EUROPEAN AFFAIRS COMMITTEE

Paris, 5 April 2024

POLITICAL OPINION

Political opinion on action by the European Union against medicine shortages

The European Affairs Committee of the French Senate,

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

Having regard to the conclusions of the European Council of 29 and 30 June 2023,

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

Having regard to Regulation (EU) 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,

Having regard to Council Regulation (EU) 2022/2372 of 24 October 2022 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,

Having regard to the Communication from the European Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 26 April 2023, “Reform of the pharmaceutical legislation and measures addressing antimicrobial resistance”, COM(2023) 190 final,

Having regard to the Proposal for a Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a "One Health" approach, COM(2023) 191 final,

Having regard to the Proposal for a Directive of the European Parliament and of the Council to introduce a Union code relating to medicinal products for human use and repealing Directive 2001/83/EC and Directive 2009/35/EC, COM(2023) 192 final,

Having regard to the Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisations and supervisions of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006, COM(2023) 193 final,

Having regard to the Communication from the European Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 24 October 2023, "Addressing medicine shortages in the EU", COM(2023) 672 final,

Having regard to the Political Opinion of the European Affairs Committee of the French Senate of 20 October 2022 on the European Commission's Pharmaceutical Strategy for Europe,

Having regard to Senate Information Report "Shortage of medicines: seeking the right remedy urgently", (No 828 Volume I, 2022-2023) – 4 July 2023 – by Laurence Cohen, produced in the name of the committee of inquiry on shortages of medicines,

Action needed by the European Union in compliance with the treaties

Whereas shortages of medicines are increasingly frequent in Union Member States;

Whereas the provision of medicines is the responsibility of the Member States;

Whereas the Union took action during the COVID-19 pandemic to organise the joint purchase of vaccines and thus avoid competition between Member States;

Whereas different types of shortages are noted by the Commission which distinguishes those requiring coordinated action at Union level in order to remedy them;

Whereas the working party on shortages of medicines, set up by Regulation (EU) 2022/123 and composed of representatives of the Member States, will be responsible for adopting and updating a list of critical medicine shortages, based on reports from the competent authorities of the Member States;

Is in favour of action by the Union against shortages of medicines in compliance with the competences of the Member States;

Supports the proposal of a typology of shortages put forward by the Commission provided that it respects principles of subsidiarity and proportionality;

Supports the adoption of a list of critical medicine shortages by the Medicine Shortages Steering Group (MSSG) established in Regulation (EU) 2022/123;

Increased reporting and informing obligations for marketing authorisation holders

Whereas the European Commission proposes that marketing authorisation holders report earlier to the competent authority of the Member State concerned, and to the European Medicines Agency (EMA) in the case of a medicine covered by a centralised marketing authorisation, regarding any decision to withdraw a product from the market, either definitively or temporarily, or any temporary disruption in the supply of a medicine in a given State;

Whereas the Commission has proposed measures in this case to facilitate the transfer of the marketing authorisation;

Whereas the Commission also proposes to strengthen the obligations of marketing authorisation holders regarding the provision of information to the Member States' competent

authorities and to the EMA, enabling them to assess the risk of shortage and to address it;

Whereas it is necessary to improve forecasts of medicine supply and demand;

Supports the measures proposed by the Commission with a view to strengthening the reporting and information obligations of marketing authorisation holders;

Stresses that they must be accompanied by measures aimed at facilitating the transfer of the marketing authorisation to another holder in the event of a medicine being withdrawn from the market;

Recommends that the EMA can facilitate such a transfer by publishing on its website the list of companies wishing to organise such a transfer;

Requests that Annex II of Proposal for a Regulation COM(2023) 193 final, hereinafter “the Proposal for a Regulation”, which specifies the list of obligations where failure to comply may result in financial penalties in the form of fines, should be modified to include notification and information obligations;

Requests that information collected directly by the EMA from marketing authorisation holders in the event of a critical shortage should be shared with the competent authorities of the Member States;

Recommends that use be made of information in systems currently in force within the Union, notably the European Medicines Verification Organisation, so that marketing authorisation holders do not have to provide the same information several times;

Considers that the competent authorities of the Member States and the EMA should also publicise potential shortages on their websites and provide information in real time on the availability of medicinal products, mainly to enable doctors to adapt their prescriptions;

Calls for a strengthening of links between the European Centre for Disease Prevention and Control, on the one hand, and the competent authorities of the Member States, on the other hand, to better anticipate the demand for medicines;

A useful obligation to establish shortage prevention plans whose effectiveness must be reinforced

Whereas the Proposal for a Regulation requires marketing authorisation holders to draw up a shortage prevention plan for all medicines in their portfolio;

Believes that these plans constitute a useful tool for evaluating risks and anticipating supply tensions;

Considers it necessary to restrict the scope of this measure to critical medicines only;

Requests that the regularity and quality of these plans be evaluated by the EMA;

Calls for an increase in the EMA's budget to enable it to fulfil this mission adequately;

Hopes that these plans can be communicated at any time to the competent authorities of the Member States who could thus call upon the EMA to report any failure with regard to their regularity or quality;

Recalls that data provided by marketing authorisation holders in this respect may be the subject of a legitimate request for confidentiality;

Supports the introduction of dissuasive penalties to encourage compliance with the obligation to establish shortage prevention plans and hence that Annex II of the Proposal for a Regulation be modified accordingly;

Requests that the Proposal for a Regulation should specify that marketing authorisation holders are required to implement the shortage prevention plan in the event of real or potential need;

A list of critical medicines based on both therapeutic and industrial criticality

Whereas the Proposal for a Regulation provides for the Commission to adopt a list of the Union's critical medicines, on the

basis of a proposal from the steering group provided for by Regulation (EU) 2022/123;

Whereas the Commission has anticipated this measure by publishing an initial list of critical active substances;

Whereas this list has been drawn up based on the therapeutic criticality of active substances, evaluated using a method identifying three levels of risk relating to two criteria: therapeutic indication and availability of a suitable alternative;

Whereas six Member States, including France, have produced a list of essential active substances and these have been passed on to the Commission;

Supports the establishment of a list of critical medicines for the Union;

Recalls that this must not be a simple compilation of national lists but must contain critical active substances at Union level;

Asks that the selection of critical active substances be made in a transparent manner by an independent team which must select substances of which the clinical interest for patients has been demonstrated;

Calls for patients' associations to be involved in producing the Union list of critical medicines;

Recalls the need also to evaluate the industrial criticality of medicines, active substances and finished products, by mapping the value chain and identifying vulnerabilities;

Asks that marketing authorisation holders respond to requests for information from the Commission concerning their industrial operations to enable it to assess supply chain vulnerability;

Calls for guarantees for the confidentiality of information transmitted by marketing authorisation holders in this context;

Availability of stocks, which determines the effectiveness of a voluntary cooperation mechanism between Member States

Whereas, in the Proposal for a Regulation, the Commission does not specify the measures it is likely to take in the event of a critical shortage of medicines;

Whereas the Commission indicates that it may use an implementing act to request that holders of the marketing authorisation for a critical medicinal product build up their inventory;

Whereas certain Member States have imposed a stockpiling obligation on marketing authorisation holders that corresponds to their needs;

Whereas the Commission has put a medicine solidarity mechanism in place which should allow for the transfer of medicines from one Member State to another where necessary, on a voluntary basis;

Whereas this transfer will be organised with the assistance of the EMA, which will identify needs;

Whereas this transfer can only take place on condition that the medicines are available in another Member State, but it is currently difficult to assess the inventory of medicines available in a given Member State;

Whereas the transfer of medicines from one Member State to another requires the implementation of regulatory flexibility, which may concern labelling or package leaflets;

Whereas the Proposal for Directive COM(2023) 192 final allows for Member States to decide whether the package leaflet will be made available in paper or electronic format, or both;

Whereas the Proposal for a Directive also states that the Commission may have the authority to adopt delegated acts in order to make the electronic version of the leaflet compulsory;

Requests that the Commission specify in the Proposal for a Directive the measures that it is expected to be authorised to take in the context of managing critical medicine shortages;

Recommends that each Member State be able to set stockpiling obligations for marketing authorisation holders according to their own needs and that the Commission propose measures to promote a

joint strategic approach with regard to stockpiling medicines, provided that Member States remain free to participate;

Supports the creation of a voluntary solidarity mechanism with regard to medical products;

Emphasises that such a mechanism presupposes that supply difficulties are limited to a small number of Member States;

Considers that a Member State's participation in this solidarity mechanism must be conditional on the implementation of a stockpiling obligation at national level;

Calls for greater transparency by Member States regarding stocks that marketing authorisation holders have available on their territory;

Approves the possibility of applying regulatory flexibility when this can help address a critical shortage of medicines, provided that this has been evaluated by the national competent authority of the Member State concerned and presents no danger to patient safety;

Requests that patients should, in all cases, be provided with a package leaflet in their own language in electronic or paper format, in accordance with their wish;

Is opposed to any withdrawal of the possibility for patients to obtain a leaflet in paper format;

Calls for the deletion, in the Proposal for Directive COM(2023) 192 final, of the provision allowing the Commission to adopt delegated acts in order to make the use of electronic leaflets compulsory;

The European Health Emergency Preparedness and Response Authority (HERA) and public procurement, two instruments to promote in tackling medicine shortages

Whereas Regulation (EU) 2022/2372 provides for a review of HERA's missions in 2024;

Whereas the budget of the EU4Health programme was recently reduced by €1 billion;

Whereas it is necessary to carry out an analysis of the industrial criticality of medicine production value chains;

Whereas Regulation (EU) 2022/123 sets out the role of the EMA and the Medicine Shortages Steering Group with regard to medicine shortages and tackling these shortages;

Whereas reliable information is required on supply and demand for critical medicines;

Whereas the Commission deems it necessary to take into account the guarantees offered by candidates in terms of security of supply during the execution of public procurement procedures;

Whereas HERA is already organising joint public procurement contracts to purchase vaccines;

Whereas a regrettable lack of transparency surrounded contracts for the advance purchase of COVID-19 vaccines;

Requests that HERA's missions be extended beyond health emergencies only, to participation in managing critical medicine shortages and evaluation of the industrial vulnerability of critical medicinal products;

Would like HERA to carry out an analysis of the industrial criticality of critical medicines and map the supply sources of the main active ingredients and inputs of these medicines, together with an assessment of the resulting supply risks;

Considers that a clear definition of the missions of EMA and HERA is needed to ensure that their actions are complementary;

Hopes that, as part of the next multiannual financial framework, HERA's budget will be increased;

Recommends that parallel trade in medicines should be restricted in the event of a critical shortage;

Supports joint public procurement procedures directed by HERA and the possibility of Member States to become involved on a voluntary basis;

Considers that these joint public procurement agreements must be conducted with full transparency;

Requests that the criterion linked to guarantees in terms of security of supply should be taken into account when awarding public procurement contracts;

The necessary development of the Union's production capacities

Whereas the Commission has established a Critical Medicines Alliance enabling national authorities, industry, representatives from civil society, the Commission and European Union agencies to implement coordinated action at Union level against medicine shortages;

Whereas the concentration of production of certain inputs or active ingredients increases supply chain vulnerability;

Whereas the Commission intends to create a network of international partners in order to strengthen supply chain resilience while promoting regulatory convergence among partners in this network;

Whereas the Proposal for a Regulation provides for the development of joint audit programmes supervised by the EMA to ensure harmony between practices of the competent authorities of the Member States responsible for monitoring production units;

Whereas the Commission supports stepping up the Union's capacities to produce medicines;

Whereas the Commission promotes the implementation of Important Projects of Common European Interest to support the development of the pharmaceutical industry throughout the Union and tackle medicine shortages;

Whereas these projects make it possible to take advantage of greater public aid, but they must include innovation;

Whereas this innovation criterion is difficult to fulfil in the context of mature medicinal products yet these medicines are most concerned by the risks of shortage;

Whereas several Member States, including France, have initiated an Important Project of Common European Interest to develop more ecological manufacturing processes;

Whereas France has launched a relocation programme for certain medicines or active ingredients;

Whereas there is a lack of consultation on relocation programmes within the Union;

Whereas relocation programmes require considerable public aid which nevertheless remains regulated by Union legislation;

Whereas it is necessary to ensure the long-term economic viability of relocation operations;

Whereas medicines produced in the Union face competition from Asian products which do not necessarily meet the same production standards, especially environmental standards;

Whereas the production of medicines within the Union may result in an increase in their price;

Whereas relocation policies may not be sufficient to guarantee an appropriate supply of critical medicines;

Whereas the Union has production units that can be mobilised at any time to enable the production of up to 325 million doses of vaccines within the framework of the EU FAB network;

Whereas the annual cost of this mechanism is €160 million;

Supports the creation of the Critical Medicines Alliance;

Hopes that the Commission will encourage marketing authorisation holders to participate actively in the work of this Alliance;

Supports measures to diversify supply chains and create a network of international partners to strengthen supply chain resilience and promote regulatory convergence and respect for European standards to guarantee the quality of medicines;

Encourages the development of joint audit programmes to inspect production units and thus limit quality defects in medicines which can often be a source of shortages;

Points out that Important Projects of Common European Interest are not necessarily a suitably adapted instrument to promote the relocation of mature medicines as they do not necessarily include an innovation component;

Hopes that the Commission will present a legal text to propose a more appropriate instrument to develop the relocation of critical medicines across the Union territory;

Recalls that any subsidy paid to support a relocation project involves considerations, especially in terms of security of supply and maintaining activity;

Considers it necessary to examine upstream of any relocation project the conditions necessary for the economic viability of the planned production, particularly in terms of price and volume of demand;

Requests that the opportunity cost of relocation operations also be assessed, insofar as subsidies awarded will not be used to finance other health system needs;

Advocates the promotion of fair conditions of competition between companies producing within the Union and those established in other parts of the world, in particular by including environmental and social criteria in good manufacturing practices that companies in third countries will have to respect;

Regrets the lack of coordination between Member States in the implementation of relocation projects;

Hopes that national relocation projects will be the subject of information gathering and consultation between Member States organised by the European Commission;

Recommends that such consultation could avoid duplication and thus guarantee the sufficient demand necessary for the economic viability of relocated production;

Supports the public production of medicines and the creation of a European non-profit pharmaceutical establishment capable of

producing critical medicines, in the event of failure or insufficient capacity in private production.