French Republic

EUROPEAN AFFAIRS COMMITTEE

Paris, 24 October 2024

POLITICAL OPINION

Political opinion on the reform of the European Union's pharmaceutical legislation

The Senate European Affairs Committee,

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

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, "Pharmaceutical Strategy for Europe", COM(2020) 761 final,

Having regard to Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems,

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

Having regard to Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use.

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,

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 and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004C,

Having regard to Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use,

Having regard to Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU,

Having regard to Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU,

Having regard to the Commission Staff Working Document of 11 August 2020 presenting a joint evaluation 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 of the Council of 16 December 1999 on orphan medicinal products, SWD(2020) 163 final,

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 26 April 2023: "Reform of the pharmaceutical legislation and measures addressing antimicrobial resistance", COM(2023) 190 final,

Having regard to the Council Recommendation of 13 June 2023 on stepping up EU actions to combat antimicrobial resistance in a One Health approach, 2023/C 220/01,

Having regard to the Proposal for a Directive of the European Parliament and of the Council on the 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 authorisation and supervision 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 Senate Resolution no. 120 (2023-2024) of 10 May 2024 on European Union action against medicine shortages,

Having regard to Senate Resolution no. 127 (2022-2023) of 9 June 2023 on the Proposal for a Regulation of the European Parliament and of the Council on fees and charges payable to the European Medicines Agency, amending Regulation (EU) 2017/745 of the European Parliament and of the Council and repealing Council Regulation (EC) No 297/95 and Regulation (EU) 658/2014 of the European Parliament and of the Council,

Having regard to the Senate information report entitled "For a Europe of medicines serving patients", no. 63 (2022-2023) of 20 October 2022 drafted by Ms Pascale Gruny and Ms Laurence Harribey on behalf of the European Affairs Committee,

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

Assessment procedures that must guarantee patient safety

Whereas the European Medicines Agency (EMA) is responsible for assessing marketing authorisation applications (MA) for medicinal products so as to guarantee their efficacy and patient safety;

Whereas biosimilar medicines vary more than generic medicines from the reference medicine;

Whereas the adoption of Directive 2010/84/EU has allowed the reinforcement of pharmacovigilance measures designed to monitor any adverse reactions that a medicine placed on the market may cause;

Considering the time needed to carry out the studies requested by the EMA in connection with a conditional marketing authorisation;

Whereas it is necessary to ensure optimum use is made of the EMA's resources;

Whereas today scientific assessment by EMA takes an average of 400 days whereas the regulatory assessment time is 210 days;

Whereas the incomplete nature of certain MA applications tends to prolong the assessment process;

Whereas it is necessary to guarantee the consistency of MA applications relating to medicinal products for human use;

Whereas digitalising MA application procedures is of interest in terms of the time it saves for MA applicants and for the EMA;

Whereas the PRIME (Priority Medicines) scheme introduced by the EMA has been a success;

Whereas the European Commission desires to institutionalise this scheme;

Whereas the Commission foresees that this scheme will benefit medicines of major interest for public health without providing a definition of this notion;

Whereas it would be the responsibility of the EMA to decide which medicines could benefit from this scheme;

Whereas the Commission is proposing to institutionalise the progressive data examination procedure requested by the EMA as part of the assessment of an MA application, a procedure that was used during the COVID-19 pandemic;

Whereas the Commission is proposing to create a temporary emergency marketing authorisation procedure in the event of a public health emergency as defined by Regulation (EU) 2022/2371;

Whereas the Commission wishes to create a regulatory sandbox to allow access to innovative healthcare technologies for which current regulatory requirements cannot be met due to the specific nature of these technologies;

Reiterates that any changes to the regulations relating to the assessment of MA applications must guarantee patient safety;

Considers that the obligation to draw up a risk management plan could validly be removed for the placing on the market of generic medicines, but not for that of biosimilar medicines due to the fact that they vary more from the reference medicines;

Also considers that given the pharmacovigilance measures currently in force, the removal of the obligation to renew the MA after five years is acceptable;

Supports, given the time needed to submit new studies, less frequent renewal of conditional MAs, namely every two years from the third year onwards;

Is opposed to the reduction to 180 days of the assessment period for MA applications examined by the EMA;

Is in favour of a reduction in the number of committees within the EMA, thereby integrating the Committee for Orphan Medicinal Products and the Paediatric Committee into the Committee for Medicinal Products for Human Use;

Reiterates the need to strengthen public funding of the EMA to enable it to carry out missions that do not directly benefit MA applicants or holders;

Wishes to see the development of digitalised MA procedures;

Supports the institutionalisation of the EMA's PRIME scheme subject, firstly, to better defining the criteria for selecting the priority medicines eligible for this scheme and in particular the notion of "*major interest for public health*", and secondly, to ensuring the transparency of the scientific opinions on these medicines by requiring that such opinions be reasoned and published;

Considers it necessary to clarify the notion of "*exceptional therapeutic breakthrough*" which would allow the medicine to benefit from progressive examination of the data necessary to obtain an MA;

Requests that the eligibility criteria for medicines which will be able to benefit from a temporary emergency MA be defined and that the conditions of implementation of this procedure required to guarantee patient safety be clarified;

Considers that the setting up of a regulatory sandbox must remain an exception and be conditional upon the absence of an alternative therapy and the introduction of an appropriate assessment process;

Demands increased transparency on the criteria for the EMA recommending the creation of a regulatory sandbox, the implementation of such a system requiring tighter control over both the selection criteria and the prior testing;

Argues that this system should not be considered equivalent to a clinical trial, which implies that prior testing must be done before making the product available to patients;

Considers it necessary to strengthen the pharmacovigilance measures and the follow-up of patients concerning the medicines placed on the market under a regulatory sandbox arrangement;

Medicines more respectful of the environment without limiting access to them

Whereas the Commission desires to promote the One Health principle, which is a global approach that recognises the interplay between human health, animal health and the environment;

Whereas the presence of pharmaceuticals in the environment produces adverse effects on human health and animal health, in particular with regard to antimicrobial resistance;

Whereas the Commission desires to tighten up the requirements relating to the Environmental Risk Assessment (ERA) for medicines-related risks;

Whereas medicines authorised before 30 October 2005 were not subject to an ERA;

Whereas the Commission is proposing that the EMA be able to draw up a list of these medicines that it considers as potentially harmful to the environment in order to ask the MA holder to conduct an ERA;

Whereas older medicines are more exposed to the risk of shortages;

Whereas the Commission is proposing that an MA be denied if the ERA is incomplete or insufficiently substantiated or if the risks identified in the ERA have not been sufficiently addressed by the applicant;

Supports the tightening of the requirements relating to the environmental risk assessment, in particular for antimicrobial medicines;

Is in favour of an extension of the obligation to conduct an ERA for medicines authorised before 30 October 2005 and considered as potentially harmful to the environment by the EMA;

Requests the implementation of measures, financial in particular, to support MA holders which will have to reduce the environmental impact of the critical medicines concerned in order to avoid any risk of shortages;

Reiterates that medicine production more respectful of the environment must not be at the expense of patients' access to medicines addressing an unmet medical need, priority antimicrobials, medicines of major interest for public health and medicines that can be considered an exceptional therapeutic breakthrough;

Therefore asks that the denial of an MA application not presenting a satisfactory ERA not be systematic and that the Commission take account of criteria such as the absence of alternative treatments or the manifest goodwill of the applicant;

Reducing the price of medicines by strengthening the position of the Member States in negotiations with MA holders and by facilitating the entry onto the market of generic or biosimilar medicines as soon as the protection granted to the reference medicines comes to an end

Whereas the most innovative medicines have high prices;

Whereas under the terms of Article 168(7) of the Treaty on the Functioning of the European Union, the pricing and reimbursement of medicines are respectively negotiated and set by the Member States;

Whereas the Member States have difficulties in obtaining information on the costs of producing medicines;

Whereas MA holders receive public funding to develop medicines;

Whereas the Commission is proposing to allow comparative advertising where the summary of product characteristics demonstrates and supports the claims of the advertising in question;

Whereas this summary does not include the conclusions of the studies carried out as part of the comparative assessment of the medicine in order to determine its price and reimbursement;

Whereas the Commission wishes to strengthen cooperation between the competent authorities in the Member States in charge of pricing and reimbursement;

Whereas Regulation (EU) 2021/2282, which is intended to allow the development of joint assessments of health technologies, will be applicable in January 2025;

Whereas price reductions are generated by the arrival on the market of generic or biosimilar medicines;

Whereas generic or biosimilar medicines must be able to enter the market as soon as the protection of the reference medicine expires;

Considers it necessary to increase transparency on the public funding of the development of medicines, in order to help the Member States in their negotiations on the pricing of such medicines with the MA holders;

Therefore requests that the MA holder publicly declare any direct financial support received from a public authority or publicly funded body for activities relating to research and development of medicines subject to a national or centralised marketing authorisation, regardless of which entity received that financial support;

Also requests that any indirect financial support received from a public authority or body financed by EU funds or publicly funded

by its Member States, including tax breaks, should be publicly declared;

Is opposed to any authorisation of comparative advertising in the pharmaceutical legislation;

Welcomes the measures taken by the Commission to strengthen cooperation between the competent authorities in the Member States in charge of pricing and reimbursement, with the aim of facilitating the sharing of information and good practices;

Considers it necessary for the Member States to boost the financial and human resources of the competent national authorities in charge of pricing and reimbursement to allow their effective participation in the joint assessments provided for Regulation (EU) 2021/2282;

Hopes that the Commission will consider setting up a solidarity fund to enable certain Member States to acquire new medicines whose price is too high for them given their resources, as long as this price is fair and equitable;

Supports the measures proposed by the Commission to extend the conditions of use of products covered by patent to enable developers of generic or biosimilar medicines to conduct the studies necessary to the determination of the price of the medicines and their level of reimbursement;

Requests that it be made clear that an authorisation to use products covered by patent for this purpose may not be denied in the name of the protection of intellectual property rights;

A limited reduction in the regulatory data protection period so as not to discourage research, but accompanied by incentive mechanisms

Whereas the Commission is proposing to reduce the regulatory data protection period from eight to six years;

Whereas this measure could have an impact on research and development, which remains essential to the development of new medicines;

Whereas the Commission is proposing that MA holders should benefit from an extra regulatory data protection period if they meet a certain number of criteria;

Whereas the Commission is proposing to grant an additional two years of regulatory data protection to the holder of an MA if it can show that it has released and continuously supplied a sufficient quantity of the medicinal product in the presentations necessary to cover the needs of patients in the Member States where the MA is valid, within two years of this MA grant;

Whereas the effective placing on the market of a medicine depends on decisions and negotiations involving the MA holders but also the competent authorities in the Member States;

Whereas the Commission is proposing to define what will be considered as a medicine addressing an unmet medical need;

Whereas the EMA must issue guidelines to specify the criteria for identifying such medicines;

Whereas it will be up to the MA applicant to demonstrate to the EMA that the medicinal product addresses an unmet medical need;

Whereas the Commission is proposing to grant the holder of an MA for a medicine addressing an unmet medical need an additional six months of regulatory data protection;

Whereas the Commission is proposing to grant the holder of an MA an additional six months of regulatory data protection when the clinical trials submitted in support of the initial MA application use a relevant and evidence-based comparator;

Whereas it is difficult to determine a comparator that is relevant to each competent national authority in charge of the pricing and reimbursement of a medicine;

Whereas Regulation (EU) 2021/2282 is intended to allow the conduct of joint assessments of health technologies to determine their price and level of reimbursement;

Whereas the Commission is proposing to grant an additional year of regulatory data protection to an MA holder which obtains, during the period of data protection, an authorisation for a new therapeutic indication for which it demonstrates, with supporting data, significant clinical benefit in comparison with existing therapies;

Whereas a new therapeutic indication allows MA holders to generate additional revenues;

Whereas it is necessary to limit the impact on the price of medicines of the incentives offered in the form of extensions to the regulatory data protection period;

Whereas it is necessary to support research within the Union;

Whereas there is potential interest in repurposing medicines that are no longer protected by a patent to benefit the health of patients;

Proposes to set the regulatory data protection period for medicines benefiting from an MA at seven years and six months;

Considers that it would be difficult to implement the incentive measure proposed by the Commission for a medicinal product to be released and continuously supplied in a sufficient quantity in the presentations necessary to cover the needs of patients in the Member States where the MA is valid;

Proposes instead to create an obligation for the MA holder to submit a pricing and reimbursement request within twelve months of a Member State's request for a given medicine, on pain of

financial penalties, and opposes any waiver based on the criteria for the designation of the medicine;

Considers that this twelve-month period may be increased to twenty-four months for SMEs and the non-profit organisations;

Asserts the need to establish criteria for designating a medicine as addressing an unmet medical need;

Calls, however, for a more precise definition of these designation criteria taking into account the impact of the treatment on patients' quality of life and defining the notion of exceptional therapeutic breakthrough;

Wishes to see complementary measures adopted to guarantee the transparency of the EMA's opinions relating to the designation of a medicine as addressing an unmet medical need;

Asks that the EMA consult patients' organisations, developers of medicines and healthcare professionals in order to draw up guidelines on the designation of a medicine addressing an unmet medical need;

Requests that holders of an MA for a medicine addressing an unmet medical need benefit from an additional twelve months of regulatory data protection;

Considers that the conduct of clinical trials in support of an initial MA application using a relevant and evidence-based comparator should not give rise to an additional period of regulatory data protection;

Believes that an MA holder which obtains, during the period of data protection, an authorisation for a new therapeutic indication for which it demonstrates, with supporting data, significant clinical benefit in comparison with existing therapies should benefit from an additional six months of regulatory data protection;

Supports the Commission's proposal to allow the granting of four years of regulatory data protection when a new therapeutic indication not previously authorised in the EU is found;

Recommends that when the research and development of a medicine has mainly taken place within the European Union, the holder of the corresponding MA should be able to benefit from an additional six months of regulatory data protection;

Requests that the regulatory data protection period never be more than eight years and six months;

Limiting the consumption of antimicrobials while ensuring their availability and the development of new products

Whereas 35,000 people die every year in the EU as a direct result of infections caused by antimicrobial-resistant bacteria;

Whereas antimicrobial resistance (AMR) implies parsimonious use of these medicines and that this limits companies' commercial interest in developing new ones or producing the ones that exist already;

Whereas the Commission is proposing a definition of priority antimicrobials which will allow it to target the incentives on the development of new antimicrobials that it intends to implement;

Whereas the Commission wishes to strengthen the requirements regarding information on antimicrobials provided to healthcare professionals and patients;

Whereas on 13 June 2023 the Council adopted a recommendation aimed at reducing antimicrobial consumption;

Whereas the Commission is proposing that MA holders placing a priority antimicrobial on the market should be able to benefit from a transferable data exclusivity voucher that entitles them to an additional year of regulatory data protection;

Whereas there is no data on the potential cost of these vouchers which will be covered by the Member States' budgets;

Whereas there is no data allowing the effectiveness of these vouchers in encouraging the development of new antimicrobials to be assessed;

Whereas reflection is being undertaken by HERA on launching an initiative on joint purchasing of antimicrobials by Member States with revenue guarantees for the holders of the corresponding MAs;

Supports the criteria used by the Commission to define a "priority antimicrobial";

Welcomes the aim of providing more comprehensive information on the use of antimicrobials and the risks of antimicrobial resistance to healthcare professionals and patients;

Supports the objectives proposed by the Council Recommendation of 13 June 2023 on stepping up EU actions to combat antimicrobial resistance in a One Health approach;

Rejects the possibility of creating data transferability exclusivity vouchers;

Supports the development of voluntary joint antimicrobial purchasing procedures based on a revenue guarantee model for MA holders;

Calls for consideration of the setting up of a mechanism for paying for innovation supported by the Member States that wish to do so with the aim of supporting the developers of new priority antimicrobials;

A need to develop orphan medicinal products whilst limiting the risk of overcompensation

Whereas the Commission wishes to remove the criterion of financial profitability provided for by the Regulation (EC) No 141/2000 to designate an orphan medicinal product;

Whereas the advantages granted to holders of MAs for orphan medicinal products are above all justified by a lower return on

investment due to the limited number of patients concerned by these medicines;

Whereas there are significant differences in prevalence among the orphan diseases;

Whereas orphan medicinal products will be considered as medicines addressing an unmet medical need;

Whereas the Commission is proposing to define the criteria for designating the orphan medicinal products that address an important unmet medical need;

Whereas the rewards granted for the development of orphan medicinal products can lead to overcompensation with excessive benefits being granted to MA holders in relation to the financial difficulties they face to place an orphan medicine on the market, in particular when this involves repurposing an active substance already used for other indications;

Whereas the Commission is proposing to modulate the market exclusivity period enjoyed by holders of an MA for an orphan medicinal product;

Whereas it is proposing to extend this exclusivity period by twelve months when the holder of an MA for an orphan medicinal product obtains an authorisation for a new therapeutic indication for a different orphan condition;

Whereas it is also proposing to extend this exclusivity period by twelve months when the MA holder can demonstrate that the medicinal product is released and continuously supplied in sufficient quantities in the presentations necessary to cover the needs of patients in the Member States where the MA is valid, within two years of the MA grant;

Requests that the financial criterion for designating orphan medicinal products be maintained;

Wishes to see the criteria for designating an orphan medicinal product addressing an important unmet medical need include the prevalence of the disease;

Reiterates the need to define the notion of exceptional therapeutic breakthrough;

Is favourable to a modulation of the market exclusivity period granted to holders of MAs for orphan medicinal products;

Requests that the market exclusivity period granted to the holder of an MA for an orphan medicinal product be reduced when the MA was granted on the basis of a well-established use of the active substance within the European Union and increased for orphan medicinal products addressing an important unmet medical need;

Therefore asks that the MA holder be granted a market exclusivity period of five years when the MA was granted on the basis of a well-established use of the active substance within the European Union, nine years as standard and ten years for orphan medicinal products addressing an important unmet medical need;

Supports the measure granting a twelve-month extension of market exclusivity when the holder of an MA for an orphan medicinal product obtains an authorisation for a new therapeutic indication for a different orphan condition;

Considers that it would be difficult to implement the Commission's proposal intended to guarantee adequate supplies in all of the Member States by granting a twelve-month extension of the market exclusivity period for the holder of an MA that meets this objective, in line with its position on the proposed two-year extension of the regulatory data protection period for MA holders when the same objective is achieved;

Considers that it would be more effective to compel MA holders, on pain of financial penalties, to submit a request to set the price and level of reimbursement for a medicine a Member State

wishes to see marketed on its territory within one year of such a request;

An effective system to support the development of paediatric medicines

Whereas the Commission has not put forward any specific new incentives for the development of paediatric medicines;

Whereas these medicines may be orphan medicines or address an unmet medical need and thus benefit from the incentives provided for those medicines;

Whereas the Commission considers the two-year extension of the market exclusivity period granted to the holder of an MA for an orphan medicinal product for which a paediatric investigation plan has been completed and validated as ineffective and therefore proposes to abolish this existing measure;

Whereas an applicant for an MA must submit a paediatric investigation plan containing measures to assess the quality, safety and efficacy of a medicinal product in all subsets of the paediatric population that may be concerned;

Whereas the Commission is proposing that it now be obligatory to propose such a paediatric investigation plan when the disease for which the medicine is developed only occurs in adult populations and the medicine's mechanism of action may be effective against a childhood disease;

Whereas the Commission is proposing that the paediatric investigation plans should be able to be evolutionary and completed as clinical developments progress ("stepwise PIPs");

Considers the incentives proposed by the Commission for the development of paediatric medicines adequate where they can be considered as addressing an unmet medical need or as orphan medicinal products if this is the case;

Approves the abolition of the two-year extension of market exclusivity for holders of an MA for orphan medicinal products for which a paediatric investigation plan has been submitted;

Supports the measures proposed by the Commission to broaden the range of cases where a paediatric investigation plan must be submitted and to develop stepwise paediatric investigation plans.