Critical Medicines Act Factsheet

Critical Medicines Security Fund

Strengthening industrial competitiveness through a Critical Medicines Security Fund and flexible state aid rules

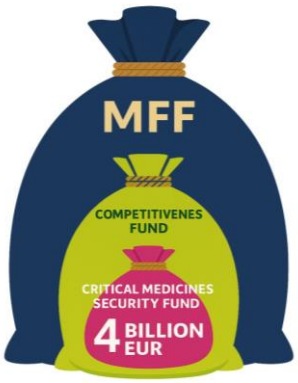
In line with the Critical Medicines Alliance strategic report, an ambitious European investment plan is needed to strengthen production capacities for critical medicines in Europe with EU-level coordination.

It should rely on a combination of an EU funding programme and dedicated state aid guidance allowing support for **strategic projects to increase capacity and for innovative production processes, also via environmental and digital upgrades.** Funding solutions should be simple, fast and clear, and we support the idea of a "**one-stop-shop**" system as proposed by the CMA Strategic Report.

The Commission should support companies and one designated authority in the Member States by introducing a streamlined, **fast-track approval process** with reduced bureaucracy, higher grant thresholds, and flexibility on standard aid ceilings to incentivise investments in production capacity that address supply chain vulnerabilities for **critical medicines strategic projects**.

Need for a Critical Medicines Security Fund in the Multiannual Financial Framework (MFF)

To encourage private sector investment in medicine manufacturing in Europe, the EU should allocate **€4 billion under the MFF with a dedicated "critical medicines security fund"** to support upgrades to security of supply or environmental improvements and **for approximately 150 production sites in Europe*** and could facilitate the "reshoring" of a limited number of molecules of national security interest to the EU.



Need for new state aid guidance for off-patent medicines production

The state aid guidance that accompanies the Critical Medicines Act does not address the specific barriers that off-patent medicine manufacturers face regarding State aid, including IPCEI and regional aid. The Commission must revise these guidelines and make them fit for purpose to support:

MITIGATING GEOPOLITICAL RISKS
through reshoring production

INCREASING EXISTING PRODUCTION
through automation and innovation

BOOSTING EFFICIENCY
to reduce reliance on resources

* Calculation based on: Commission approves €28.8 million Austrian support, times 150 projects, rounded down to 4 billion.

Current aid instruments fail to secure the supply of critical medicines

None of the potential aid instruments listed by the State aid guidance are sui- table to increase security of supply of critical medicines in a significant manner.

- Instruments such as **Important Projects of Common European Interest (IPCEI)** not only have length and not harmonised administrative burdens across Member States, but they are also limited to innovation for new molecules. defined in a narrow way and are therefore not suitable for generic medicines, which make up 9 out of 10 medicines on the critical medicines list[2]. In line with the Draghi report, the definition of innovation should be expanded, in the case of off-patent medicines to **innovative manufacturing processes.**
- **Regional aid** requires the investment to be made in an underdeveloped region, which is often not feasible for generic medicine producers who operate under narrow margins.
- The **Services of General Economic Interest (SGEI)** framework is also not well-suited to support critical medicine manufacturing due to its restrictive nature, particularly the imposition of Public Service Obligations (PSOs) on private providers, which reduce

A dedicated State aid framework is essential to secure European critical medicines production

To strengthen European production of critical medicines, we need **dedicated State aid guidelines** for securing European critical medicines production.

A new State aid instrument should be created, tailored to the unique characteristics of the sector, especially the need to address supply chain resilience, and should include clear and sector-specific criteria for State aid compatibility. This approach would not only provide targeted support to critical investments but also ensure legal certainty for both Member States and producers, avoiding the risk of overenforcement that can arise from ad hoc or fragmented application of the existing rules, and which can discourage investments in Europe.

A targeted GBER exemption could accelerate support for critical medicines production

As an additional or alternative option, the Commission could consider introducing a **new exemption category under the General Block Exemption Regulation** (GBER) for aid granted to producers of critical medicines, as was done in 2023 for key sectors aligned with the Green Deal Industrial Plan[3]. A targeted GBER amendment for critical medicines would similarly facilitate, simplify, and speed up the granting of aid in a sector essential to public health and strategic autonomy.

(1) See the Union List of Critical Medicines: Union list of critical medicines | European Medicines Agency (EMA).

(2) Commission Regulation (EU) 2023/1315 of 23 June 2023 amending Regulation (EU) No 651/2014 declaring certain categories of aid compatible with the internal market in application of Articles 107 and 108 of the Treaty and Regulation (EU) 2022/2473 declaring certain categories of aid to undertakings active in the production, processing and marketing of fishery and aquaculture products compatible with the internal market in application of Articles 107 and 108 of the Treaty.

(3) See https://ec.europa.eu/commission/presscorner/detail/en/ip_23_1523

In addition, the definition of innovation in IPCEI should be adjusted in relation to critical medicines to make the instrument applicable to off patent medicine production, in line with the Draghi report:

''First-of-a-kind facility' means a new or substantially upgraded active pharmaceutical ingredient or finished dosage form (medicine) manufacturing facility, or a facility for the production of other critical components (key starting materials, key intermediates) predominantly used in medicine or active pharmaceutical ingredient manufacturing, which provides innovation with regard to the manufacturing process or final product that is not yet substantively present or committed to be built within the Union, including innovation that concerns improvements in automation, continuous manufacturing, yield improvements or other chemistry or biotechnology processes that contribute to an increase in the level of security, safety or reliability, energy and environmental performance of the production process or site, that would enable the reintroduction into Europe of production that would be compliant with EU chemical, biotechnological or environmental regulations (whereas it may not be compliant in productions outside of Europe), or in the implementation of production processes or other investments on the site that reduce energy, solvents, waste or water resource use in resource intensive chemical or biotechnological processes.

MEDICINES FOR EUROPE **RECOMMENDATIONS:**

ARTICLES 7, 15 and 16 OF THE COMMISSION PROPOSAL: STATE AID AND EU FUNDING

1. The regulation should introduce a **"one-stop-shop"** to coordinate European and national funds on critical medicines and to streamline the fast-track approval process with reduced bureaucracy (Article 7).
2. The **MFF should allocate €4 billion to medicine manufacturing** to support upgrades for security of supply or environmental improvements to approximately **150 production sites in Europe** which could facilitate the "reshoring" of a limited number of molecules of national security interest to the EU (Article 16).
3. The European Commission should issue **new *ad hoc* State aid and regional aid guidelines** specific to critical medicines for financing projects that are aimed to improve the security of supply of medicines in Europe in terms of capacity (increased manufacturing of medicines in Europe) and in terms of innovative manufacturing processes (improved manufacturing of medicines in Europe) (Article 15).