R É P U B L I Q U E F R A N Ç A I S E

SÉNAT

EUROPEAN AFFAIRS COMMITTEE

Paris, 20 October 2022

POLITICAL OPINION

On the pharmaceutical strategy for Europe presented by the European Commission

① The Senate European Affairs Committee,

② Having regard to Articles 114 and 168 of the Treaty on the Functioning of the European Union,

③ Having regard to Article 6 of the Treaty on European Union,

④ Having regard to Article 35 of the Charter of Fundamental Rights,

⑤ Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use,

⑥ 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,

⑦ Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use,

⑧ Having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products,

⑨ 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,

⑩ Having regard to Regulation (EU) No 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products,

⑪ Having regard to Regulation (EU) No 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU,

⑫ Having regard to Regulation (EU) No 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices,

⑬ Having regard to the Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 851/2004 establishing a European Centre for Disease Prevention and Control (COM(2020) 726 final),

⑭ Having regard to the Proposal for a Regulation of the European Parliament and of the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU (COM(2020) 727 final),

⑮ Having regard to the Proposal for a Council Regulation on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level (COM(2021) 577 final),

⑯ Having regard to Regulation (EU) No 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014,

⑰ Having regard to Regulation (EU) No 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe, the Framework Programme for

Research and Innovation, laying down its rules for participation and dissemination,

⑱ Having regard to the Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights and public health and the World Trade Organization (WTO) General Council Decision of 30 August 2003 on the implementation of Paragraph 6 of the Doha Declaration,

⑲ Having regard to the joint assessment of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and Regulation (EC) No 141/2000 of the European Parliament and the Council of 16 December 1999 on orphan medicinal products (SWD(2020) 163 final),

⑳ Having regard to the communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 25 November 2020 presenting the Pharmaceutical Strategy for Europe (COM(2020) 761 final),

㉑ Having regard to the communication from the Commission to the European Parliament and the Council of 3 February 2021 presenting Europe's Beating Cancer Plan (COM(2021) 44 final),

㉒ Having regard to the European Parliament resolution of 24 November 2021 on a Pharmaceutical Strategy for Europe,

㉓ Having regard to the Senate information report No 737 (2017-2018) by M. Jean-Pierre Decool, drawn up on behalf of the fact-finding mission on the shortage of medicines and vaccines, entitled *Shortages of medicines and vaccines: reinforcing public health ethics in the medicine supply chain*, submitted on 27 September 2018,

㉔ Considering that access to healthcare is a fundamental right of all citizens of the European Union;

㉕ Considering the essential nature of medicines for the provision of care;

㉖ Considering that it is the responsibility of the Commission and the Member States to ensure that all citizens of the European Union have access to good quality, effective and safe medicinal products at an affordable price across all of the Union territory;

㉗ Considering that patients must be at the centre of all health policy;

㉘ Thanks the European Commission for addressing the question of access to medicinal products within the European Union and makes the following observations:

㉙ ***On initiatives promoting research***

㉚ Considering the need for the European Union to support research in the medical field in order to meet the needs of patients;

㉛ Considering that this support must be financial, technical and regulatory;

㉜ Considering that Regulation (EU) No 536/2014 will not be implemented in full until 2025;

㉝ Considering the difficulties in organising joint research programmes in several Member States of the Union;

㉞ Considering that digital technology is essential today for the development of cutting-edge research;

㉟ Considering that correctly completed, readable and interoperable databases can assist research and in particular the development of more personalised treatments;

㊱ Welcomes the budget allocated to research in the “Horizon Europe” framework programme and that intended to promote access to care in the “EU4 Health” programme;

㊲ Asks the Commission to promote access to European research funding for small structures, by dedicating a team to provide them with administrative support;

㊳ Hopes that the Commission will develop a monitoring tool in order to identify the most innovative technologies upstream;

㊴ Considers it essential that the Commission should be able to continue to finance projects identified as the most promising, outside the framework of the "Horizon Europe" programme, by submitting them to continuous assessment;

㊵ Hopes that the Commission will consider the possibility of harmonising the conditions under which non-interventional research takes place within the Union;

㊶ Invites the Commission to offer standard contracts setting out the relationship between clinical trial sponsors and hospital sites;

㊷ Calls on the Commission to encourage research laboratories to use technologies such as artificial intelligence and high performance computing, to benefit cutting-edge research and in line with the "Horizon Europe" programme;

㊸ Supports the Commission in its aim to create databases to promote research while ensuring the protection of patients' personal data;

㊹ Calls upon the Commission to support actors in the field who will have to complete these databases as part of the "EU4Health" programme;

㊺ ***On the aims of research projects funded by the European Union***

㊻ Considering that, in accordance with Regulation (EU) No 2021/695, the Commission must define with the Member States those research projects that may benefit from European funding;

㊼ Considering that the pharmaceutical strategy for Europe must add its support to Europe's Beating Cancer Plan;

㊽ Considering that there is a strong link between human health and animal health;

㊾ Considers that European funds must be directed as a priority towards fields where treatment options are limited, where patient survival rates are low and where there is limited commercial interest for companies;

50 Calls on the Commission to define the notion of unmet medical needs in order to direct funding more effectively;

51 Hopes that cancer research, the fight against antimicrobial resistance and the development of treatment against rare diseases and childhood diseases shall be considered as priorities by the Commission;

52 Asks that public funding should be directed as a matter of priority towards funding potential treatments that are genuinely innovative, and not to developing treatments that are similar to those already on the market;

53 Hopes that, in the context of cancer research, funding will be provided for studies allowing treatment de-escalation in the interest of patients and those assessing the possibilities opened up by combining existing treatments;

54 Considers that the Commission should also fund research aimed at the repurposing of medicinal products not covered by a patent;

55 Considers that the reduction in the use of antibiotics must be proportionate to the objective being pursued, namely the protection of human health and animal health;

56 Asks the Commission to publish calls for research projects focusing exclusively on rare diseases and paediatric diseases;

57 ***On initiatives to promote faster access to medicines***

58 Considering that new innovative and promising medicinal products must be put on the market quickly once they are considered safe and effective;

59 Considering that patients must have the advantage of the most comprehensive information when they are offered a new treatment;

60 Considering that vaccines against COVID-19 were able to be put on the market very quickly as a result of a continuous assessment procedure, where data was assessed as it was produced rather than waiting until after the marketing authorisation application had been submitted;

61 Considering that joint health technology assessments may promote faster access to medicinal products;

62 Calls on the Commission to provide a legislative framework for the European Medicines Agency's PRIME programme and to foster early dialogue with laboratories to make medicines available to patients more quickly, especially in cases of unmet medical needs;

63 Would like the Commission to promote continuous assessment within the European Medicines Agency to allow faster access to treatment;

64 Calls on the Commission to organise a dialogue between the European Medicines Agency and the Member States' competent authorities regarding medicine marketing authorisation, assessment and pricing in order to be able to define as soon as possible, and to harmonise if possible the nature of the studies requested by each authority in order to accelerate the release of medicines onto the market;

65 Recommends supporting voluntary initiatives by Member States to strengthen joint health technology assessment;

66 ***For sustainable and environmentally-friendly medicines***

67 Considering that medicine manufacture can result in the release into the environment of various residues likely to have an impact on human or animal health, or on the environment;

68 Considering that these residues can be toxic or have an impact on the endocrine system and, in addition, may promote antimicrobial resistance;

69 Considering that the production of medicines is not climate-neutral;

70 Considering that medicines that are dispensed but not used represent a cost for public finances;

71 Considering that the environmental impact of the production of medicines must be considered in an international context for greater efficacy;

72. Calls on the Commission to strengthen requirements for environmental risk assessment;

73. Hopes that the Commission will support research and innovation for pharmaceutical products that are less harmful to the environment;

74. Calls on the Commission to strengthen controls and audits along the entire medicine production chain, particularly outside the Union, to ensure compliance with good manufacturing practice and associated environmental standards;

75. Recalls that the pharmaceutical industry must be environmentally-friendly and climate-neutral throughout the medicinal product lifecycle;

76. Hopes that the Commission will propose recommendations to limit the dispensing of medicines that will not be used;

77. Calls on the Commission to work towards developing common international standards with the aim of reducing the environmental impact of the pharmaceutical industry;

78. Considers that the awarding of public contracts relating to the purchase of medicinal products must take into account compliance with demanding environmental standards;

79. Emphasises, however, that producing medicines that are more respectful of the environment must not be to the detriment of access to care for patients;

80. ***On the fight against medicine shortages***

81. Considering the absence of a European regulatory framework to fight against medicine shortages outside of public health emergency situations;

82. Considering that the number of disruptions of supply is increasing from year to year in the all Member States of the Union;

83. Considering that these disruptions of supply can have dramatic consequences for patients;

㉞ Considering that they also generate significant financial costs;

㉟ Considering that old medicines are worse affected;

㊱ Considering that the causes of these disruptions of supply are varied;

㊲ Considering that only part of the pharmacopoeia is covered by marketing authorisations issued by the European Medicines Agency, while the placing of other medicines on the market requires the intervention of a national competent authority;

㊳ Considering that this marketing authorisation sets out the conditions for the manufacture of medicines and the rules relating to packaging and labelling;

㊴ Considering that marketing authorisation holders are responsible for the manufacturing process of the medicines concerned and must guarantee an appropriate and continuous supply in order to cover patients' needs;

㊵ Considering that the importing of medicines falls within the scope of the competent national authorities;

㊶ Considering that the Commission must ensure the proper functioning of the single market regarding medicines;

㊷ Calls on the Commission to define in the pharmaceutical legislation, jointly with the European Medicines Agency, the notion of disruption in the supply of medicines and of critical medicines, based on therapeutic criticality, which takes into account therapeutic interest and the existence of possible alternatives, and industrial criticality resulting from vulnerabilities in the production chain;

㊸ Considers that, in this context, manufacturers should provide the European Medicines Agency with all the information necessary to assess the industrial criticality of a medicine;

㊹ Hopes that the Commission will suggest that the platform provided for in Regulation (EU) No 2022/123 will be used by national competent authorities and marketing authorisation holders to report disruptions in the supply of critical medicines that they observe or anticipate, outside of public health emergency periods;

95 Recommends that the Commission work to simplify the renewal of marketing authorisations for critical medicines when the renewal application concerns production methods and when these have no impact on patient health;

96 Supports the possibility of dispensing critical medicines when the information on the secondary packaging and the package leaflet is not in the language of the State where the medicine is dispensed, provided that the pharmacist has been able to provide the patient with all this information in electronic format or paper format;

97 Calls on the competent authorities of the Member States, regarding the marketing authorisation for medicines, to adapt some of the criteria relating to these authorisations and, in the event of a shortage, allow the importation of medicines intended for another Member State, provided that this does not jeopardise patient safety;

98 Hopes that drug companies will draw up business continuity plans with a view to setting up production risk analysis procedures to remedy any production shortcomings or any problem with a supplier;

99 Calls on the Commission to strengthen controls relating to facilities and standards for manufacturing medicines;

100 Supports the introduction of an obligation for marketing authorisation holders to build stockpiles of critical medicines at Union level;

101 Recommends that marketing authorisation holders draw up management plans for critical medicine shortages, the content to be defined by the European Medicines Agency;

102 ***To ensure the health sovereignty of the Union***

103 Considering the gradual transfer in recent years of the production of medicinal products and active substances from the Union to third States;

104 Considering that the COVID-19 pandemic highlighted the European Union’s dependency on third States in the health sector and that there is a risk that this dependency will accentuate shortages and cause harm to patients in the Union;

(105) Considering that the European Commission has already put forward proposals to reduce this dependency in the event of a public health emergency;

(106) Considering that the production of medicinal products is fragmented, whereas the production of certain active substances is particularly concentrated in the hands of suppliers in third States;

(107) Considering that it is not possible to produce the entire pharmacopoeia within the European Union and that no Member State can claim autonomy in the health field on its own;

(108) Considering the Commission’s support for the European Union’s goal of open strategic autonomy;

(109) Considering the importance of a skilled workforce for the development of an industry;

(110) Welcomes the fact that the Commission has made proposals to enable the European Union to have the necessary tools to deal with a future health crisis;

(111) Hopes that the Commission will encourage the development of major projects of common European interest in the field of health;

(112) Calls on the Commission to develop a real industrial policy in the field of health, by analogy with the action taken to reduce the Union’s dependency with regard to semi-conductors;

(113) Considers that the action of the Union and the Member States must focus on medicinal products with a clinical criticality linked to therapeutic interest and possible alternatives, and on the industrial criticality of the medicinal product linked to a production chain dependent on third States;

(114) Hopes that the Commission will facilitate the implementation of financial and tax measures to help maintain medicine production sites within the Union and encourage investment there;

(115) Recalls that public aid granted in this context must above all make it possible to guarantee the supply of critical medicines for patients, which implies that this aid is to be used for the production of both old medicines and innovative medicines;

116 Welcomes the Commission's proposals to promote the training of a skilled workforce for the pharmaceutical industry;

117 Supports, subject to intellectual property rights and trade secrets, growth in the public management of medicine production, possibly within the framework of public-private partnerships, when manufacturers abandon markets and the missing medicines are considered critical for Union patients;

118 ***On procurement contracts and joint purchase of medicines***

119 Considering the vital role played by procurement contracts in public procurement;

120 Considering the need for Member States to limit public expenditure;

121 Considering the public health issues related to medicinal products;

122 Considering that, given their size, some markets in the Union may not be of interest to market authorisation holders;

123 Recommends, for the acquisition of mature medicines, not encouraging the use of increasingly large procurement contracts where the main attribution criterion is price but instead recommends including security of supply, ecological impact and industrial impact within the Union among the attribution criteria;

124 Calls on the Commission to support voluntary initiatives by Member States to conduct joint negotiations for the purchase of medicines, especially the most innovative;

125 ***On the price of medicinal products***

126 Considering that determining the price of medicinal products and the conditions for their reimbursement falls within the competence of the Member States;

(127) Considering that a price that is too low is unlikely to ensure security of supply and the health sovereignty of the Union;

(128) Considering that the particularly high prices of the most recent innovative products may limit access to care within the European Union;

(129) Considering the impact on the price of medicines of releasing generic medicines onto the market;

(130) Considering the need to guarantee fair competition between manufacturers of originator medicinal products and manufacturers of generic medicines;

(131) Considering the massive investment by public authorities in the field of medical research;

(132) Considering that price generally determines the actual release onto the market of the medicine by the marketing authorisation holder;

(133) Considering that prices must be consistent with the standard of living in the Member State where the medicines are marketed;

(134) Considering the difficulty, for the competent authorities of the Member States in charge of fixing the price of medicines, in determining the cost of research;

(135) Calls on the Commission to support Member States in assessing especially innovative medicines to determine in particular whether they bring real value added compared to other medicines on the market;

(136) Considers that the Commission should encourage voluntary coordination and the sharing of information, provided trade secrets are respected, between the Member States' competent authorities in charge of setting the price of medicines;

(137) Calls on the Commission to increase transparency in research costs in order to provide the Member States' competent authorities with essential information for negotiating with market authorisation holders;

138 Calls on the Commission to propose guidelines to help the competent authorities of the Member States set a fair and equitable price for recent medicines;

139 Hopes that the Commission will consider setting up a solidarity fund to enable certain Member States to acquire recent medicines which would be costly in relation to their resources, provided that this is a fair and equitable price;

140 Encourages public bodies working in research to take minority shareholdings in private law structures allowing the marketing of medicines in which these structures have participated;

141 Calls on the Commission to ensure compliance with European competition rules in the pharmaceutical sector to avoid, in particular, any obstacle to placing generic medicines on the market;

142 Asks the Commission to take the necessary measures to oversee parallel exports of medicines;

143 ***On intellectual property***

144 Considering that research in the medical field is a long, costly and risky process;

145 Considering that the protection of intellectual property is essential in order to promote research;

146 Considering that the supplementary protection certificate is intended to limit the impact of excessive delays between filing the patent application and obtaining the marketing authorisation;

147 Considering that some treatments, such as those intended to treat rare diseases or paediatric diseases, do not have the same commercial potential as other treatments;

148 Considering that the marketing of generic medicines must be compliant with the rights conferred on the holder of the patent for the originator medicinal product;

149 Calls for the duration of the commercial exclusivity granted to marketing authorisation holders for an orphan medicinal product, in accordance with Regulation (EC) No 141/2000, to be extended for the most serious diseases and when the estimated profitability of

the medicine is deemed insufficient, by favouring medicines that have not been the subject of a marketing authorisation for another pathology;

150 Requests that the duration of the extension to the supplementary protection certificate granted under Regulation (EC) No 1901/2006 be increased when the therapeutic indication of the medicinal product is for childhood diseases only and that this duration be extended when the turnover achieved by the pharmaceutical laboratories is considered insufficient or the time needed to obtain the marketing authorisation is longer;

151 Hopes that the Commission will initiate deliberation as soon as possible to determine the best way to unify the conditions for issuing supplementary protection certificates;

152 Calls on the Commission to help Member States anticipate changes in the healthcare system resulting from the marketing of innovative treatments;

153 Recommends that the Commission clarify the conditions under which manufacturers of generic medicines will be able to conduct trials on patented products and have access to studies carried out by the patent holder, without infringing the latter's rights;

154 Calls on the Commission to consider the possibility of obliging the marketing authorisation holder producing an originator medicinal product and who does not wish to distribute this product on a specific market, to grant a public body or a manufacturer of generic medicines the right to market it, under fair and reasonable licence conditions;

155 ***Ensuring that medicinal products are released onto the market within a reasonable timeframe***

156 Considering that Directive 2001/83/EC does not impose sufficient obligations on marketing authorisation holders regarding the actual release onto the market or withdrawal of a medicinal product;

157 Considering the unequal timeframes for access to innovative medicines from one Member State to another;

(158) Considering that the time limits inherent in determining the price of medicines and the conditions for their reimbursement fall within the competence of the Member States;

(159) Calls on the Commission to introduce, as part of the marketing authorisation, measures to encourage future marketing authorisation holders to place their medicinal products on the market in all Member States;

(160) Calls on the Commission to further regulate the conditions under which the marketing authorisation holder may withdraw medicinal products from the market of a Member State, other than for reasons of inadequate safety or efficacy of the medicinal product;

(161) Hopes that the Commission will promote voluntary cooperation between Member States in order to achieve joint health technology assessments.