
Amendment 28 **Paragraph 20**	
Supports the Commission in its efforts to conduct a structured dialogue with players in the pharmaceutical value chain, public authorities, non-governmental patient and health organisations and the research community to address weaknesses in the global medicines manufacturing and supply chain **beyond public health emergencies;**	146. Supports the Commission in its efforts to conduct a structured dialogue with relevant actors in the pharmaceutical value chain, public authorities, non-governmental patient and health organisations, healthcare professionals, including pharmacists, and the research community as one of the tools to address the root causes of medicine shortages and the weaknesses in the global manufacturing and supply chain **for critical medicines, pharmaceutical raw materials, intermediate products and active pharmaceutical ingredients, as well as identify opportunities for innovation;**

[5] https://www.who.int/medicines/publications/druginformation/WHO_DI_30-2_Medicines.pdf?ua=1

Justification & result: *ECL pointed out that the revision of the pharmaceutical supply chain cannot be limited to public health emergency situations. This idea was acknowledged in the final text, since it encompasses critical steps such as the provision of raw materials, intermediate ingredients and APIs. ECL does not understand how a more comprehensive overview of the supply chain and its weaknesses can open to opportunities for innovation. The word "innovation" is often abused.*	
Amendment 29 **Paragraph 21**	
Calls on the Commission to **take stock of the lessons learnt with the negotiations around COVID-19 vaccines and** facilitate **clear contracts** between the EMA and industry on preventing **and managing pharmaceutical supply chain disruptions**. **Contracts should come with conditionalities and sanctions should a stakeholder not fulfill its commitments**; encourages the Commission to work with World Trade Organization members to facilitate trade in health products, increase resilience in global supply chains through stable access to raw materials, and contribute to an effective response in the event of a health emergency;	161. Calls on the Commission to facilitate **agreements** between the EMA and non-EU regulatory agencies on preventing **emergencies and coordinating responses to them** with full respect for the highest EU standards of personal data protection; encourages the Commission to work with World Trade Organization members to facilitate trade in health products, increase resilience in global supply chains through stable access to raw materials, and contribute to an effective response in the event of a health emergency;
Justification & result: *Point 161 is confusing to ECL as it is not clear how "agreements on preventing emergencies" can be facilitated.*	
Amendment 30 **Paragraph 23**	
Calls on the Commission to further facilitate access to global markets for the EU pharmaceutical industry, including small and medium-sized enterprises **and public clinical research centers**, through a level playing field and a regulatory framework facilitating trade agreements that prize **value-based** competitiveness, in order to make the pharmaceutical sector a	160. Calls on the Commission to further facilitate access to global markets for **the EU pharmaceutical industry, including SMEs**, through a level playing field and a robust and clear regulatory framework promoting the highest standards of quality and safety at international level and facilitating trade agreements that prize **innovation-based**

strategic pillar of the EU **to the benefit of citizens' health**;	competitiveness, in order to make the pharmaceutical sector a strategic pillar of the EU; calls on the Commission to ensure that trade agreements contribute to improved access to safe, effective and affordable medicines in the EU and in third countries; highlights the importance of removing trade and non-tariff barriers in third countries, and ensuring fair access to international markets for companies operating in the EU;
Justification & result: *SMEs bring to the market approx 40% of innovative medicines. The same medicinal products that come to the market with limited evidence of their effectiveness and high prices (Staff Working Document, European Commission). Whilst acknowledging that SMEs have fewer resources than large pharmaceutical companies, ECL strongly believes that the human and financial resources placed in science by public clinical research centers and charities should not be overlooked and underestimated. ECL's suggested amendments were unfortunately not adopted.*	
Amendment 31 **Added paragraph**	
Calls on the Commission to recognise the value to innovation and scientific knowledge brought by independent public research centers and academia.	37. Calls on the Commission to develop mechanisms to provide channels of information, communication and appropriate advice so as to make **participation in innovation projects more accessible at European level, above all for SMEs and research centres**;
Justification & result: *ECL called for the contribution of academia and non-commercial research centres to be acknowledged. Instead, references are made to SMEs and research centers only. These seem to be placed at the same level when, in actual fact, the level of incentives and regulatory support they receive are very different. The EMA's definition of SME refers to industries with fewer than 250 employees or a turnover smaller than €50m. Nevertheless, the incentives in terms of market exclusivity are applied to all pharmaceutical industries with no distinctions.*	