MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION on the shortage of medicines - how to deal with an emerging problem (2020/0000(INI))

AMENDMENTS

Please see the amendments suggested by the Association of European Cancer Leagues (ECL), developed in collaboration with France Assos Santé and the European Association of Hospital Pharmacists (EAHP), and other members of the European Public Health Alliance (EPHA).

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Proposed Text	Amendment
Amendment 1 **Recital A**	
whereas **the increase in global demand has** aggravated shortages of medicines in the EU, undermining health services in the Member States and **exposing** patients to considerable risks; whereas the Member States have a duty to find swift and effective solutions through closer European integration;	whereas shortages of medicines **have worsened exponentially in recent years** in the EU, undermining health services in the Member States **entailing considerable risks for the health and safety of** patients, **including disease progression and/or worsening of symptoms, increased exposure to falsified medicines, medication errors or adverse events occurring when the missing medicine is substituted by another one, avoidable transmission of infectious diseases, significant psychological distress;** whereas the Member States have a duty to find swift and effective solutions through closer European integration;
Justification: *The incidences of medicines shortages reported in most EU countries have increased exponentially. For example, in France, there were 1,499 medicine shortages in 2019, compared to 868 in 2018 (compared to 44 in 2008). In the Netherlands, the number of drug shortages almost doubled in 2019: 1,492 in 2019, compared to 769 in 2018. In the Czech Republic, 2,208 products were affected by supply interruptions in 2019, compared to 1,630 in 2018 and 19 in 2008.* *The impact of medicine shortages on patients includes:*	

• *Disease progression and/or worsening of symptoms as a result of the delay of treatment: Treatment outcomes are negatively affected due to delay in treatment, interruption of medicine scheduling, and potential reduction of dose;* • *Avoidable transmission of infectious diseases: Vaccines are frequently reported as being in shortage, with Hepatitis B, Pneumococcal, Tuberculosis, Tetanus, HPV and Hepatitis A among those evidenced; HIV and Syphilis treatments have also been missing over the past 10 years;* • *Increased exposure to falsified medicines: Medicine shortages can result in patients procuring treatment from unreliable sources (online, abroad, etc.) out of desperation;* • *Significant emotional distress for patients and their families: Delays in treatment of life-threatening diseases (including cancer) can be particularly traumatic.* *Medicine shortages can also impair the health of patients who are switched to an alternative therapy, causing:* • *Increased risk of medication or administrative errors;* • *Increased risk of adverse events, greater toxicity or development of drug resistance in some patients;* • *Suboptimal treatment or therapeutic failures.* *See: https://www.europeancancerleagues.org/wp-content/uploads/EPHA-Medicine-Shortages-Position-2020.pdf and https://www.eahp.eu/sites/default/files/eahp_2019_medicines_shortages_report.pdf*

Amendment 2 **Recital D**	
whereas the consequence of growing demand coupled with price suppression is the concentration of supply, a reduction in the number of chemicals manufacturers and a lack of alternative solutions should problems arise;	whereas the consequence of growing demand coupled with price suppression is the concentration of **active pharmaceutical ingredients** supply, a reduction in the number of chemicals manufacturers and a lack of alternative solutions should problems arise;
Justification: *It should be specified that growing demand and price suppression are not responsible for the general concentration of supply but for the concentration of active pharmaceutical supply in Asia.*	

Amendment 3 **Recital E**	
whereas stocks of **'strategic'** medicines are inadequate, with chemicals that are cheap and easy to produce and **mature** medicines being in particularly short supply; whereas pharmaceutical firms operate on a just-in-time basis;	whereas stocks of medicines are inadequate, with chemicals that are cheap and easy to produce and **older, yet essential,** medicines being in particularly short supply; whereas pharmaceutical firms operate on a just-in-time basis;

Justification: *The expression 'older, yet essential' illustrates better what is meant by 'mature' medicines.* *The shortage of stocks concerns all medicines. In the absence of a definition of what can be considered 'strategic', it is necessary to secure the stock of wider range of medicines.*	
Amendment 4 **Point 1, 2, 3 – switch order**	
1. Stresses the geostrategic imperative that the Union regain its sovereignty and independence with regard to health care and secure its supply of medicines and medical equipment; 2. Points out that, while public health policies are a Member State matter, it is incumbent upon the EU to coordinate and complement national measures to guarantee affordable and high-quality health services for European citizens; 3. Stresses **the need for health policies to focus on patients' interests** and for closer cooperation between Member States;	1. Stresses **importance of putting the interest and safety of patients at the centre of European health policy** and for closer cooperation between Member States; 2. Points out that, while public health policies are a Member State matter, it is incumbent upon the EU to coordinate and complement national measures to guarantee **the protection of public health and access to** affordable and high-quality health services for European citizens; 3. Stresses the geostrategic imperative that the Union regain its sovereignty and independence with regard to health care and secure its supply of medicines and medical equipment;
Justification: *Strengthening the EU's role is important. However, the patient's interests should be put in the centre of this endeavour. The interests and the safety of patients, who are very much affected by medicine shortages, must be the number one priority of any EU shortage strategy. The need for the Union to regain its health sovereignty and independence and to secure the supply of medicines and medical equipment follows from this priority.* *Article 168 TFEU about protection of public health: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E168&from=EN*	
Amendment 5 **Point 4**	

Calls on the Commission and the Member States to take **whatever action is needed** to **restore European health sovereignty and local pharmaceutical manufacturing**, giving priority to essential **and strategic** medicines; calls on the Commission to map out potential production sites in the EU;	Calls on the Commission and the Member States to take **necessary actions** to **ensure security of supply of medicinal products**, giving priority to essential medicines **and 'medicines of major therapeutic interest'**; calls on the Commission to map out potential production sites in the EU;
Justification: *Security of supply is by definition the objective of a strategy to combat medicine shortages, where local production could be one possible aspect. Local production should not be regarded as the end goal: the end goal is the security of supply of medicines.* *Action taken should be proportionate and priority should also be given to medicines of major therapeutic interest and to the WHO essential medicines list.*	
Amendment 5 **Point 4(a)**	
	Calls on the Commission and the Member States to adopt the following common definition of 'medicines of major therapeutic interest' (MMTI): medicines or classes of medicines for which an interruption of treatment is likely to jeopardise the vital prognosis of patients in the short or medium term, or represents a significant change in patient outcomes with regard to the severity or potential evolution of the disease;
Justification: *In France, 'medicines of major therapeutic interest' (MMTI) were defined in Law No 2016-41 of 26 January 2016 as 'medicines or classes of medicines for which an interruption of treatment is likely to jeopardise the vital prognosis of patients in the short or medium term, or represents a significant loss of opportunity for patients with regard to the severity or potential evolution of the disease'. This definition was formulated by an extended working group consisting of representatives of patients, manufacturers, hospital and dispensing pharmacists, learned societies, administrations and relevant agencies. Its adoption at EU level would permit the development of a European strategy to combat medicine shortages focused on patients' interests and the real risks they face in the event of a disruption in supply.*	
Amendment 6 **Point 6**	
Urges the Commission and the Member States to introduce **tax and financial incentives in return for appropriate**	Urges the Commission and the Member States to introduce **measures that would** encourage producers to **diversify their**

commitments and to authorise state aid to encourage producers to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification;	**sources of supply, in particular raw materials, and** to locate their operations in Europe, from compound manufacturing to packaging and distribution; emphasises the strategic significance of this sector and the importance of investing in European companies, in the interests of resource diversification; **all public funding being conditioned to the full transparency and traceability of investments, as well as to supply obligations on the European market and to accessible prices of medicine;**
Justification: *It is essential to encourage manufacturers to diversify their sources of supply, particularly in raw materials. Indeed, if a delocalisation of chemical production has been observed in the past decades and production interruption can occur in all territories (France, Italy, Spain, Japan, China, etc.). A single source of supply, even when located on EU territory, therefore increases the risk of shortages. Therefore, focus should be put on diversifying the supply to lower the risk of supplier dependence.* *It is necessary to evaluate all incentive measures before their implementation, in order to strike a good balance between the cost for public finances and the expected benefits the measure should bring. All incentives shall be accompanied by clear and binding obligations in terms of supplying the European market for affordable and fair prices, the latter having to take account of public funding and aid received, including tax allowances. To achieve this result, transparency and traceability of public funding are essential. In addition, not only tax and financial incentives should be considered as incentives.*	
Amendment 7 **Point 9**	
Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of strategic importance for health care; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;	Calls on the Commission and the Member States to create one or more European non-profit pharmaceutical undertakings which operate in the public interest to manufacture priority medicines of **major therapeutic interest at a high risk of shortage**; stresses the key contribution that can be made by new technologies and artificial intelligence in enabling European laboratory researchers to form networks and share their objectives and findings;
Justification: *To avoid supply shortages of drugs of major therapeutic interest or those at high risk of shortages, it is necessary to set up an immediate and reinforced European public response, including through the creation of one or more European pharmaceutical*	

establishments to non-profit and general interest. *The current challenge is to establish, in collaboration with healthcare professionals, patient associations and manufacturers, the list of these drugs. This will have to take into account indicators reflecting the possible history of shortages, the fragility of the market and the production chain (e.g., the number of laboratories using the drug on the European market, the number of suppliers of active ingredients, the percentage of packaging sites and active ingredients outside the EU, etc.).*

Amendment 8 **Point 12**	
Recommends **the introduction of centralised management to bring about** greater transparency in the distribution **chain** and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve **breaks in supply**;	Recommends greater transparency in the **production and** distribution **chains of medicines** and the creation of a European supply management unit tasked with developing a European strategy to prevent and resolve **supply disruptions**;
Justification: *Overall, greater transparency is needed. The term 'breaks in supply' should be replace with the more commonly used expression 'supply disruptions'.* *The creation of a European unit for the prevention and management of supply disruptions, bringing together the EMA and national medicines agencies, would allow better coordination of policies to combat shortages within the EU. In addition, the responsibility for defining a European strategy to prevent and resolve supply disruptions is political in nature and should therefore rest with the European Commission, under the control of the European Parliament.*	

Amendment 9 **Point 14**	
Calls on the Commission to create a European contingency reserve of medicines of **strategic importance for health care, supplies of which are critical**, along the lines of the 'RescEU' mechanism**, in order to alleviate shortages outside crisis periods**;	Calls on the Commission to create a European contingency reserve of medicines of **major therapeutic interest at a high risk of shortage, which would constitute an emergency supply for Member States,** along the lines of the 'RescEU' mechanism;
Justification: *The creation of a strategic European reserve of medicinal products of major therapeutic interest at a high risk of shortage, which would complement the safety stock obligations imposed by certain states on MA holders without replacing them, could constitute a source of 'emergency supply for the Member States in the event of shortage or disruption of supply.* *The current challenge is to establish a list of such medicines, in collaboration with healthcare professionals, patient associations and manufacturers. This will have to take into account indicators reflecting the possible history of shortages, the fragility of the market and the*	

production chain (e.g. the number of laboratories using the drug on the European market, the number of suppliers of active ingredients, the percentage of packaging sites and active ingredients outside the EU, etc.).	
Amendment 10 **Point 15**	
Calls on the Commission and the Member States to **adopt a joint definition of 'medicines of strategic importance for health care' and of 'criticality', emphasising the value of these medicines for public health, the lack of alternatives and** the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;	Calls on the Commission and the Member States to **define, in collaboration with healthcare professionals, patient and consumer associations and manufacturers, an evolving list of medicines of major therapeutic interest at high risk of shortage, by using monitoring indicators such as the history of shortages and indicators reflecting** the vulnerability of the production chain; calls for a European regulatory authority to be designated to carry out the task of setting quotas for the allocation of medicines from that reserve to the Member States;
Justification: *The current challenge is to establish, in collaboration with relevant stakeholders, a list of medicines of major therapeutic interest at high risk of shortages, reinforcing immediate European public health response. This list shall be revised, when necessary, at regular intervals. The objective is to take into account indicators reflecting the possible history of shortages and the fragility of the market and the production chain (for example: the number of laboratories operating the drug on the European market, the number of suppliers of active ingredients , the percentage of packaging sites and active ingredients outside the EU, etc.).*	
Amendment 11 **Point 16**	
Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice **in the area of stock management**; considers that the European Medicines Agency (EMA) **could** be designated as the regulatory authority tasked with preventing shortages of essential medicines, with a correspondingly wider remit and more staff;	Calls on the Commission and Member States to develop innovative and coordinated strategies and to step up exchanges of good practice **by means of a European Joint Action on preventing medicine shortages; to provide for the preparation and publication of European shortage management and prevention plans by marketing authorisation holders for medicines of major therapeutic interest**; considers that the European Medicines Agency (EMA) **should** be designated as the regulatory authority tasked with **coordinating**

	exchanges between Members States to prevent shortages of essential medicines, with a correspondingly wider remit and more staff;
Justification: *A joint action on the prevention of medicine shortages, funded by the EU Health Programme, would permit the development of initiatives for the exchange of good practice between Member States and contribute to the formulation of common prevention measures.* *To ensure a continuous supply of medicines of major therapeutic interest, shortage management and prevention plans drawn up by the marketing authorisation holders would make it possible to provide for the stockpiling of medicines, the creation of alternative production sites for raw materials and the manufacture of pharmaceutical specialities and, where appropriate, the identification and stockpiling of pharmaceutical specialities which could substitute for medicines that are unavailable.* *EMA should be closely involved by the European Commission since the agency together with the Heads of Medicines Agencies (HMA) has considerably supported the efforts on combatting medicines shortages. Also, EMA is already working together with the HMA task force on increasing cooperation and coordination among Member States. These efforts should be supported through sufficient numbers of staff dedicated to this topic.*	
Amendment 12 **Point 18**	
Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders regarding shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of problems, shortages and requirements in each Member State, with a view to preventing stockpiling;	Calls on the Commission to set up an innovative centralised digital platform for sharing information provided by national agencies and all stakeholders **(including manufacturers, wholesalers and pharmacists)** regarding **available stocks and** shortages of medicines and medical equipment; welcomes the introduction by the EMA of the SPOC and i-SPOC systems; calls for existing information systems to be improved so as to provide a clear overview of problems, shortages and requirements in each Member State, with a view to preventing stockpiling;
Justification: *It should be specified who is covered by the term 'all stakeholders'. Specific reference should be made to manufacturers, wholesalers and pharmacists to ensure that these actors on the one hand can access the platform and on the other hand are obliged to share information via this platform.* *Some member states, such as Romania, have established alert systems that make it easier to anticipate and prevent possible shortages by monitoring the stocks of medicines available to*	

manufacturers. Adopting a similar system at EU level would allow measures to prevent and / or mitigate shortages to be taken as soon as possible.	
Amendment 13 **Point 19**	
Considers it essential to improve communication with healthcare professionals and patients on medicine availability through the use of innovative digital tools providing real-time data on the availability, location, quantity and price of a given medicine, in compliance with data protection legislation;	Considers it essential to improve **an early** communication with healthcare professionals and patients on medicine availability through the use of innovative digital tools providing real-time data on the availability, location, quantity and price of a given medicine, in compliance with data protection legislation; **recommends the inclusion of information for healthcare professionals on available alternatives;**
The innovative digital tool should not only provide real-time information on the availability of a specific medicine, but in case of a shortage it should also suggest alternatives to healthcare professionals. Also, it should be ensured that healthcare professionals have access to the information in the tool as early as possible.	
Amendment 14 **Explanatory Statement – paragraph 9**	
The European response to the shortage of medicines must be based on three pillars: a return to health sovereignty by securing **supplies**, stepping up European action to better coordinate and supplement Member State health policies, and enhancing cooperation between them.	The European response to the shortage of medicines must be based on three pillars: a return to health sovereignty by **securing the diversification of supply**, stepping up European action to better coordinate and supplement Member State health policies, and enhancing cooperation between them.
Different factors have led over the past years to the concentration of supply of medicines with many products now only being sold by one supplier in a number of EU countries. The first pillar should thus also ensure that this root cause of medicines shortages is tackled.	
Amendment 15 **Explanatory Statement – paragraph 11**	
Above all, this calls for relocation back to the European Union of plants producing active ingredients and medicinal end products **of strategic importance for health care, given that breaks in supply put at grave and immediate risk patients with serious conditions who are unable**	Above all, this calls for relocation back to the European Union of plants producing active ingredients and medicinal end products **of major therapeutic interest, for which an interruption of treatment is likely to jeopardize the vital prognosis of patients in the short or medium term, or**

to obtain officially recommended alternative treatments.	**represents a significant change in patient outcomes with regard to the severity or potential evolution of the disease;**
Justification: *In France, 'medicines of major therapeutic interest' (MMTI) were defined in Law No 2016-41 of 26 January 2016 as 'medicines or classes of medicines for which an interruption of treatment is likely to jeopardise the vital prognosis of patients in the short or medium term, or represents a significant loss of opportunity for patients with regard to the severity or potential evolution of the disease'. This definition was formulated by an extended working group consisting of representatives of patients, manufacturers, hospital and dispensing pharmacists, learned societies, administrations and relevant agencies. Its adoption at EU level would permit the development of a European strategy to combat medicine shortages focused on patients' interests and the real risks they face in the event of a disruption in supply.*	
Amendment 16 **Explanatory Statement – paragraph 12+bullets**	
With this goal in mind, the following major steps should be taken: • Measures **to foster relocation activities and authorisation of state aid (tax concessions and funding)**, in order to encourage firms to operate in Europe, from the compound manufacturing to the packaging and distribution stages, with the precise locations of possible production sites in the European Union to be mapped out. • Making security of supply a priority criterion in tendering procedures with the Commission recommending the best offer to the Member States. • The creation of one or more non-profit European pharmaceutical undertakings capable of producing certain medicines of **strategic importance for health care in emergencies (vulnerable production chain with either a single production line or an ingredient that is particularly difficult to obtain or no longer profitable for pharmaceutical companies to manufacture).**	With this goal in mind, the following major steps should be taken: • Measures encourage manufacturers **to diversify their sources of supply, particularly raw materials,** in order to encourage firms to operate in Europe, from the compound manufacturing to the packaging and distribution stages, with the precise locations of possible production sites in the European Union to be mapped out. • Making security of supply a priority criterion in tendering procedures with the Commission recommending the best offer to the Member States. • The creation of one or more non-profit European pharmaceutical undertakings capable of producing certain medicines of **major therapeutic interest at high risk of shortage.** • Inviting marketing authorisation holders for medicinal products of major therapeutic interest to draw up European plans for the prevention and management of shortages, which would make it possible to foresee the availability of

• **Making our continent a world leader in the development of innovative treatments for tomorrow. European research programmes are among the best in the world and must receive stronger support from the European Union, in terms of funding and coordination, the pooling of results and access to essential information. The European research programmes for the development of COVID-19 treatments and vaccines are an example of what the European Union will need to do in the future, that is to say carry out more joint research, covering a wider range of sectors. The European Union has the tools, infrastructure and researchers needed to take the lead in medical research and innovation for the development of treatments and medical equipment. By diversifying our resources learning once again to produce active ingredients in the European Union, and investing heavily in research, innovation, the bioeconomy and biotechnology, it will be possible to develop and manufacture the medicinal products of the future.**,	stocks, the setting up of different production sites of raw materials and manufacturing of substances and, where appropriate, the identification and stock of pharmaceutical substances that may constitute an alternative to missing medicines.
Justification: *In order to tackle medicine shortages in Europe, it is essential to encourage manufacturers to diversify their sources of supply, particularly in terms of raw materials. A single source of supply, even located on EU territory, increases the risk of shortages.* *The current challenge is to establish a list of medicines of major therapeutic interest at high risk of shortages, in collaboration with stakeholders. The objective is to take into account indicators reflecting the possible history of shortages and the fragility of the market and the production chain (for example: the number of laboratories operating the drug on the European market, the number of suppliers of active ingredients , the percentage of packaging sites and active ingredients outside the EU, etc.).* *The aim of prevention and management plans is to avoid shortages and reduce their impact when they occur. They must be drawn up in the light of an analysis of the manufacturing and*	

distribution risks, and include clearly defined measures with regard to building up stocks, diversifying the sources of supply of raw materials (and in particular active pharmaceutical ingredients), and the construction of other manufacturing sites for production resilience. While funding and supporting research and innovation in Europe are essential, they are not directly linked to the problem of shortages, which mainly concern older essential medicines: at least 60% of the shortages observed each year concern MAs that have been deposited for at least 10 years.	
Amendment 17 **Explanatory Statement – paragraph 13+bullets**	
More vigorous action at European level to better coordinate and supplement Member State health policies • Anticipating difficulties and crises in the health sector through the creation of a European reserve of medicines of **strategic importance for health care** along the lines of the 'RescEU' mechanism set up by the Commission. The aim here is to develop a number of health strategies at European level, with a joint reserve of priority medicines and vaccines, with harmonised prices, to enable Member States to deal with supply problems. • More systematic joint procurement to bring down the costs of certain medicines and items of equipment. It is easier to negotiate with suppliers when representing 446 million consumers. • Greater transparency in the distribution chain with the introduction of centralised management, **obtaining more information** from all stakeholders, making pharmaceutical companies, manufacturers and distributors more accountable, alongside the management and marketing authorities. The results	More vigorous action at European level to better coordinate and supplement Member State health policies • Anticipating difficulties and crises in the health sector through the creation of a European reserve of **major therapeutic interest at high risk of shortage** along the lines of the 'RescEU' mechanism set up by the Commission. The aim here is to develop a number of health strategies at European level, with a joint reserve of priority medicines and vaccines, with harmonised prices, to enable Member States to deal with supply problems. • More systematic joint procurement to bring down the costs of certain medicines and items of equipment. It is easier to negotiate with suppliers when representing 446 million consumers. • Greater transparency in the distribution chain with the introduction of centralised **information** management, **supported by mandatory input** from all stakeholders, making pharmaceutical companies, manufacturers and distributors more accountable, alongside the management and marketing authorities. The results in terms of public health justify the imposition

in terms of public health justify the imposition of special requirements by the authorities, particularly as regards **'strategic'** medicine stocks, given that pharmaceutical firms generally operate on a 'just-in-time' basis.	of special requirements by the authorities, particularly as regards medicine stocks, given that pharmaceutical firms generally operate on a 'just-in-time' basis.
Justification: *The creation of a strategic European reserve of medicinal products of major therapeutic interest at high risk of shortage, which would complement the safety stock obligations imposed by certain states on MA holders without replacing them, could constitute a source of 'emergency supply for the Member States in the event of shortage or disruption of supply.* *The shortage in stocks concerns all medicines, pharmaceutical companies working on a just-in-time basis. This is the reason why, in France, the law n ° 2019-1446 of December 24, 2019 of social security funding for 2020 obliges manufacturers to build up to 4 months of stock for all medicines. These security stocks must be located on European territory.* *Information included in the centrally managed database should be obtained on a mandatory basis from all stakeholders. Stakeholders should also be required to submit this information as early as possible.*	
Amendment 18 **Explanatory Statement – paragraph 14+bullets**	
Closer cooperation between Member States • Real-time management of medicine stocks in each Member State and prevention of stockpiling. The Commissioner responsible for health should oversee a task force working in conjunction with the EMA, national agencies and manufacturers, in order to anticipate heavier demand on stocks and regulate the movement of medicines within the single market in accordance with the needs of each Member State. This is the kind of European solidarity and coordination that must now emerge. • The introduction of simplified legislation and more flexible regulatory measures in times of	Closer cooperation between Member States • Real-time management of medicine stocks in each Member State and prevention of stockpiling. The Commissioner responsible for health should oversee a task force working in conjunction with the EMA, national agencies and manufacturers, in order to anticipate heavier demand on stocks and regulate the movement of medicines within the single market in accordance with the needs of each Member State. This is the kind of European solidarity and coordination that must now emerge. • The introduction of simplified legislation and more flexible regulatory measures in times of crisis in order to alleviate shortages and facilitate the movement of medicines between Member States:

crisis in order to alleviate shortages and facilitate the movement of medicines between Member States: acceptance of different packaging formats, a reuse procedure to enable marketing authorisation holders to obtain approval in another Member State, longer expiry periods, use of veterinary medicinal products and acceptance of a degree of coordination without this being regarded as a concerted practice, etc. • The introduction of innovative digital tools for the sharing of information regarding shortages of medicines and medical equipment in the Member States.	acceptance of different packaging formats, a reuse procedure to enable marketing authorisation holders to obtain approval in another Member State, longer expiry periods, use of veterinary medicinal products and acceptance of a degree of coordination without this being regarded as a concerted practice, etc. • The introduction of innovative digital tools for the sharing of information regarding shortages of medicines and medical equipment in the Member States **with all stakeholders**.
Justification: *It should be ensured that all stakeholders, including those at the end of the supply chain, such as pharmacists, have access to the information on shortages.*	
Amendment 19 **Explanatory Statement – paragraph 15**	
A genuine **industrial** strategy must be developed for the pharmaceutical sector to enable the European Union to regain its health sovereignty and **invest in the cutting-edge research needed to make Europe the world leader in innovation and excellence in the health sector.**	A genuine **public health** strategy **focused on patients' interests** must be developed for the pharmaceutical sector to enable the European Union to regain its health sovereignty and **to end the medicine shortages which affect all the Member States, undermining their health services and entailing considerable risks for the health and safety of patients.**
Justification*: The interests and the safety of patients, who are very much affected by medicine shortages, must be the number one priority of any EU shortage strategy. The need for the Union to regain its health sovereignty and independence and to secure the supply of medicines and medical equipment follows from this priority.* *While funding and supporting research and innovation in Europe is essential, it is not directly connected to the problem of medicine shortages, which mainly concern old essential medicines.*	