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Committee on the Environment, Public Health and Food Safety

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COMPROMISE AMENDMENTS 1 - 35

Draft report
Dolors Montserrat
(PE681.109v01-00)

A Pharmaceutical Strategy for Europe
(2021/2013(INI))

AM_Com_NonLegCompr

Compromise Amendment 1 (on the scope and objectives of the strategy and other relevant EU policies such as research)
EPP, S&D, RE, Greens/EFA, ID, ECR, The Left
Compromise amendment replacing Amendments: **57, 58, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 135, 136, 137, 138, 139, 140, 141, 143, 145, 146, 134, 178, 255, 283, 313, 317, 377, 430, 500, 605, 632, 698, 716, 629, JURI 1, JURI 14, ITRE 1, ITRE 3, ITRE 4, ITRE 39, and ITRE 42**

Amendment 1
Motion for a resolution
Subheading 1

Motion for a resolution	*Amendment*
Putting patients at the centre of all health policies	Putting patients at the centre of all health policies

Or. en

Amendment 1
Motion for a resolution
Paragraph -1 (new)

Motion for a resolution	*Amendment*
	-1. Recalls that healthcare is a human right enshrined in the Universal Declaration of Human Rights; regrets the disparities into the access to high quality healthcare services, including access to medicinal products, among Member States and also between different regions within Member States; calls for national and European measures, including where appropriate legislative measures, to address these disparities and guarantee the rights of patients to universal, affordable, effective, safe and timely access to essential and innovative medicines;

Amendment 1
Motion for a resolution
Paragragh -1 a (new)

Motion for a resolution	*Amendment*
	-1a. Points out that being responsible for pharmaceutical legislation as well as complementing public health policies, the Union should strive to coordinate national measures to guarantee access to affordable and high-quality health services for all EU citizens and residents;

Or. en

Amendment 1
Motion for a resolution
Paragraph -1 b (new)

Motion for a resolution	*Amendment*
	-1b. Stresses the geostrategic imperative for the Union to regain its independence with regard to healthcare, its need for a diversified supply chain, to secure rapidly, affordably and efficiently its supply of medicines, medical equipment, medical devices, active substances, diagnostic tools and vaccines, and to prevent shortages thereof, prioritising the interest and safety of patients

Or. en

Amendment 1
Motion for a resolution
Paragraph -1 c (new)

Motion for a resolution	*Amendment*
	-1c. Underlines that COVID-19 has brought unprecedented challenges for health systems and their sustainability,

but also had a dramatic impact on patients, including those suffering from chronic conditions, and their ability to access treatments and care; calls on the Commission and Member States to assess and address the overall impact of the pandemic on patients and on the resilience of the healthcare systems and to work collaboratively to ensure no patient is left behind and that continuity of care is ensured even during emergency situations;

Or. en

Amendment 1
Motion for a resolution
Paragraph -1 d (new)

Motion for a resolution	*Amendment*
	-1d. Underlines that public investment in research should aim to strengthen public health and address unmet medical needs, especially those in the areas not covered by the private sector, defined with the involvement of regulators, academia, healthcare professionals, patients and payers at early stages of R&D, to ensure research priorities respond to societal needs; points out that embedding meaningful patient involvement and dialogue throughout the entire life cycle of medicines and other therapies is an indispensable requirement to achieve high-value innovation and the overall success of the strategy which also requires an adequate consultation with consumer and patient representatives throughout the implementation of the Pharmaceutical Strategy;

Or. en

Amendment 1
Motion for a resolution
Paragraph -1 e (new)

Motion for a resolution	*Amendment*
	-1 e. Calls on the Commission to leverage and coordinate the Pharmaceutical, Industrial, Digital Strategies and the renewed EU trade policy and other relevant policies to promote European competitiveness and ensure the EU is capable to compete with challenger regions;

Amendment 1
Motion for a resolution
Paragraph 1

Motion for a resolution	*Amendment*
1. Stresses that 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 ***and*** treatment of diseases;	1. 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,*** treatment of diseases ***and quality of life of patients***;

Or. en

Compromise Amendment 2 (on the investments in R&D on pharmaceuticals)

EPP, S&D, RE, Greens/EFA, ID, ECR, The Left

Compromise amendment replacing Amendments: **134, 152, 153, 154, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 171, 172, 173, 177, 193 562 and ITRE 40**

Amendment 2
Motion for a resolution
Paragraph 2

Motion for a resolution	*Amendment*
2. ***Considers that investment in research has not been sufficient*** to meet the therapeutic needs of patients ***with*** rare diseases, paediatric cancers and neurodegenerative diseases or to deal with antimicrobial resistance (AMR);	2. ***Recalls that public and private investments should be oriented with the necessary regulatory and legislative measures*** to meet the therapeutic ***and diagnostic*** needs of patients***, including*** rare ***and chronic*** diseases, ***rare adult cancers and*** paediatric cancers and neurodegenerative diseases ***as well as*** to deal with antimicrobial resistance (AMR);

Or. en

Amendment 2
Motion for a resolution
Paragraph 2 b (new)

Motion for a resolution	*Amendment*
	2 a. Welcomes the intention of the European Commission to assess and review the existing incentives framework calls on the Commission to stimulate competition by adapting a regulatory framework and stimulating investments in off-patent orphan and paediatric medicines, including for oncology, paediatric cancers, and neurological diseases;

Or. en

Compromise Amendment 3 (on AMR)

EPP, S&D, RE, Greens/EFA, ID, ECR, The Left

Compromise amendment replacing Amendments **67, 174, 175, 176, 180, 181, 182, 183, 184, 185, 186, 187, 188, 190, 191, 214, 230, 231, 233, 235, JURI 33, ITRE 49, ITRE 79**

Amendment 3
Motion for a resolution
Paragraph 2 d (new)

Motion for a resolution	*Amendment*
	2 b. Highlights the serious and constantly increasing risks of AMR to public health, environment, food production, and economic growth; recognises the value of public health campaigns aimed at the prevention of infections using vaccines;

Or. en

Amendment 3
Motion for a resolution
Paragraph 2 e (new)

Motion for a resolution	*Amendment*
	2c. Considers that antimicrobial resistance constitutes a serious threat to public health; calls on the Commission and Member States to fund projects aimed at improving diagnostics and developing new antibiotics as well as suggesting a protocol for the prudent use of antibiotics and an awareness campaign for health professionals to encourage more targeted treatment based on patients' actual needs;

Or. en

Amendment 3
Motion for a resolution
Paragraph 2 f (new)

Motion for a resolution	*Amendment*
	2d. Invite ***the Innovative Medicines Initiative and invites the European Investment Bank to play a more active role in financing innovative initiatives in the field of antimicrobial resistance; stresses the importance of implementing the joint action plan on antimicrobial resistance and health infections; notes the need to facilitate access to new antibiotics while maintaining access to old ones;***

Or. en

Amendment 3
Motion for a resolution
Paragraph 3

Motion for a resolution	*Amendment*
3. Considers it imperative that a common EU therapeutic guide for antimicrobials be introduced and that communication campaigns on AMR be coordinated through a single calendar at EU level;	3. Considers it imperative that a common EU therapeutic guide for antimicrobials be introduced, ***setting up traceable antimicrobial use reduction targets at EU level*** and that communication campaigns on AMR be coordinated through a single calendar at EU level ***to create more awareness on antimicrobial resistance, its variants and its consequences***; ***underlines that the 'One Health' approach should guide the reduction and use optimisation for antimicrobials, as well as the development of new medicines, including antimicrobial agents; calls on the Commission and member states to assess the existing legislative framework related to AMR and, where appropriate, come forward with a proposal to revise it;***

Or. en

Compromise Amendment 4

EPP, S&D, RE, ID

Compromise amendment replacing Amendments **195, 193, 187, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 216, 217, 218, 219, 221, 222, 224, 225, 226, 229, 232, 249, 307, 234, ITRE 41, ITRE 43, ITRE 44, ITRE 45, ITRE 59 and ITRE 76**

Amendment 4
Motion for a resolution
Paragraph 4

Motion for a resolution	*Amendment*
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 projects promoted by the pharmaceutical industry combating rare diseases, paediatric cancers, neurodegenerative ***diseases*** and AMR, with the aim of finding more therapeutic options 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 evaluate the implementation of national plans to fight these diseases;	4. 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 combating ***cancers*** paediatric cancers ***especially 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 optionsand meeting the needs of patients and health systems;

Or. en

Amendment 4
Motion for a resolution
Paragraph 4 a (new)

Motion for a resolution	*Amendment*
	4a. 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 on the Member States to support research and development that focuses on the unmet medical needs; Stresses that the system based solely on research incentives will not achieve the objectives in the fight***

against rare diseases;

Or. en

Amendment 4
Motion for a resolution
Paragraph 4 b (new)

Motion for a resolution	*Amendment*
	4b. Calls on the Commission to provide public research funding to investigate the use of repurposed, off-label and off-patent products that can be used safely and effectively in patients; stresses that medicines resulting from publicly funded research must be equally available across the Union for a fair and affordable price and, where appropriate, the MAH may consider voluntary non-exclusive licencing for these products*; *emphasizes the EU funding should be steered towards projects where research is needed the most;

Or. en

Amendment 4
Motion for a resolution
Paragraph 4 d (new)

Motion for a resolution	*Amendment*
	4c. 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 the so-called value added medicines as well as recognise this category of affordable innovation with appropriate incentives and its value for healthcare systems;

Amendment 4
Motion for a resolution
Paragraph 4 e (new)

Motion for a resolution	*Amendment*
	4d. 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 incentivizes less so-called 'me too' pharmaceuticals which do not have an added value or highly expensive pharmaceuticals that offer only minor improvements for patients;

Amendment 4
Motion for a resolution
Paragraph 4 f (new)

Motion for a resolution	*Amendment*
	4 e. Calls on the Commission to revise the Regulation on orphan medicinal products (EC/141/2000) and the Regulation on medicinal products for paediatric use (EC/1901/2006)[1b] ; calls for an assessment of the effectiveness of funding and of public-private partnership projects, especially with a view to improve the relationship between local health authorities, universities and industry; recognises that further improvements are needed to address the needs of the patients that these regulations aim to cover and calls on the Commission to allow for measures targeting important underserved areas, to streamline, simplify and adjust regulatory procedures;

[1a] OJ L 18, 22.1.2000, p. 1–5

[1b] OJ L 378, 27.12.2006, p. 1–19

Amendment 4
Motion for a resolution
Paragraph 4 g (new)

Motion for a resolution	*Amendment*
	4f. Highlights the fact that scientifically recognised integrative medicine approved by public health authorities can bring benefits to the patients in relation to the parallel effects of several diseases and their treatments such as cancer; stresses the importance to develop a holistic, integrative and patient-centric approach and to encourage the complementary use of these therapies where appropriate under the supervision of healthcare professionals;

Amendment 4
Motion for a resolution
Paragraph 4 h (new)

Motion for a resolution	*Amendment*
	4 g. Calls on the Commission to support additional research in underrepresented populations including the elderly, children, women and patients with comorbidities, including obesity as a primary morbidity as well as where it exists as a gateway chronic disease to other noncommunicable diseases; Stresses the need to take gender into account in the research, diagnosis, treatment and impact of medicines and therapeutics as women across their lifespan remain under-represented in biomedical and health research and data; underlines that consequently, the evidence base is weaker for women as well as for older people, leading to many conditions being underdiagnosed with women, such as cardiovascular disease;

Or. en

Amendment 4
Motion for a resolution
Paragraph 4 i (new)

Motion for a resolution	*Amendment*
	4 h. Calls on the Commission to build on the work of the Europe's Beating Cancer Plan and ensure that Europe becomes the worldwide centre of excellence for R&D in emerging, innovative fields of medicine; underlines that State-of-the art technologies, such as nanomedicines, stand to provide solutions to current treatment challenges in areas such as cancer and cardiovascular diseases; highlights that these innovative fields of medicine should be authorised by the centralised approval framework for nanomedicines;

Or. en

Amendment 4
Motion for a resolution
Paragraph 4 j (new)

Motion for a resolution	*Amendment*
	4 i. Calls on the Commission to ensure that EU funding for biomedical research and development must be made conditional on the full transparency and traceability of investments, on ensuring supply in all Member States, and on facilitating the best outcome for patients, including in terms of accessibility and affordability of manufactured medicines;

Compromise Amendment 5 (on national pricing criteria)

EPP, S&D, RE, Greens/EFA, The Left

Compromise amendment replacing Amendments **220, 232, 236, 237, 239, 240, 241, 242, 243, 244, 245, 246, 247, 248, 251, 252, 253, 254, 257, 250, 279, 280, 372, 375, 454, 238, 633, 716, JURI 13, ITRE 24, ITRE 25, ITRE 50, ITRE 51, ITRE 53 and ITRE 57**

Amendment 5
Motion for a resolution
Paragraph 5

Motion for a resolution	*Amendment*
5. Calls on the Commission to promote dialogue with the Member States and stakeholders to assess new criteria for national pricing, such as whether a product is 'Made in Europe', whether ***the EU invested*** in the product to support research, or whether prices should be adapted to the value of the therapeutic benefit of the medicine, and the primary and broader needs of the population;	5. 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 costs for patients and without prejudice to the sustainability of the health system; these criteria should include high environmental manufacturing standards, robust supply chain management and investment in innovation and research***; ***further recommends to the Commission and Member States that pricing also reflects whether any type of public funding was used to support innovation, manufacturing and research***, the value of the therapeutic benefit of the medicine, ***whether the medicine in question is a generic or biosimilar*** and the primary and broader needs of the population; ***underlines that such dialogue should further encourage cooperation in pricing negotiations and, where appropriate, joint procurement; recalls that national pricing should be based on transparency of factors such as public and private research, development costs and added therapeutic value; calls on the Commission to promote information sharing among Member States on medicine net prices through the EURIPID***

collaboration;

Or. en

Amendment 5
Motion for a resolution
Paragraph 5 a (new)

Motion for a resolution	*Amendment*
	5 a. Calls on the Commission to explore the possibility to establish, subject to conditionalities, a European fund, co-financed by the Member States, for negotiating and purchasing the orphan medicines and other new, personalised medicines, as to guarantee equal access for patients from different Member States to effective therapeutics, treatments and prevent individual health care units from excessive costs when treating rare diseases;

Or. en

Amendment 5
Motion for a resolution
Paragraph 5 b (new)

Motion for a resolution	*Amendment*
	5b. Calls on the Commission to work with Member States to introduce measures to increase transparency into the research, development and production of medicinal products; Calls for greater price transparency and invites Member States to continue to share their best-pricing practices on a voluntary basis; stresses that pricing should remain a national competence, taking account of diversity across the EU;

Compromise Amendment 6 (on strategies to increase the affordability and availability of medicines)

EPP, S&D, RE, Greens/EFA

Compromise amendment replacing Amendments: **250, 258, 259, 260, 261, 262, 263, 264, 265, 266, 267, 268, 269, 270, 271, 272, 273, 274, 275, 276, 281, 284, 285, 287, 288, 331, 332, 277, 603, JURI 2, JURI 4, JURI 6, JURI 11, JURI 22, ITRE 17 and ITRE 62**

Amendment 6
Motion for a resolution
Paragraph 6

Motion for a resolution	*Amendment*
6. Calls on the Commission to review the incentive system, increase price transparency, highlight the causes limiting affordability and patient access to medicinal products, and propose sustainable solutions that also promote competition;	6. Calls on the Commission to ***periodically evaluate and*** review the incentive system, increase price transparency, ***and*** highlight the causes limiting affordability and patient access to medicinal products; ***further calls on the Commission to address the root causes of shortages of pharmaceuticals*** and propose sustainable solutions that also promote ***on and off-patent*** competition ***and the timely entry to market of generics and biosimilars***; ***stresses the importance of striking the right balance between on the one hand awarding incentives in medicines development, particularly where no treatment alternatives exist and on the other safeguarding the public interest by preventing competition distortion, unintended effects and ensuring the affordability and availability of medicinal products;*** ***further calls on the Commission, especially DG Competition, and national competent authorities to be alert of anti-competitive conduct and investigate anti-competitive practices in the pharmaceutical industry***

Or. en

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

Motion for a resolution	*Amendment*
	6a. Calls for maximum transparency in the use of public research and development funding and for easy public access to information regarding patenting/licensing conditions, the findings of clinical trials and public/private contributions;

Or. en

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

Motion for a resolution	*Amendment*
	6 b. Stresses the importance of generic, biosimilar and value added medicines for consistently increasing equitable access for patients and making the healthcare systems sustainable in a European Union where access is still uneven; calls urgently on the Commission to ensure healthy competition at the expiry of intellectual property exclusivities by ensuring accessibilty to biosimilars from day one and by removing all barriers to access competition, such as patent linkage and banning IP evergreening practices that unduly delay access to medicines and allowing single global development;

Or. en

Amendment 6
Motion for a resolution
Paragraph 6 c (new)

Motion for a resolution	*Amendment*
	6 c. Insists on the need to ensure equal access to affordable drugs within the EU; promote collective negotiation of the price of medicines with pharmaceutical industries such as the Beneluxa initiative and the Valetta Declaration; considers that pharmaceutical industries should respect a conditionality on the affordable price of medicines in the framework of publicly funded research;

Amendment 6
Motion for a resolution
Paragraph 6 d (new)

Motion for a resolution	*Amendment*
	6 d. Stresses that commercial withdrawals can have serious consequences in terms of availability of medicines and thus hamper patients' access to timely and equitable access to high quality treatment; underlines that commercial withdrawals of essential medicines should take place in situations where substitute and equivalent treatment are available for patients and should be subject to extended early notification obligations to for MAHs and distributors, to ensure that Member State authorities are able to manage the situation with MAHs and distributors to in the interest of patients

Compromise Amendment 7 (on the role of generic and biosimilar medicines)

EPP, S&D, RE, Greens/EFA, ID, ECR, The Left

Compromise amendment replacing Amendments: **62, 108, 113, 147, 149, 144, 289, 290, 291, 292, 293, 294, 295, 296, 297, 298, 299, 300, 301, 302, 303, 304, 305, 308, 309, 310, 311, 312, 315, 318, 319, 498, JURI 32, ITRE 25**

Amendment 7
Motion for a resolution
Paragraph 7

Motion for a resolution	*Amendment*
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 for the industry 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;	7. ***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 quality of healthcare; calls on the Commission to ***provide*** 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 ***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 medicines, ***as defined by the European Medicines Agency***; ***in respect of individual patient needs and clinicians' freedom to prescribe the best treatment choice for each patient, while keeping the patient always informed and at the centre of all decision-making;***

Or. en

Amendment 7
Motion for a resolution
Paragraph 7 a (new)

Motion for a resolution	*Amendment*
	7 a. Encourages Member States to evaluate measures to promote the use of financial savings generated in the national health system from the use of biosimilars and reinvest them in a transparent and tangible way to improve the quality of the care services; calls on the European Commission to encourage Member States to support the transparent practices of biosimilar-related cost savings; calls on the European Commission to facilitate arrangements such as gainsharing programmes;

Amendment 7
Motion for a resolution
Paragraph 7 b (new)

Motion for a resolution	*Amendment*
	7 b. Stresses the need for the Commission to continue preventing anti-competitive practices to ensure a competitive market of generic and biosimilar;

Amendment 7
Motion for a resolution
Paragraph 7 c (new)

Motion for a resolution	*Amendment*
	7 c. Stresses the importance of improving education on biosimilars; calls on the European Commission to promote relevant educational and communication activities amongst healthcare professionals by setting up a dedicated Europe-wide online resource centre;

Compromise Amendment 8 (on the delayed arrival of medicines on the market)

EPP, S&D, RE, ID, ECR, The Left

Compromise amendment replacing Amendments: **320, 321, 322, 323, 324, 325, 326, 327, 328, 329, 330 and 61**

Amendment 8
Motion for a resolution
Paragraph 8

Motion for a resolution	*Amendment*
8. Welcomes the fact that the Commission will launch a pilot project to better understand the root causes of the delayed arrival of medicines on the market; ***further welcomes the fact that the Commission will continue to monitor mergers between pharmaceutical companies to avoid distortions of competition;*** stresses the need to reduce medicine approval times at national level and align them with European Medicines Agency (EMA) times, in order to ensure rapid and equal access to medicines for everyone in the EU;	8. Welcomes the fact that the Commission will launch a pilot project to better understand the root causes of the delayed arrival of medicines on the market; ***calls on the Commission to look at the huge differences across EU of the average number of days between approval of a medicine and the moment it is available to the patients and to propose new ways to improve the regulatory process and its implementation and to implement innovative solutions to reduce the delay of medicines' market entry***; ***emphasises that any revision of the regulatory procedures and approaches to the assessment of scientific evidence must be cautiously undertaken in order to adequately take patients' benefit and safety aspects into consideration***; stresses the need to reduce medicine approval times***, setting, where appropriate, a time limit for market access*** and align them with European Medicines Agency ***times for decision making***, in order to ensure rapid and equal access to medicines for everyone in the EU ***and avoid discrimination between EU citizens***; ***recalls that MAH and distributers could also play a key role on the availability of medicinal products across the EU by avoiding discontinuation of products and delay arrival to the market due only to commercial factors.***

Or. en

Compromise Amendment 9 (on public private partnerships and innovation)
EPP, S&D, RE, Greens/EFA, ID, ECR
Compromise amendment replacing Amendments: **195, 333, 334, 335, 336, 337, 338, 339, 340, 341, 365, 401 and 723**

Amendment 9
Motion for a resolution
Paragraph 9

Motion for a resolution	*Amendment*
9. Highlights the benefits of public-private partnership tenders for national health systems in funding research into and the production of innovative medicines;	9. Highlights the benefits of public-private partnership tenders for national health systems in funding research into and the production of innovative medicines ***and medicines repurposing, and that academia-pharma coopertion are essential for the exchange of knowledge and information for the benefit of all patients across the Union***; ***stresses that such collaboration must guarantee that research priorities are driven by patient and public health needs and that public funds are invested in a transparent manner, ensuring availability and affordability of products resulting from these partnerships and public funds; calls on the Commission to ensure that the European Partnership for Health Innovation is driven by public interest considerations; calls on the Commission to adopt and implement a general policy on such conditionalities under Horizon Europe;***

Or. en

Compromise Amendment 10 (on HERA)

EPP, S&D, RE, Greens/EFA

Compromise amendment replacing Amendments**150, 342, 343, 344, 370, 371, 400, 406, 639, 646, ITRE 18 and ITRE 19**

Amendment 10
Motion for a resolution
Paragraph 9 a (new)

Motion for a resolution	*Amendment*
	9 a. Takes note of the Commission proposal to establish a Health Emergency Preparedness and Response Authority (HERA); considers that the Authority should identify health threats, initiate and support the development of innovation, establish at European level a list of medicinal products of major therapeutic interest, facilitate their production within the EU, promote the joint purchase and build up strategic stocks of those medicines;
	Calls for the allocation of sufficient resources and power autonomy to broadly address all the cross-borders threats to health that EU could face in the middle term and beyond the sole COVID-19 pandemic, including resources for the development of new therapeutics against viral and bacterial pathogens;

Or. en

Amendment 10
Motion for a resolution
Paragraph 9 b (new)

Motion for a resolution	*Amendment*
	9 b. Calls the Commission to ensure that HERA is public-interest driven and contributes effectively to the development, availability and affordability of safe and effective medical countermeasures;
	Reiterates its position that the Commission should consider the creation of a European model of the US

Biomedical Advanced Research and Development Authority; welcomes that the Commission has made a proposal for a European HERA but expresses its disappointment that the European Parliament is not involved in its proper role as a co-legislator;

Compromise Amendment 11 (on new joint procurement practices)

EPP, S&D, RE, Greens/EFA, ECR, The Left

Compromise amendment replacing Amendments: **256, 344, 346, 347, 348, 349, 350, 351, 352, 353, 354, 355, 356, 357, 358, 359, 360, 361, 362, 368, 369, 374, 450, 597, 624, 634, 635, 636, 652, ITRE 28, ITRE 29 and ITRE 82**

Amendment 11
Motion for a resolution
Paragraph 10

Motion for a resolution	*Amendment*
10. Stresses the importance of new joint EU public procurement contracts by the Commission and the Member States, especially for emergency medicines and unmet therapeutic needs;	10. 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 their access at EU level***; ***calls for exploration of such practices in areas like rare diseases and cancer with a clear outline of milestones, objectives and commitments undertaken by all parties involved; highlights the need to ensure high levels of transparency in these initiatives and apply lessons learned from the joint procurement of COVID-19 products; stresses that joint procurement shall not risk impacting supply flows negatively by increasing the risk of shortages in the EU;*** ***Joint procurement should be based on shared responsibilities and a fair approach with rights and obligations for all parties involved. Clear commitments should be provided and respected with manufacturers delivering the agreed production levels and the authorities purchasing their agreed reserved volumes;*** ***If joint procurement is deployed, the awarding process should take into account qualitative criteria such as the ability of the manufacturer to ensure security of supply during a health crisis;*** ***highlights that joint public procurement***

should have a clearly defined scope as there can be for example new innovative antibiotics, new vaccines and curative medicines, and medicines for rare diseases while taking into consideration the need for a more balanced public private investment and including clear liability for manufacturers as well as the need for sufficient flexibility for Member States in line with national specificities whilst honouring the undertaken commitments;

Or. en

Amendment 11
Motion for a resolution
Paragraph 10 a (new)

Motion for a resolution	*Amendment*
	10a. Welcomes the reference in the strategy to the fact that actions in the area of public procurement can foster competition and improve access to medicines; urges the Commission, in the context of Directive 2014/24/EU, to swiftly propose guidelines for the Member States, notably on how to best implement the most economically advantageous tender (MEAT) criteria, looking beyond the lowest price criteria only; emphasises that security of supply is an essential factor and must be used as a qualitative criterion in connection with the award of public pharmacy contracts and calls for tender for the supply of medicines; emphasises the importance of diversified supplies and soustainable procurement practices for pharmaceuticals; proposes that investments in the manufacture of active ingredients and medicinal end products in the EU should also be retained as an essentail criterion, as well as the number and location of production sites, the reliability of supply, the reinvestment of profits into R&D and the application of

social, environmental, ethical and quality standards;

Or. en

Amendment 11
Motion for a resolution
Paragraph 10 b (new)

Motion for a resolution	*Amendment*
	10 b. Considers that, in times of crisis, part of the Union joint procurement could, where appropriate and upon request, be pre-allocatedto low- and middle-income third countries, in a spirit of solidarity;
	Calls on the Commission and the Member States to consider introducing procurement procedures under which contract may be awarded to a number of successful tenderers, including joint tenderers;

Or. en

Compromise Amendment 12 (on expanding and increasing the efficiency of the pharmaceutical industrial base)

EPP, S&D, RE, Greens/EFA, ID

Compromise amendment replacing Amendments: **115, 378, 379, 380, 381, 382, 383, 384, 385, 386, 387, 388, 389, 390, 391, 392, 393, 394, 396, 399, 407, 410, 444, 568, ITRE 2, ITRE 26, ITRE 61**

Amendment 12
Motion for a resolution
Paragraph 11

Motion for a resolution	*Amendment*
11. Is concerned that the affordability of medicines remains a challenge for national health systems, and that innovative medicines are expensive; welcomes the Commission's intention to review pharmaceutical legislation to promote robust competition and to stabilise and balance national drug pricing systems	11. Is concerned that ***accessibility and*** affordability of medicines ***remain*** a challenge for national health systems, and that innovative medicines are expensive ***or not even brought to the market in certain Member States for commercial reasons; Calls on the Commission to look into policy options that help secure that centrally authorized medicines are marketed in all EU Member States and not just in those that are commercially interesting; stresses the need to ensure that any form of incentive at EU level leads to fair and affordable pricing of pharmaceuticals, particularly innovative ones, across all EU Member States;*** welcomes the Commission's intention to review pharmaceutical legislation to promote robust and fair competition and to support the Member States to stabilise and balance national drug pricing systems and to ***promote fair*** national drug pricing systems ***and to ensure equal access to medicines and medical products across Member States***; ***highlights that decisions on the*** pricing ***and reimbursement of medicines are the purview of Member States***;

Or. en

Amendment 12
Motion for a resolution
Paragraph 11 a (new)

Motion for a resolution	*Amendment*
	11 a. Calls the Commission to consider new processes for promoting the repurposing of medicinal products; calls on the Commission to facilitate a broader off-label use of medicines, including less expensive medicines and medicines used for rare cancers among others, whenever there is strong scientific evidence of efficacy and safety for patients; in addition, highlights the opportunity for a new framework to support the marketing and use of drugs with approved new indications, to make drug repurposing more attractive in the EU;

;Or. en

Amendment 12
Motion for a resolution
Paragraph 11 b (new)

Motion for a resolution	*Amendment*
	11b. Calls on the Commission to develop European health strategies on the basis of a common basket of medicines for the treatment of cancer, infections, rare diseases and other areas particularly affected by shortages; calls on the Commission to consider the option of common pricing criteria to make such medicines affordable; believes that facilitating faster access, without compromising the safety, would be especially beneficial for patients with severe chronical diseases; suggests accordingly to allow patients to take part in the decisions on risk-benefit from early access to new and innovative medicines and treatment;

Or. en

Amendment 12
Motion for a resolution
Paragraph 11 c (new)

Motion for a resolution	*Amendment*
	11c. encourages the inclusion of disease-based communities in the European Medicines Agency's Scientific Advice processes, for rare cancers and diseases, to provide regulators with their expertise of the disease and factor in its rarity and unmet needs;

Or. en

Amendment 12
Motion for a resolution
Paragraph 11 d (new)

Motion for a resolution	*Amendment*
	11 d. Urges the Commission and the Member States to introduce financial incentives, where appropriate, to preserve and expand the EU's pharmaceutical industrial base, from the production of active pharmaceutical ingredients to medicine manufacturing, packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies in order to diversify resources and encourage the development of innovative production technologies capable of enhancing the responsiveness of entire production lines; recalls that all public funding should facilitate the best outcomes for patients, including in term of accessibility of manufactured medicines, and by respecting transparency, traceability and supply obligations' conditionalities;

Or. en

Compromise Amendment 13 (on the future of EU pharmaceutical industry)

EPP, S&D, RE, ID, ECR

Compromise amendment replacing Amendments: **411, 413, 414, 415, 416, 419, 420, 421, 423, 424, 425, 427, 428, 432, 434, 435, 438, 440, 442, 444, 447, 451, 452, 453, 456, 457, 460, 462, 466, 469, 470, 479, 481, 482, 489, 543, 234, 238, 473, 565, 412, 417, 418, 422, 426, JURI 7, JURI 26, JURI 34, ITRE 34 and ITRE 69**

Amendment 13
Motion for a resolution
Paragraph 12

Motion for a resolution	*Amendment*
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;	12. Insists that a competitive, ***self-sufficient and sustainable*** EU pharmaceutical industry is ***of*** strategic ***importance for the Union as it fosters innovation, research, high-quality employment and is*** more responsive to patients' needs; points out that the industry needs a stable ***and predictable*** regulatory environment, while limiting ***administrative burden***, ***safeguarding the principle of prevention and the availability of safe, effective and quality medicines on the EU market***; ***underlines that the marketing authorisation system should build on the existing legislative framework and prevent duplication and additional administrative burdens;***

Or. en

Amendment 13
Motion for a resolution
Paragraph 12 b (new)

Motion for a resolution	*Amendment*
	12 b. Welcomes the strong focus and several initiatives included in the pharmaceuticals strategy on the need to optimize and modernize the existing regulatory framework, such as the revision of the variations legislation, more digitalised and efficient regulatory processes, the implementation of the Electronic product information (ePI), streamlining API assessment, and better GMP/ Manufacturing management and resources; urges the Commission to advance fast on this agenda making the best use of existing digital tools at EU level (telematics);

;;Or. en

Amendment 13
Motion for a resolution
Paragraph 12 c (new)

Motion for a resolution	*Amendment*
	12 c. Calls on the Commission to expand the role of EMA in the assessment of drug-device/diagnostic combination products to simplify the fragmented supervisory framework; believes that greater regulatory agility and efficiency can be achieved by adopting a more expertise-driven scientific assessment on marketing authorisations within the European Medicines Agency(EMA);

Or. en

Amendment 13
Motion for a resolution
Paragraph 12 d (new)

Motion for a resolution	*Amendment*
	12 d. Believes that fostering and building on an attractive European industrial eco-system for the pharmaceutical sector is one of the key conditions to continue to foster relocation of production facilities back to the EU; Further believes that such relocation can help make the European healthcare systems become more independent from third countries and more resilient to disruptions given that breaks in supply put patient at risk when they are not able to obtain recommended alternative treatments;

Or. en

Amendment 13
Motion for a resolution
Paragraph 12 e (new)

Motion for a resolution	*Amendment*
	12 e. Calls on the Commission to include in the EU Statistics on Income and Living Conditions (EU-SILC) data on self-reported lack of access to medicines, as so far access to medicines in not measured in the EU-SILC;

Or. en

Amendment 13
Motion for a resolution
Paragraph 12 f (new)

Motion for a resolution	*Amendment*
	12 f. Supports the adaptation of existing frameworks for the acceptability in decision making and adoption of AI technologies to provide a pathway through which AI can be developed, adopted and implemented in healthcare systems through inclusivity, capacity and

trust; reiterates that with all AI-based technologies, human oversight must at all times be guaranteed; believes that legislation should not lag behind innovation; calls on the Commission to introduce a degree of regulatory flexibility in order to be able to respond more rapidly and effectively to new requirements and products, while respecting safety and ethical criteria, ;

Or. en

Compromise Amendment 14

EPP, S&D, RE, Greens/EFA, ID, ECR, The Left

Compromise amendment replacing Amendments **463, 467, 472, 475, 480, 484, 485 and 500**

Amendment 14
Motion for a resolution
Paragraph 12 g (new)

Motion for a resolution	*Amendment*
	12 g. Calls on the Commission to facilitate assessment processes that allow for early and iterative dialogue on data and evidence as they are generated; calls on the EMA and national medicine agencies to prioritise the submission of data from randomised controlled clinical trials that compare an investigational medicine according to the EMA definition against the standard treatment;

Or. en

Amendment 14
Motion for a resolution
Paragraph 12 h (new)

Motion for a resolution	*Amendment*
	12 h. Notes that decisions taken regarding the EU's pharmaceutical regulatory environment will have implications beyond Europe's borders, given that several third countries recognize and rely on EU requirements, particularly when it comes to the facilitation of exports and the waiving of requirements to test these in third countries when they come from the EU; therefore emphasizes the importance of maintaining such mutual recognition agreements with third countries where possible and ensuring that these remain up to date;

Or. en

Amendment 14
Motion for a resolution
Paragraph 12 i (new)

Motion for a resolution	*Amendment*
	12 i. Points out that the EU should focus on developing adequate capacity for the sustainable production of active substances, raw materials and medicines which reduce dependence on external sources; advocates providing greater legal certainty for drug developers;

Or. en

Compromise Amendment 15 (on supplementary protection certificates)

EPP, S&D, RE, Greens/EFA, ECR

Compromise amendment replacing Amendments: **63, 196, 282, 490, 492, 493, 494, 495, 496, 499, 501, JURI 16, JURI 20, JURI 21**

Amendment 15
Motion for a resolution
Paragraph 12 j (new)

Motion for a resolution	*Amendment*
	12 j. Calls on the Commission to evaluate the added value of the supplementary protection certificate (SPC) mechanism in order to prevent delays in access to generic medicines and improve financial sustainability of healthcare systems;

Amendment 15
Motion for a resolution
Paragraph 13

Motion for a resolution	*Amendment*
13. Calls on the Commission to revise the use of supplementary protection certificates based on technological and scientific advances to prevent generic and biosimilar medicines from becoming less competitive inside and outside the EU;	13. ***Draws attention to differences in the validity of patents and*** supplementary protection certificates (***SPCs) in the various Member States;*** Calls on the Commission to revise the use of supplementary protection certificates based on technological and scientific advances to ***allow*** generic and biosimilar medicines ***to become more*** competitive inside and outside the EU; ***Calls on the Commission to evaluate the impact that a proposal for a unitary SPC would have on the generic and biosimilar medicines market entry, and on equitable patient access to treatments and based on such evaluation propose where appropriate a unitary SPC;*** ***underlines that the use of SPCs should be allowed only for exceptional and justified cases;***

Or. en

Compromise Amendment 16 (on employment in the pharmaceutical sector)
EPP, S&D, RE, Greens/EFA, ID, ECR
Compromise amendment replacing Amendments: **502, 503, 504, 505, 506, 507 and ITRE 77**

Amendment 16
Motion for a resolution
Paragraph 14

Motion for a resolution	*Amendment*
14. Stresses the importance of creating quality jobs in the EU along the entire pharmaceutical value chain, with the support of the NextGenerationEU instrument; calls on the Commission to propose measures to promote employment in the pharmaceutical sector, facilitating talent retention and mobility at EU level;	14. ***Underlines that the pharmaceutical sector remains an important industrial pillar as well as a driving force in terms of job creation;*** Stresses the importance of creating quality jobs in the EU along the entire pharmaceutical value chain ***and the medical field, including the health workforce***, with the support of the Next Generation EU instrument; calls on the Commission to propose measures to promote employment ***and skill-building*** in the pharmaceutical ***and medical*** sector ***in all EU Member States***, facilitating ***geographical balance,*** talent retention and ***employment opportunities across the whole EU***;

Or. en

Compromise Amendment 17 (on innovative and new medicines)

EPP, S&D, RE, ECR

Compromise amendment replacing Amendments: **508, 509, 510, 511, 512, 513, 514, 515, 516, 517, 518, 519, 520, 521, 522, 523, 524, 525, 526, 527, 528 and 574**

Amendment 17
Motion for a resolution
Paragraph 15

Motion for a resolution	*Amendment*
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; 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;	15. Highlights the fact that gene and cell therapies, personalised medicine, ***radionuclide therapy***, ***and*** nanotechnology, next-generation vaccines***,*** ***including the m-RNA derivatives***, 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; 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 reduce costs for health systems, and strengthening their efficacy, sustainability and resilience;*** urges the Commission to ***promote sufficient expertise and to*** develop appropriate regulatory frameworks, to guide new business models***,*** ***consistently ensure high standards for safe products***, and to 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;***

Or. en

Amendment 17
Motion for a resolution
Paragraph 15 a (new)

Motion for a resolution	*Amendment*
	15 a. Recognises that Advanced therapy medicinal products (ATMPs) are fundamentally different from traditional pharmaceuticals as they address the root causes of disease and that their fundamental durability and potential curative nature can allow them to be the future of medicine; acknowledges that regulatory bodies such as the EMA are set to review and approve dozens of ATMPs over the coming years, underlining the need for the Commission to establish in addition to its ATMP Action Plan a robust regulatory landscape that facilitates access for all the eligible European patients, and to continue to build on Europe's position as a major player in ATMPs in order for Europe to remain globally competitive in ATMP development;

Or. en

Amendment 17
Motion for a resolution
Paragraph 15 b (new)

Motion for a resolution	*Amendment*
	15 b. Calls on the Commission to ensure that the existing coordinating bodies will facilitate cross-border treatments based on ATMP and to ensure that patients across Europe enjoy equitable access to innovative therapies;

Amendment 17
Motion for a resolution
Paragraph 15 c (new)

Motion for a resolution	*Amendment*
	15 c. Urges the Commission to work with the EMA to create a one-stop-shop for ATMP developers to seek guidance and communication on their applications;

Amendment 17
Motion for a resolution
Paragraph 15 d (new)

Motion for a resolution	*Amendment*
	15 d. Urges the European Commission and EMA to consider the full life-cycle of all innovative medicines and therapies including gene and cell therapies, personalised medicine, nanotechnology, next generation vaccines, and ensure a fit-for-purpose framework for off-patent competition at the time of loss of exclusivity; calls on the Commission to establish a regulatory framework for nanomedicines and nanosimilars, and calls for these products to be approved through a compulsory centralised procedure;

Or. en

Compromise Amendment 18 (on clinical trials)

EPP, S&D, RE, Greens/EFA, ID, ECR, The Left

Compromise amendment replacing Amendments: **170, 529, 531, 532, 533, 534, 535, 536, 537, 540, 541, 542, 544, 530, 538, 376, ITRE 36 and ITRE 60**

Amendment 18
Motion for a resolution
Paragraph 16

Motion for a resolution	*Amendment*
16. Calls on the Commission to fully implement the Clinical Trials Regulation[9] ; welcomes the revision of pharmaceutical legislation to adapt it to cutting-edge products, scientific advances and technological transformation; supports a new framework for the design of innovative trials and the pilot project to adopt a framework for the reuse of off-patent medicines; welcomes the launch of a vaccine platform to monitor vaccine efficacy and safety, supported by an EU-wide clinical trials network;	16. Calls on the Commission to fully implement the Clinical Trials Regulation[9]***to facilitate the launch of large clinical trials carried out in a harmonized and coordinated manner at European level; stresses that patient associations should be more involved in defining research strategies for public and private clinical trials, in order to ensure that they meet the unmet needs of European patients***; welcomes the revision of pharmaceutical legislation ***to reduce the red tape and*** to adapt it to cutting-edge products, scientific advances and technological transformation; supports ***clinical trials that are more patient-centred as well as*** a new framework for the design of innovative trials and the pilot project to adopt a framework for the reuse of off-patent medicines; welcomes the launch of a vaccine platform to monitor vaccine efficacy and safety, supported by an EU-wide clinical trials network; ***Urges the Commission to ensure more transparency in clinical trial results, with pharmaceutical companies sharing participant-level data, both positive and negative results, protocols and other trial documents, in a timely manner;***

Or. en

Amendment 18
Motion for a resolution
Paragraph 16 a (new)

Motion for a resolution	*Amendment*
	16a. Calls on the Commission to ensure continuous dialogue between the ECDC, EMA and vaccines developers on the establishment and functioning of the vaccine platform to monitor vaccine efficacy and safety;

Amendment 18
Motion for a resolution
Paragraph 16 b (new)

Motion for a resolution	*Amendment*
	16b. Calls for full implementation of the rules governing clinical trials in order to consolidate a clear and proportionate set of rules to ensure legal certainty for operators ; calls on the Commission to improve the participation of public researchers in clinical trials and to allow clinical trials in several Member States simultaneously for long-term research;

Compromise Amendment 19 (on the current framework for authorisation)

EPP, S&D, RE, ID, ECR

Compromise amendment replacing Amendments: **449, 464, 545, 546, 547, 548, 549, 550, 551, 552, 553, 554, 555, 556, 557, 558, 559, 561, 604, 631, 668, 677, 716 and ITRE 21**

Amendment 19
Motion for a resolution
Paragraph 17

Motion for a resolution	*Amendment*
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;	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 ***and evaluate if further regulatory flexibilities could contribute to a more efficient authorisation system*** , ***while safeguarding high level of safety, quality and effectiveness;***
	welcomes the fact that the strategy recognises that the better use of electronic product information (ePI) will support the better delivery of information to patients and support a wider availability of medicines, especially in critical situations;
	further calls on the Commission to work with the EMA ***and the EU regulatory network*** , ***including the industry and all relevant stakeholders*** to develop ***and implement*** the use of electronic product information ***leaflet (ePI)*** for all medicines in the EU ***in all the languages of the Member States where the medicines are marketed***;

Or. en

Compromise Amendment 20 (on conditional marketing authorisation)

EPP, S&D, RE, Greens/EFA, ID, ECR

Compromise amendment replacing Amendments: **142, 234, 238, 458, 459, 473, 565, 566, 567 and 571**

Amendment 20
Motion for a resolution
Paragraph 18

Motion for a resolution	*Amendment*
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; 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; asks for the time before the final evaluation to be reduced from five to three years;	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 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 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(AM 567);

Or. en

Amendment 20
Motion for a resolution
Paragraph 18 a (new)

Motion for a resolution	*Amendment*
	18a. Encourages the Commission in cooperation with the EMA to consider how already established tools like accelerated authorisation, early dialogue, PRIME SCHEME and expanded guidance can be used to make medicine available to patients at a faster pace, especially medicine that has potential to

address an urgent public health threat or an unmet medical need; Calls on the Commission to further the application of EMA's PRIME scheme for life-saving medicines and include a PRIME designation in the legislative framework, without affecting the safety of patients; recalls that accelerated schemes should not be misused where sufficient evidence on regular marketing authorisation is lacking;

Amendment 20
Motion for a resolution
Paragraph 18 b (new)

Motion for a resolution	*Amendment*
	18b. Calls on the Commission, the EMA and the competent authorities to capitalise on all the pragmatic efforts made during the COVID-19 crisis, in particular as regards regulatory flexibility with a view to effectively tackling medicine shortages also in emergency situations;

Or. en

Compromise Amendment 21 (on SMEs)

EPP, S&D, RE, ID, ECR

Compromise amendment replacing Amendments: **345, 436, 461, 474, 560, 698, 712, JURI 19, JURI 31, ITRE 15 (part 2), ITRE 37 (withdrawn) and ITRE 38**

Amendment 21
Motion for a resolution
Paragraph 18 d (new)

Motion for a resolution	*Amendment*
	18d. Calls on the Commission to create an innovation ecosystem that facilitates the exchange of experience and access for SMEs and contributes to the EU becoming a hub for global medical innovation; notes that the Commission should seek new advisory strategies to facilitate access to innovation funds for smaller companies; points out that bureaucratic hurdles and complexity make it difficult for SMEs or public research centres to take full advantage of European innovation programmes; Underlines the need to promote access to funding lines to support the work of new start-ups and SMEs, while respecting criteria established condition;
	Supports the Commission's Intellectual Property action plan proposal to update a series of existing tools and make them fit for the digital age;
	calls for the IP system to be made more effective for SMEs through measures to simplify IP registration procedures, to improve access to strategic IP advice, to facilitate the use of IP as a lever to access funding for example through the the Intellectual Property Helpdesk for SMEs; highlights the need to allocate more resources at EU level to the fight against unfair and abusive practices in the market for medicines;

*(*under subheading: ***Increasing resilience: secure supply chains, sustainable medicines, crisis preparedness and response mechanisms)***

Compromise Amendment 22 (on addressing shortages)

EPP, S&D, RE, Greens/EFA, ID

Compromise amendment replacing Amendments: **402, 277, 314, 397, 10, 575, 577, 579, 581, 582, 583, 584, 585, 586, 587, 589, 590, 591, 592, 593, 594, 595, 596, 597, 598, 599, 600, 601, 602, 606, 607, 610, 576, 588, 578, 580, 626, 630, 647, 651, 720, JURI 8, ITRE 7, ITRE 11, ITRE 23, ITRE 27, ITRE 30 and ITRE 32**

Amendment 22
Motion for a resolution
Subheading 3

Motion for a resolution	*Amendment*
Increasing resilience: secure supply chains, sustainable medicines, crisis preparedness and response mechanisms	Increasing resilience: ***prevention of medicine shortages,*** secure supply chains, sustainable medicines, crisis preparedness and response mechanisms

Or. en

Amendment 22
Motion for a resolution
Paragraph 19

Motion for a resolution	*Amendment*
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, 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;	19. 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 ***medicines*** 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 ***such a system should be capable of determining the volume of existing medicine stock and demand provide data capable of detecting, predicting and***

preventing shortages of medicinal products; moreover, calls on the Commission 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***; calls on the Commission to develop a mechanism to safeguard transparency in production and supply chains in the event of emergencies ***and beyond***; ***stresses in this regard the importance of monitoring and fighting against counterfeit pharmaceuticals;***

Or. en

Amendment 22
Motion for a resolution
Paragraph 19 a (new)

Motion for a resolution	*Amendment*
	19 a. Further reiterates its call on the Commission and the Member States to ensure that MAHs and wholesale distributors comply with the requirements of Directive 2001/83/EC in order to secure appropriate and continued supplies of medicines as well as with the respect of notification obligations in the event of temporary or permanent supply interruption, and to further clarify these obligations to ensure that MAHs report medicine shortages within the established timeframes; stresses the need to apply dissuasive and proportionate sanctions in the event of non-compliance with these legal obligations in line with the existing legislative framework;

Insists that the Public Service Obligation (PSO) as established in Article 81 of Directive 2001/83 is not sufficient to ensure that the EU as a whole is sufficiently supplied; calls on the Commission to implement the recommendations of the EU Executive Steering Group on Shortages of Medicines Caused by Major Events in order to prevent and mitigate supply disruption during the pandemic and beyond;

Amendment 22
Motion for a resolution
Paragraph 19 b (new)

Motion for a resolution	*Amendment*
	19 b. Recalls that the root causes of medicines shortage should be addressed and tackled as a matter of urgency, taking into account the links between the supply chain and production challenges;
	calls on the Commission therefore to ensure that the revision of the general pharmaceutical legislation builds on a good understanding of the root causes of medicine shortages; highlights the need for the Union's pharmaceutical industry to have a diversified supply chain and a medicine shortage risk mitigation plan to cope with any vulnerabilities and risks to their supply chain; ; stresses, however, that systemic sustainable policies need to be put into place, before applying disproportionate regulatory requirements, obligation to supply, penalties or ill-conceived stockpiling fragmenting the single market or threatening products' economic sustainability, which may lead to further shortages;

Amendment 22
Motion for a resolution
Paragraph 19 c (new)

Motion for a resolution	*Amendment*
	19c. Considers it important that the Internal Market for medicines is safeguarded and that unjustified import and export restrictions, that can cause harm to the internal market and decrease affordability, should be avoided and addressed by the Commission if they occur; calls on the Commission to assess] and where necessary address the impacts of parallel trade with regards to shortage of medicines in the Member States and to tackle problems adequately by taking the necessary action to ensure that medicines reach all patients in the EU in a timely manner;
	Calls on the Commission to use all the means at its disposal to prevent counterfeit medicinal products from entering the market, since such products are often of low quality and dangerous to health, and have a major economic impact;
	notes that technical assistance to the Member States is necessary for the proper implementation of the European Medicines Verification System;

Amendment 22
Motion for a resolution
Paragraph 19 d (new)

Motion for a resolution	*Amendment*
	19d. Welcomes the fact that the Commission will continue to monitor mergers between pharmaceutical companies to avoid distortions of competition;

Or. EN

Amendment 22
Motion for a resolution
Paragraph 19 e (new)

Motion for a resolution	*Amendment*
	19e. Calls on the Commission to consider creating a European contingency reserve for critical medicinal products that are at high risk of shortage, along the lines of the 'RescEU' mechanism, in order to alleviate recurrent shortages;

Compromise Amendment 23 (on data and GDPR)

EPP, S&D, RE, Greens/EFA, ID, ECR, The left

Compromise amendment replacing Amendments: **412, 417, 418, 422, 429, 433, 439, 443, 446, 455, 465, 468, 471, 478, 483, 486, 487, 488, 530, 538, 539, JURI 17, JURI 18, JURI 23, ITRE 64, ITRE 66, ITRE 70 and ITRE 72**

Amendment 23
Motion for a resolution
Paragraph 19 f (new)

Motion for a resolution	*Amendment*
	19 f. Welcomes the initiative to build interoperable digital infrastructure for the European Health Data Space, which will integrate 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 a consistent application and enforcement of the General Data Protection Regulation (GDPR) in all EU Member States is the foundation for such initiatives;

Or. en

Amendment 23
Motion for a resolution
Paragraph 19 g(new)

Motion for a resolution	*Amendment*
	19g. Requests the Commission to work with Member States to ensure full and harmonised application of the GDPR in regards to conducting clinical research across the EU;

Or. en

Amendment 23
Motion for a resolution
Paragraph 19 h (new)

Motion for a resolution	*Amendment*
	19h. Highlights the need to promote the use of health data in full compliance with GDPR; ; further believes that it is of utmost importance to enable and promote trust and data innovation in digital health, which will be possible through education and capability building for regulators, industry and patients;
	highlights the need to promote both primary and secondary use of aggregated health data and the need in this regard for a clearer definition of secondary data use vs. primary data collection;

Or. en

Amendment 23
Motion for a resolution
Paragraph 19 i (new)

Motion for a resolution	*Amendment*
	19i. Stresses that, due to the sensitive nature of health data, the Commission and all relevant agencies should safeguard and guarantee that its processing operations respect the data protection principles of lawfulness, fairness, transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity and confidentiality; Member States and EU bodies should strictly respect the principles of data protection as set out in Article 4 of Regulation (EU) 2018/1725 of the European Parliament and of the Council, while also determining appropriate technical and organisational security measures in accordance with Article 33 of that Regulation;

Compromise Amendment 24 - (impact of medicines shortage on patients)
EPP, S&D, RE, Greens/EFA, ID, ECR, The left

Compromise amendment replacing Amendments: **576 and 588**

Amendment 24
Motion for a resolution
Paragraph 19 j (new)

Motion for a resolution	*Amendment*
	19j. Recalls that medicines shortages have a direct impact on patients' health, safety and the continuation of their treatment, particularly for vulnerable populations such as children, the elderly, pregnant women, people affected by a disability, patients with chronic diseases or cancer or people in intensive care unit (ICU);

Or. en

Compromise Amendment 25 - (structured dialogue with stakeholders)

EPP, S&D, RE, Greens/EFA, ID, ECR

Compromise amendment replacing Amendments: **90, 398, 403, 404, 578, 580, 611, 612, 613, 614, 615, 616, 617, 618, 619, 620, 621, 622, 623, 625, 627, 628, 638, 669, 671, 681, 716, JURI 25, JURI 30, ITRE 5, ITRE 6, ITRE 14, ITRE 35**

Amendment 25
Motion for a resolution
Paragraph - 20

Motion for a resolution	*Amendment*
	-20. Recognises the multiple drivers of shortages and therefore the importance of ensuring the involvement of manufacturers and other supply chain stakeholders to prevent and manage medicines' shortages;

Or. en

Amendment 25
Motion for a resolution
Paragraph 20

Motion for a resolution	*Amendment*
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;	20. 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 shortages of medicines 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***; ***calls on the Commission to ensure a balanced representation of stakeholders;***

Or. en

Amendment 25
Motion for a resolution
Paragraph 20 a (new)

Motion for a resolution	*Amendment*
	20 a. On the basis of this structured dialogue, urges the Commission, the Member States and stakeholders to draw up, as soon as possible, a clear and ambitious policy roadmap to secure and modernise Europe's existing manufacturing capacity for medicines, technology and active pharmaceutical ingredients;

Or. en

Amendment 25
Motion for a resolution
Paragraph 20 b(new)

Motion for a resolution	*Amendment*
	20 b. Believes that in addition to the structured dialogue on manufacturing and supply chain, a wider political High Level Pharmaceutical Forum is also needed, bringing together policymakers, regulators, payers, patient organizations, industry representatives and other relevant stakeholders in the healthcare supply chain, in order to share the lessons learnt from the COVID- 19 emergency situation and to establish an effective policy framework to prevent shortages in the long-term and enable access to medicines for patients, reduce delays as well as ensure competiveness and innovation;

Or. en

Compromise Amendment 26 (on relations between health organisations)

EPP, S&D, RE, Greens/EFA, ID, ECR, The left

Compromise amendment replacing Amendments **642, 643, 644, 640 and 641**

Amendment 26
Motion for a resolution
Paragraph 21

Motion for a resolution	*Amendment*
21. Calls on the Commission to facilitate agreements between the EMA and non-EU regulatory agencies on preventing emergencies and coordinating responses to them; 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;	21. Calls on the Commission to facilitate agreements between the EMA and non-EU regulatory agencies on preventing emergencies and coordinating responses to them ***in full respect of the highest EU standards for 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;

Or. en

Compromise Amendment 27 - (Sustainable and environmentally friendly Medicines)

EPP, S&D, RE, Greens/EFA, The left

Compromise amendment replacing Amendments: **215, 431, 653, 654, 655, 656, 657, 658, 659, 660, 661, 662, 663, 664, 665, 666, 667, 670, 672, 673, 674, 675, 676, 678, 679, 680, 682, 684, 685, 687, 688, 689, 690, 692, 697, ITRE 68, ITRE 81 and ITRE 84**

Amendment 27
Motion for a resolution
Paragraph 22

Motion for a resolution	*Amendment*
22. Stresses the need for the pharmaceutical industry to be environmentally friendly and climate-neutral throughout the life cycles of medicinal products; calls on the Commission to strengthen inspection and auditing throughout the production chain; urges the Commission to ensure quality environmental sustainability standards for active pharmaceutical ingredients imported from non-EU countries; calls on the Commission to address the problem of domestic pharmaceutical waste, with measures to reduce packaging and the size of containers to ensure they are no larger than necessary, and to bring medical prescriptions into line with real therapeutic needs;	22. Stresses the need for the pharmaceutical industry to be environmentally friendly and climate-neutral throughout the life cycles of medicinal products ***while ensuring access to safe and effective pharmaceutical treatments for patients***; calls on the Commission to strengthen inspection and auditing throughout the production chain ***particularly outside the EU***; urges the Commission to ensure quality environmental sustainability standards for active pharmaceutical ingredients imported from non-EU countries; calls on the Commission to address the problem of pharmaceutical household-waste, with measures to reduce packaging and the size of containers to ensure they are no larger than necessary, ***while ensuring convenient and safe handling for patients or consumers with limited mobility,*** and to bring medical prescriptions into line with real therapeutic needs; ***encourages the Commission to consider the potential of e-leaflets, as a complementary measure to the current paper information tools, to reduce use of paper in packaging while also maintaining equal access to important information; acknowledges steps taken already by the pharmaceutical industry like, for example, the Eco-Pharmaco-Stewardship initiative;***

Or. en

Amendment 27
Motion for a resolution
Paragraph 22 a (new)

Motion for a resolution	*Amendment*
	22a. Considers that the European Green Deal constitutes a major opportunity to encourage pharmaceutical manufacturers to participate to the green recovery plan by producing in compliance with environmental and ecological standards;
	stresses that for pharmaceutical waste should be handled in line with the objectives and targets of the circular economy; believes that the pharmaceutical industry should have the same requirements and standards on packaging and waste management as other sectors; calls on the Commission to create a uniform framework for packaging that takes into account user-friendliness and the circumstances for industry;

Amendment 27
Motion for a resolution
Paragraph 22b (new)

Motion for a resolution	*Amendment*
	22b. Calls on the Commission to develop clear guidance on the role of procurement policy in promoting greener pharmaceuticals;

Or. en

Amendment 27
Motion for a resolution
Paragraph 22 c (new)

Motion for a resolution	*Amendment*
	22 c. Calls on the Commission to respond to the demands of the European

Parliament in its resolution of 17 September 2020 on a strategic approach to pharmaceuticals in the environment, in particular to revise the pharmaceutical legislation to strengthen the environmental risk assessment requirements and conditions of approval and use for medicines provided that marketing authorisations are not delayed nor refused solely on the grounds of adverse environmental impacts; further calls on the Commission to speed up the catch-up procedure for environmental risk assessments of human medicines authorized before 2006 where they are not available;

Or. en

Amendment 27
Motion for a resolution
Paragraph 22 d (new)

Motion for a resolution	*Amendment*
	22 d. Recalls that information such as the impact of pharmaceuticals on water, environmental behaviour and degradability, plays a key role in risk management and that this type of information should be transparent and made available to all relevant stakeholders; welcomes the Commission's efforts to address the problem of pharmaceuticals in the environment; stresses the need to continue and to step up these efforts, in particular as regards investments in technologies providing more effective solutions for the removal of pharmaceuticals from waste water, the assessment of the environmental impact of veterinary medicines, the development of continuous monitoring and data sharing on potential significant sources of this type of pollution;

Amendment 27
Motion for a resolution
Paragraph 22 e (new)

Motion for a resolution	*Amendment*
	22e. Insists that the pharmaceutical strategy for Europe should consider the objectives of the Zero Pollution Action Plan for water, air and soil;

Amendment 27
Motion for a resolution
Paragraph 22 f (new)

Motion for a resolution	*Amendment*
	22f. Calls on the Member States and the Commission to support research, development and innovation in the field of pharmaceuticals that are equally effective for patients and intrinsically less harmful for the environment;
	stresses the importance of investment into finding new alternative non-animal methodologies for drugs development, without lowering the level of protection for human health and without prejudice for innovation in the field of pharmaceuticals;

(under subheading: ***The EU is leading the world in healthcare)***

Compromise Amendment 28 (on trade and medicines)

EPP, S&D, RE, ID, ECR

Compromise amendment replacing Amendments: **700, 701, 702, 703, 704, 705, 706, 707, 708 and JURI 35**

Amendment 28
Motion for a resolution
Paragraph 23

Motion for a resolution	*Amendment*
23. Calls on the Commission to further facilitate access to global markets for the EU pharmaceutical industry, including small and medium-sized enterprises, through a level playing field and a regulatory framework facilitating trade agreements that prize innovation-based competitiveness, in order to make the pharmaceutical sector a strategic pillar of the EU;	23. Calls on the Commission to further facilitate access to global markets for the EU pharmaceutical industry, including small and medium-sized enterprises, through a level playing field and a ***robust and clear*** regulatory framework ***promoting the highest standards on quality and safety at international level,*** facilitating trade agreements that prize innovation-based 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;***

Or. en

Compromise Amendment 29- (Patent and TRIPs agreements)

EPP, S&D, RE, ID, ECR

Compromise amendment replacing Amendments: **64, 65, 426, 437, 445, 448, 497, 640, 641, 650, 709, 710, 711, 722, JURI 9, JURI 10, JURI 12, JURI 27, JURI 29, ITRE 54, ITRE 55, ITRE 56, ITRE 58**

Amendment 29
Motion for a resolution
Paragraph 23 a (new)

Motion for a resolution	*Amendment*
	23 a. 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 as well as 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; calls on the Commission to propose a revision of that regulation to provide for the possibility to temporarily authorise the granting of compulsory licenses in the event of a health crisis in order to allow the production of generic versions of life-saving medicines; recalls that this is one of the public health flexibilities in the field of patent protection already included in the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), as further reaffirmed by the 2001 Doha Declaration; calls on the Commission to ensure that the implementation of the EU free trade agreements (FTAs) does not interfere with the possibilities of invoking flexibilities provided by the TRIPS Agreement and to provide guidance to

Member States in order to encourage voluntary licencing over immediate compulsory licencing; stresses that FTAs should not focus exclusively on enforcing Intellectual Property standards in third countries, but take into account the impact on generic and biosimilar medicines in the EU and in third countries, as well as include coordination on regulatory standards;

Or. en

Compromise Amendment 30 - (WHO and global access)

EPP, S&D, RE, Greens/EFA, ID, The left

Compromise amendment replacing Amendments: **715, 717, 718 and 719**

Amendment 30
Motion for a resolution
Paragraph 24

Motion for a resolution	*Amendment*
24. Reiterates its commitment to continue working with the Commission and the World Health Organization to standardise effective, ***safe*** and sustainable regulatory frameworks for medicinal products;	24. Reiterates its commitment to continue working with the Commission and the World Health Organization to standardise ***safe,*** effective and sustainable regulatory frameworks for medicinal products ***and improve access to and affordability of medicines globally***;

Or. en

Compromise Amendment 31 - (on HTA)

EPP, S&D, RE, Greens/EFA, ID, ECR

Compromise amendment replacing Amendments: **151, 363, 376, 405, 629 and ITRE 31**

Amendment 31
Motion for a resolution
Paragraph 24 a (new)

Motion for a resolution	*Amendment*
	24a Welcomes the agreement reached by Parliament and Council on Regulation on Health Technology Assessment (HTA) and calls for a swift adoption and thorough implementation so as to foster greater converge between Member States on the evaluation of health technologies and to faciliate rapid access to innovative treatments for patients;

Amendment 31
Motion for a resolution
Paragraph 24 b (new)

Motion for a resolution	*Amendment*
	24b Points out that new health technologies should demonstrate their clinical added-value and cost-effectiveness compared to what is already available on the market; emphasizes that health technology assessment is a tool to support this analysis and that currently such assessment is 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 according to the agreed timeframe;

Or. en

Compromise Amendment 32 (on the scope of the strategy, role of pharma industry, generics and biosimilars, pharma and environment)

EPP, S&D, RE, Greens/EFA, ID

Compromise amendment replacing Amendments: **30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, ITRE 74, 55, 68, 78, 81, 84, 88, 89, 91, 92, 93, 94, 98, 99, 101, 103, 104, 107, 109, 110, 111, 112, 114, 117, 119, 121, 122 and ITRE B**

Amendment 32
Motion for a resolution
Recital A

Motion for a resolution	*Amendment*
A. whereas ***health is*** fundamental ***to the well-being of Europeans and*** equitable access to ***healthcare is a pillar of the EU; whereas*** safe, affordable medicines ***are needed to combat all diseases***; whereas patients should be at the centre of all health policies***, alongside investment and research***;	A. whereas health is fundamental to the well-being of Europeans and equitable access to healthcare is a ***cornerstone*** of the EU ***and Member States' national health policies***; whereas ***the Charter of*** Fundamental ***Rights of the European Union recognises the fundamental right of citizens to health, quality of life and medical treatment; whereas public health systems are crucial to guaranteeing*** equitable access to ***health care and*** safe, ***effective and*** affordable medicines;***whereas ensuring patient access to medicines is one of the core objectives of the EU and the WHO, and of Sustainable Development Goal 3;***

Or. en

Amendment 32
Motion for a resolution
Recital A a (new)

Motion for a resolution	*Amendment*
	A a. whereas one of the 20 principles of the European Pillar of Social Rights, reinforced by the Porto declaration, establishes that everyone has the right to timely access to affordable, preventive and curative health care of good quality;

Or. en

Amendment 32
Motion for a resolution
Recital A b (new)

Motion for a resolution	*Amendment*
	Ab. whereas patients should be at the centre of all health policies and involved throughout the medicines regulatory pathway; whereas access inequalities exist between and within Member States and special regard should be paid to people in vulnerable situation with specific health risks, including women with a particular regard to pregnant women, children, the elderly, , persons with disabilities, patients with chronic conditions and comorbidities, patients in intensive care units (ICU) and persons on long-term medication;

Or. en

Amendment 32
Motion for a resolution
Recital A c (new)

Motion for a resolution	*Amendment*
	A c. whereas the increasing burden of chronic diseases and health needs of aging populations combined with high and rising prices of medicinal products and an increase in the societal cost of providing care cause budgetary and affordability constraints and serious threats to the sustainability of European health systems; whereas the adoption of integrated models of care for chronic and other long term conditions, underpinned by a person-centred and multi-disciplinary approach to health care is essential to deliver high quality health services;

Or. en

Amendment 32
Motion for a resolution
Recital A d (new)

Motion for a resolution	*Amendment*
	A d. whereas a competitive, trusted, innovative and resilient European research-based pharmaceutical industry is more responsive to patients' needs and to strategic interest for public health, economic growth, jobs, trade, and scientific and technological progress;

Or. en

Amendment 32
Motion for a resolution
Recital A e (new)

Motion for a resolution	*Amendment*
	A e. whereas medicine producers in the EU made a significant contribution to research investment in 2019, with over €37 billion; whereas the sector provides 800 000 direct jobs and a €109.4 billion trade surplus; whereas the sector generates about three times more employment indirectly – upstream and downstream – than it does directly; regrets that there are no aggregated data on the overall amount of public financing for the pharmaceutical sector in the EU;

Or. en

Amendment 32
Motion for a resolution
Recital A f (new)

Motion for a resolution	*Amendment*
	A f. whereas there are differences in health care systems, national regulation, implementation of EU-regulation, pricing

and authorisation processes in the different Member States; whereas these differences are a result of Member States' competences on health; whereas the differences can lead to fragmentation and unpredictable circumstances for actors in the pharmaceutical sector that operate outside their own country; whereas it is important to recognise that cooperation is required between the Commission and Member States so as to set out ambitious implementation agendas with clear timelines and the necessary long-term financing to implement concrete actions that follow from the Pharmaceutical Strategy for Europe;

Or. en

Amendment 32
Motion for a resolution
Recital A g (new)

Motion for a resolution	*Amendment*
	A g. whereas the overall consumption of pharmaceuticals continues to grow both globally and in the EU; whereas a number of pharmaceuticals continues to be prescribed, dispensed, sold or used inappropriately; whereas such misuse of pharmaceuticals means a waste of precious resources and can lead to health and environmental hazards;

Or. en

Amendment 32
Motion for a resolution
Recital A h (new)

Motion for a resolution	*Amendment*
	A h. whereas the strategy recognises the key role that generic and biosimilar medicines play in hugely increasing

equitable access for patients and for the sustainability of healthcare systems and that their entry into the market after exclusivity expiry should not be delayed;

Or. en

Amendment 32
Motion for a resolution
Recital A i (new)

Motion for a resolution	*Amendment*
	A i. whereas biosimilar medicines create opportunities beyond access to medicines, such as benefit sharing across healthcare and thus providing better health and services to patients;

Or. en

Amendment 32
Motion for a resolution
Recital A j (new)

Motion for a resolution	*Amendment*
	A j. Whereas many innovations of the pharmaceutical industry are not really offering breakthrough improvements for the patients but are either so-called 'me-too' pharmaceuticals, which are just another substance for the same indication without major benefits or offer only minor improvements with significantly higher costs; whereas it would be beneficial for patients if the framework for the pharmaceutical industry in Europe would better incentivize real breakthrough innovations;

Or. en

Amendment 32
Motion for a resolution
Recital A k (new)

Motion for a resolution	*Amendment*
	A k. whereas there is convincing evidence that pharmaceuticals leach into the environment, in particular into soil and water; whereas their presence can have adverse effects on wild animals such as fish, birds and insects and, as a result, broader impacts on the stability of individual ecosystems; whereas these medicines also appear in drinking water at lower concentrations; whereas the European Green Deal must encourage the development of a vibrant, dynamic, sustainable and clean pharmaceutical industry within the EU;

Or. en

Amendment 32
Motion for a resolution
Recital A l (new)

Motion for a resolution	*Amendment*
	A l. whereas action is required throughout the lifecycle of medicines to reduce resource use, emissions and levels of pharmaceutical waste and residues in the environment;

Or. en

Compromise Amendment 33 (on pharmaceuticals and the impact of the pandemic)

EPP, S&D, RE, Greens/EFA, ID, ECR

Compromise amendment replacing Amendments: **JURI 3, JURI 15, ITRE 9 Part 2, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 56, 59, 83, 87, 100, 102, 105, 120 and ITRE A**

Amendment 33
Motion for a resolution
Recital B

Motion for a resolution	*Amendment*
B. whereas COVID-19 has had an impact on people's health and on the economy; whereas it has highlighted both the EU's strengths and weaknesses; whereas in order to strengthen the resilience of our national health systems to cross-border threats, more European integration is necessary; whereas a European Health Union***, which contributes to an increasingly social Union, is key in this process***;	B. whereas COVID-19 has had an impact on people's ***physical and mental*** health and on the economy; whereas it has highlighted both the EU's strengths and weaknesses; whereas in order to strengthen the resilience of our national health systems to cross-border threats, more European integration is necessary ***as well as a greater sharing of epidemiological and health data at European level***; whereas a European Health Union ***should contribute to and foster closer cooperation, coordination and knowledge sharing on health between Member States and relevant stakeholders and increase the EU's capacity to combat cross-border health threats***;

Or. en

Amendment 33
Motion for a resolution
Recital B a (new)

Motion for a resolution	*Amendment*
	B a. whereas the disruption of the global supply chain ensuing from the COVID-19 pandemic has highlighted the EU's dependency on third countries in the health sector; whereas the understanding of root causes of medicine shortages is crucial for constructing an appropriate European response and tackling this long-standing challenge; whereas the

EU's open strategic autonomy and security of supply should be ensured by diversification of supply chains for essential medicines and medicinal products, including European manufacturing sites, as well as by applying public procurement rules that should not consider price as the sole criterion;

Or. en

Amendment 33
Motion for a resolution
Recital B b (new)

Motion for a resolution	*Amendment*
	B b. whereas during the COVID-19 pandemic, uncoordinated actions at national level, such as hoarding and extreme stockpiling, undermined the delivery of equitable supply in all markets; whereas this represents a lesson learnt to avoid in any future crisis situation;

Or. en

Amendment 33
Motion for a resolution
Recital B c (new)

Motion for a resolution	*Amendment*
	B c. Whereas the COVID-19 experience also demonstrated how the European pharmaceutical industry and manufacturers have been resilient and had contingency plans in place limiting disruption for critical products,; whereas this was also possible thanks to the bilateral dialogue and two-way communication established, demand visibility and close cooperation between

governments/regulators and actors, a practice which should be maintained and continued on a regular basis;

Or. en

Amendment 33
Motion for a resolution
Recital B d (new)

Motion for a resolution	*Amendment*
	B d. Whereas for the Pharmaceutical Strategy to be fully effective it is necessary that it incorporates lessons learnt from the COVID-19 crisis and takes into consideration the resilience demonstrated by the off-patent medicines industry during the COVID-19 outbreak, so as to build on in the existing European manufacturing capacity;

Or. en

Amendment 33
Motion for a resolution
Recital B e (new)

Motion for a resolution	*Amendment*
	B e. whereas the pandemic has brought to the fore a number of pre-existing problems in the global production and supply of pharmaceuticals, such as the limited capacity of least developed and middle income countries to produce vaccines, the lack of essential medicines and an unevenly functioning supply chain; whereas the EU vaccine strategy is proving successful in delivering vaccines to all citizens in the EU; whereas the EU has been at the forefront of global vaccines deliveries by continuing to export vaccines and by setting up and financing COVAX; stresses that more needs to be done to fully vaccinate low and middle

income countries;

Or. en

Amendment 33
Motion for a resolution
Recital B f (new)

Motion for a resolution	*Amendment*
	B f. whereas innovative R&D projects, such as 'VACCELERATE' have proven their worth during the pandemic and should be made sustainable in the long-term;

Or. en

Compromise Amendment 34 (on the pharmaceutical strategy links with other policies)

EPP, S&D, RE, Greens/EFA, ID, ECR

Compromise amendment replacing Amendments: **ITRE 8, 69, 70, 71, 72, 73, 74, 75, 76, 77, 79, 82, 85, 97 and 116**

Amendment 34
Motion for a resolution
Recital C

Motion for a resolution	*Amendment*
C. whereas the pharmaceutical strategy covers the full cycle of medicines, including research, testing, authorisation, consumption and disposal, and contributes to meeting the objectives of the European Green Deal, the digital transformation and climate neutrality;	C. whereas***, in the spirit of the 'One Health' approach,*** the pharmaceutical strategy covers the full ***life*** cycle of medicines ***and medical devices***, including ***collection and production of starting material,*** research, testing, ***manufacturing,*** authorisation, ***pre-and post-marketing pharmacovigilance*** consumption and disposal, and contributes to meeting the objectives of the European Green Deal, the ***Europe's Beating Cancer Plan,*** the digital transformation, ***the circular economy and the Industrial Strategy*** and climate neutrality;

Or. en

Amendment 34
Motion for a resolution
Recital C a (new)

Motion for a resolution	*Amendment*
	C a. whereas, to secure the Union's lead position in the pharmaceutical development, the strategy must focus on strengthening the innovative potential of European pharmaceutical research as well as focusing on patients' needs, acknowledging and reinforcing the link with the EU industrial strategy, the SME strategy and the European Health Data Space;

Compromise Amendment 35
EPP, S&D, RE, Greens/EFA, ECR
Compromise amendment replacing Amendments: **JURI 5, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 25, 26, 27, 28 and 29**

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regard to Article 6 TEU and Article 35 of the Charter of Fundamental Rights of the European Union on the right to preventive healthcare for all European citizens;

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regard to Articles 101 and 102 TFEU laying down rules on competition,

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products,

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency,

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— 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,

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regard to Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used in scientific procedures,

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regard to Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regard to the proposal for a Regulation of the European Parliament and of the Council on health technology assessment and the work of EUNetHTA Joint Actions,

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— Having regard to the Commission communication of 16 September 2021 Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regard to the Joint evaluation of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December2006 on medicinal products for paediatric use and Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products,

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regard to the Commission communication of 11 December 2019 on 'The European Green Deal'

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regard to the Commission communication of 10 March 2020 entitled 'A New Industrial Strategy for Europe' COM (2020) 102 final

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regard to the Commission's Strategic Agenda for Medical Ionising Applications(SAMIRA) Action Plan of 5 February 2021 in support of the European Beating Cancer Plan;

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regard to the Commission communication of 5 May 2021 on Updating the 2020 New Industrial Strategy: Building a stronger Single Market for Europe's recovery (COM(2021)350),

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regard to the Commission communication of 15 June 2021 on "Drawing the early lessons from the COVID-19 Pandemic" (COM (2021)380),

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regard to the Council's conclusions on innovation for the benefit of patients of 1 December 2014

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regard to the Council conclusions of 17 June 2016 on strengthening the balance in the pharmaceutical systems in the EU and its Member States,

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regard to its resolution of 14 February 2017 on EU options for improving access to medicines;

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regards to its resolution of 13 September 2018 on a European One Health Action Plan against Antimicrobial Resistance

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regard to its resolution of 15 January 2020 on the European Green Deal

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regard to its resolution of 10 July 2020 on the EU's public health strategy post-COVID-19(2020/2691(RSP)), calling for an EU action plan on rare and neglected diseases,

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regard to its resolution of

	17 September 2020 on a strategic approach to pharmaceuticals in the environment,

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regard to the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights and Public Health (WTO/MIN(01/DEC/2) and to the implementation of Paragraph 6 of the Doha Declaration of 1 September 2003(WTO/L/540),

Or. en

Amendment 35
Motion for a resolution
Citations

Motion for a resolution	*Amendment*
	— having regard to the 72nd World Health Assembly Resolution of May 2019 on Improving the transparency of markets for medicines, vaccines, and other health products,

Or. en