vfa. Die forschenden Pharma-Unternehmen
Research-Based Pharmaceutical Companies

Comment on the “Critical Medicines Act” regulation proposal

Key demands

- Strengthen technological sovereignty by building strategic production capacities
- Utilize existing data more efficiently to reduce bureaucratic burden
- Significantly limit the collaborative procurement of innovative medicinal products

Introduction

With its proposal for a regulation laying a framework for strengthening the security of supply of critical medicinal products (Critical Medicines Act, CMA), the European Commission pursues the objective of addressing structural weaknesses in the supply of medicinal products in the European Union. The proposed regulation responds to the experiences from the COVID-19 pandemic and aims to sustainably improve the availability and accessibility of so-called “critical medicines” (Union List of Critical Medicines, ULCM) and “medicinal products of common interest” (MPCI).

To achieve these objectives, the CMA provides a comprehensive package of measures, such as expanding European production capacities, diversifying global supply chains, improving the coordination of permit-granting and administrative processes, and introducing joint procurement procedures at the EU level.

The research-based pharmaceutical companies welcome the political goal of increasing the resilience of pharmaceutical supply chains, reducing unilateral dependencies, and ensuring long-term security of supply in Europe. The research-based pharmaceutical companies acknowledge that different product categories (ULCM and MPCI) should allow for targeted policy management.

At the same time, the proposed measures must be carefully designed so as not to inadvertently jeopardize innovative power, competitiveness, attractiveness of locations, and access to innovative medicinal products. The political will to diversify, promote technology, and improve the availability of medicinal products must be combined with a practical, innovation-friendly, and proportionate implementation process.

From the vfa’s point of view, the following are particularly important:

- To strengthen Europe's technological sovereignty in a targeted manner by promoting strategically relevant production and innovation capacities, regardless of company size;
- To make efficient use of existing data sources, specifically the EMVS (European Medicines Verification System), in order to avoid additional bureaucratic burdens and to use resources effectively; and
- To fundamentally restrict collaborative procurement for “medicinal products of common interest” and to accompany the process with protective measures to ensure that innovation and rapid access to innovative medicinal products in Germany are not unintentionally obstructed.

Regarding Article 2, Scope

New provision
The link to the Union List of Critical Medicines (ULCM, Article 131 of the proposed revision of the pharmaceuticals legislation) represents a central component for prioritizing measures within the CMA. Articles 18 to 24 (demand side measures) and the exchange of information on joint procurement initiatives for a specific medicinal product apply to both medicinal products on the ULCM and "medicinal products of common interest" (MPCI), whereas Articles 5 to 17 (conditions for investment) do not apply to MPCI.

Comments
From the perspective of the research-based pharmaceutical companies, it is important that the methodology for identifying these medicinal products in the ULCM be designed to be transparent, evidence-based, and reproducible. Updates should be made with the involvement of all relevant stakeholders, including the pharmaceutical industry.

The newly introduced category of "Medicinal Products of Common Interest" (MPCI) expands the scope of the Critical Medicines Act in a manner that is still largely unclear from the point of view of the research-based pharmaceutical companies. What is missing are additional specific criteria for selecting these products as well as transparent, risk-based assessment procedures for classification. To ensure planning certainty for companies, the methodology and scope of MPCI should be defined clearly and transparently, with the involvement of relevant stakeholders, including those from the pharmaceutical industry, healthcare, and the scientific community.

Recommendations

Updates to the existing Union List of Critical Medicines should be made with the involvement of all relevant stakeholders.

Medicinal products of common interest (MPCI) should be identified based on predictable criteria, transparent methodologies, risk-based assessment procedures, and with the involvement of the pharmaceutical industry, science, and patient representatives.

Regarding Article 3, Definitions, "medicinal product of common interest"

New provision
A "medicinal product of common interest" is a pharmaceutical that is not a critical medicinal product included in the ULCM and for which the functioning of the market in three or more Member States does not sufficiently ensure the availability and accessibility for patients in the quantities and presentations necessary to cover the needs of patients in those Member States.

Comments
The pharmaceutical industry supports the goal of improving the security of supply and access to medicinal products in the European Union. However, the research-based pharmaceutical companies have serious concerns that the definition of "medicinal products of common interest" is too broad and could inadvertently obstruct the availability of innovative therapies, particularly in countries such as Germany where access mechanisms already function well. Without a clear focus on very few specific treatment situations of patients and without a clear link to the actual access problems in the Member States, the definition and the collaborative procurement instruments linked in Articles 21, 22, and 23 harbor the risk of delaying the market launch of innovative pharmaceuticals, restricting the flexibility of market access strategies, and

resulting in price distortions in the Member States.

To ensure that collaborative procurement mechanisms are targeted, the scope of "medicinal products of common interest" should be restricted to medicinal products with a large impact on patient's health in treatment situations of high urgency. Emphasis should also be placed on situations where national procedures cannot ensure the availability of the medicinal product in several Member States with comparable healthcare systems. Here, market failure must be defined based on clear criteria and include time thresholds to ensure that subsidiary national pricing and reimbursement procedures can initially be fully exhausted. Furthermore, innovative or patented medicinal products must in principle be excluded from automatic inclusion in the category, and their inclusion must be subject to the express consent of the manufacturer. Finally, a regular review and impact assessment should be provided before a product is included in this category.

Recommendations

Restrict to medicinal products that offer significant medical benefits for patients in urgent treatment situations.

Limit to comparable access issues in Member States with similar healthcare systems, defining clear criteria for market failure and ensuring that national processes are fully exhausted.

Include innovative or patented medicinal products in this category only with the express consent of the manufacturer.

Ensure regular review and impact assessment is conducted before adding a product to this category.

Regarding Articles 7 through 14, Facilitating administrative and permit-granting processes

New provision

The EU Commission proposes that the "strategic projects" for "critical medicines" in the ULCM recognized under the proposed regulation be given preferential treatment in permit-granting and administrative procedures. The administrative and permit-granting authorities should actively support this, because they are "in the public interest" by increasing security of supply in the EU. The support provided may be administrative, regulatory, or scientific in nature. Special attention is to be paid to small and medium-sized enterprises in this respect. Project promoters of strategic projects may request those environmental assessments be coordinated or carried out jointly in accordance with several EU directives. In this case, the competent authorities shall either coordinate the individual assessments or carry out a single combined assessment.

Comments

The coronavirus crisis has shown that prioritizing permit-granting procedures for critical situations is more important than for individual "critical medicinal products." The general acceleration and flexibilization of permit-granting procedures, including the reduction and streamlining of documentation requirements, must not be abandoned at the expense of individual procedures.

Small and medium-sized enterprises (SMEs) make an important contribution to the resilience of supply chains in individual areas, such as innovation, special technologies, or regional supply. At the same time, the implementation of strategic projects to remedy structural weaknesses in the supply of medicinal products often require considerable technical, regulatory, and logistical capacities. As a result, support measures should be primarily geared to the effectiveness and feasibility of the project in question, regardless of company size. The Commission and Member States should ensure that provisions from environmental and chemical legislation do not affect the production or availability of critical medicines. If significant

regulatory hurdles emerge, a coordinated impact assessment by the Commission will be required, together with an examination of appropriate remedial measures – in close cooperation with the Coordination Group.

Recommendations

In principle, the acceleration and flexibilization of permit-granting procedures should proceed without slowing down individual procedures or creating additional documentation burdens.

Support measures should be oriented on the effectiveness and feasibility of projects, regardless of company size.

Regarding Article 15 and 16, Financial incentives

New provision

The European Commission allows Member States to provide financial support for strategic projects to secure the supply of medicinal products under certain conditions – in line with EU state aid rules (Articles 107 and 108 TFEU). Such projects can also be supported by existing EU programs such as EU4Health, Horizon Europe, or the Digital Europe Program. One of the prerequisites is the presence of a vulnerability in the supply chains, such as a strong dependency on individual manufacturers or regions.

Comments

The research-based pharmaceutical industry welcomes the possibility of financial support for strategic projects aimed at strengthening the security of supply. Existing funding initiatives such as the IPCEI “Med4Cure” already address similar goals. However, to avoid inefficient duplication of structures and an increase in bureaucratic burdens, it is essential that the CMA funding mechanisms be coordinated with existing instruments in a rigorous and practice-oriented manner, particularly with regard to market failure and the promotion of first industrial deployment.

At the same time, the CMA has so far remained vague in its definition of supply chain vulnerability. Clearly defined criteria are necessary for effective and transparent management, e.g., to assess single-source dependencies, geographical risks, or a lack of redundancies in the supply chain. However, it must be ensured that the design of such criteria does not result in complex or rigid administrative processes. The disclosure of economically sensitive supply chain information as part of vulnerability analyses must be strictly subject to confidentiality and IP protection.

To enable consistent, transparent funding decisions, the European Commission and the EMA (European Medicines Agency) should develop standardized assessment procedures with the participation of the pharmaceutical industry and avoid additional bureaucratic hurdles.

Recommendations

The CMA support mechanisms should be coordinated closely and in a practice-oriented manner with existing initiatives to avoid duplication of structures and bureaucratic burdens in a targeted manner.

The definition of supply chain vulnerability in the CMA must be clear and viable in practice, particularly taking into account the special features of innovative medicinal products and vaccines, without leading to rigid or bureaucratic procedures.

Regarding Article 18, Incentivising resilience, sustainability and positive social impacts in public procurement procedures

New provision

In the future, as part of public procurement procedures for “critical medicines,” Member States will apply additional award criteria alongside the price that will contribute to strengthening the security of supply, resilience, and sustainability. These may include requirements for stockholding,

diversification of suppliers, transparency in the supply chain, and commitments to timely delivery. The criteria will be defined in accordance with the EU Procurement Directive 2014/24/EU. In the case of “medicinal products of common interest,” criteria that favor suppliers covering significant production shares within the Union may also be taken into account, provided this is justified by market analyses and in compliance with the EU's international obligations.

Comments

The research-based pharmaceutical companies welcome the approach pursued in Article 18 CMA to establish award criteria that go beyond price alone and to take these into account in public procurement procedures. Applying the MEAT principle (Most Economically Advantageous Tender) to critical medicines is a correct and necessary step. However, the practical effectiveness of this measure will depend on the development of transparent, scientifically sound evaluation criteria and the early and continuous involvement of the pharmaceutical industry in their definition and application, which will enable the comparable and legally certain application in procurement procedures. The criteria must be transparent, proportionate, and developed in close consultation with the pharmaceutical industry in order to avoid barriers to innovation and unnecessary bureaucracy.

When applied correctly, award criteria can make an important contribution to strengthening European production sites and reducing unilateral dependencies in global supply chains. However, the definition of such criteria must not be based on blanket assumptions and must strike a balance between regulatory requirements and administrative effort.

Recommendation

Award criteria should be designed to be practice-oriented and proportionate in order to avoid bureaucracy and barriers to innovation.

Regarding Article 20, Safeguards related to Member States’ contingency stocks requirements and other security of supply measures

New provision

Measures on security of supply applied in one Member State shall not result in any negative impact in other Member States. Member States shall, in particular, avoid such an impact when proposing and defining the scope and timing of any form of requirements for companies to hold contingency stocks.

Member States shall ensure that any such requirements they impose on companies in the supply chain are proportionate and respect the principles of transparency and solidarity.

Comments

The proposal that national safeguarding measures such as national stockpiling requirements should not have adverse impacts in other Member States is expressly welcomed. This strengthens the principle of free movement of goods and counteracts protectionist tendencies.

Article 20, which deals with stockpiling requirements, addresses a key issue. Stockpiling requirements, both at the EU and national level, should basically only be applied in exceptional cases, on a risk-based basis and after evaluating alternative measures, since stockpiling can artificially exacerbate or prolong supply shortages. Instead, the production and distribution system itself provides buffers at all levels of trade. With knowledge of the medicinal products in circulation, these can be used as reserves in the event of a crisis and replace expensive centralized warehousing.

A European early warning system based on the EMVS (European Medicines Verification System) data can generate sustainable resilience. The simplification of regulatory hurdles to strengthen supply chain agility (e.g., introducing electronic patient information or exemptions from labeling in the national language) is part of the solution.

In this respect, a common understanding of responsibilities along the entire supply chain is essential. The pharmaceutical industry, wholesalers, pharmacies, and other stakeholders must be equally involved when it comes to assessing stockholding obligations, the ability to deliver, and emergency mechanisms.

The pharmaceutical industry is actively contributing suggestions for solutions, in particular through the vfa's five-point plan against supply bottlenecks. Its guidelines should also be relevant for drafting Article 20.

Recommendations

Use EMVS data to develop a European early warning system that fosters sustainable resilience, rather than relying on national stockpiling.

Integrate electronic patient information as a core component of supply strategies.

Regarding Article 21, 22, and 23, Collaborative procurements

New provision

The Regulation stipulates a number of instruments for collaborative procurement. Article 21 governs cross-border procurement of medicinal products of common interest at the request of three or more Member States, facilitated by the Commission. Article 22 regulates procurement by the Commission on behalf of or in the name of Member States, if nine or more Member States jointly request the Commission to do so. Article 23 regulates joint procurement by the Commission on behalf of nine or more requesting Member States OR on the initiative of the Commission, so that the Commission and the Member States can participate in joint procurement procedures as contracting parties. Procurement pursuant to Articles 22 and 23 may concern critical medicines with vulnerable supply chains OR medicinal products of common interest for which a joint clinical assessment report of European Health Technology Assessments (EU-HTA) has been published.

Comments

The new regulation promises opportunities for improving the availability of critical medicines. However, it also entails considerable risks for research-based pharmaceutical companies, particularly regarding pricing, competitive conditions, and market incentives in the European Union, which could inadvertently obstruct innovation and access to innovative medicinal products in countries such as Germany. In addition, there are significant risks to the attractiveness of the German market (including through an increase in parallel trade) and major risks of misuse of procurement options as cost-containment instruments, which would further weaken the competitiveness of the European Union.

Collaborative procurement instruments should therefore not be designed as a universal solution to address access problems in the European Union regarding medicinal products of common interest but must be focused on very few specific situations. To this end, the rules must be precisely tailored and accompanied by safeguards. The scope of medicinal products of common interest must be limited to very specific treatment situations of high urgency and impact for EU patients and ensure a voluntary mechanism for the manufacturer's consent to list the product (see comment Article 3). Further, collaborative procurement must be restricted to a clearly defined group of Member States with comparable access problems and health care systems, where procurement offers real added value compared to national mechanisms that have already been exhausted. It must be ensured that the procurement of medicinal products of common interest does not extend beyond the Member States that are facing access problems. At the same time, the confidentiality of procurement prices must be ensured, price differentiation according to the ability to pay must be facilitated, and the negative effects of parallel trade in the European Union, particularly to Germany, must be avoided. In addition, alongside the price, qualitative aspects and value-based criteria should be considered in procurement, to protect

competition and the sustainability of the supply chain.

The cause of differences in access to new therapies in the European Union lies in the different national price-setting and reimbursement procedures as well as existing restrictions in national health care systems. Collaborative procurement carries the risk of distracting from more sustainable solutions and implementable reforms at the national level, which are, however, essential for overcoming the challenges. That is why there is a continued need for dialogue between decision-makers at the EU and national level and stakeholders to develop evidence-based, proportionate and tailored solutions for the different Member States.

Through EFPIA, their European umbrella organization, the research-based pharmaceutical companies remain strongly committed to reducing inequalities in access to medicinal products in Europe. In April 2022, EFPIA and its member companies committed to a series of measures and proposed solutions, including (1) a voluntary commitment by the pharmaceutical industry to submit applications for price-setting and reimbursement in all EU countries no later than two years after EU marketing authorization (if local conditions allow), (2) the establishment of a European access portal to improve the visibility of access to medicinal products in the EU and to identify the causes of unavailability and delays, and (3) a conceptual framework for equity-based tiered pricing to take into account the ability to pay in different countries when setting prices for medicinal products.

Recommendations

Restrict procurement to a clearly defined group of Member States with comparable access challenges and healthcare systems.

Ensure confidentiality of procurement prices to prevent impacts on other markets.

Prevent parallel trade within the European Union, particularly to Germany.

Allow price differentiation based on the participating Member States' ability to pay.

Incorporate qualitative and value-based criteria in the procurement process.

Regarding Articles 25 and 26, Critical Medicines Coordination Group

New provision

Articles 25 and 26 of the proposed regulation provide for the establishment of a "Critical Medicines Coordination Group" to ensure strategic guidance and coordination at the EU level under the leadership of the European Commission. The group will be composed of representatives of the Member States and the Commission. Its tasks will include coordinating national procurement strategies, preparing joint initiatives, supporting strategic funding measures, and prioritizing medicinal products in the context of vulnerability analyses. The goal is to improve European cooperation to ensure the supply of critical medicines while preserving the internal market.

Comments

The research-based pharmaceutical industry recognizes the need for coordination on critical medicines. The pharmaceutical industry and other relevant stakeholders should be permanently involved in coordination so that practical knowledge, market expertise, and innovation perspectives can be incorporated in policy measures at an early stage. Professional associations, patient representatives, and the pharmaceutical industry should be particularly involved. From the perspective of the research-based pharmaceutical companies, the existing Critical Medicines Alliance lends itself as a suitable platform.

Recommendations

Involve relevant stakeholders in coordinating critical medicines.

Utilize the existing Critical Medicines Alliance as a centralized platform rather than creating a new coordination group.

Regarding Article 27, International cooperation

New provision
The Commission is tasked with exploring the possibilities of “strategic partnerships.” In doing so, it is to draw on existing partnership structures.

Comments
The mandate does not indicate to what extent the Commission has actually exhausted existing powers and institutions for initiating international cooperations. With a view to focusing on priorities, the Commission should work harder on implementing existing strategies rather than exploring new models of cooperation. The CMA should help avoid uncoordinated relocation measures that could disrupt global pharmaceutical markets.

Recommendation

Make systematic use of existing powers and institutions for international cooperation.

Regarding Article 29 through 31, Final provisions

New provision
The Commission requires marketing authorization holders and “other economic operators” to provide data on their supply and logistic chains (including precursors, excipients and packaging) upon request to the Commission and national authorities designated for the implementation of the Regulation.

Comments
Even though the Commission promises not to impose duplicate requirements on pharmaceutical companies and also promises full confidentiality, the associated bureaucratic burden and the risk of a disclosure of trade secrets are disproportionately high. The planned information obligations for market participants pursuant to Article 29 should therefore be limited to existing regulatory reporting formats (e.g., the European Shortages Monitoring Platform (ESMP) or the EMVS) and to one institution (either the EMA or the EU Commission). Further reporting obligations that could arise from the CMA must be avoided in line with the announced “once only” reduction of bureaucracy.

Recommendations

The information requirements provided for in the CMA should be systematically limited to existing reporting formats in order to avoid additional bureaucracy.

The protection of trade secrets must be strictly guaranteed.

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