Council of the European Union

Brussels, 10 September 2026
(OR. en)

12972/26

SAN 648
PHARM 150
PROCIV 172
IND 537
RECH 357
MAP 169
IPCR 83
POLMIL 366
RELEX 1138
COMPET 1049

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	9 September 2026
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2026) 262 final
Subject:	COMMISSION STAFF WORKING DOCUMENT Handbook for EU Crisis Procurement of Medical Countermeasures

Delegations will find attached document SWD(2026) 262 final.

Encl.: SWD(2026) 262 final

EUROPEAN
COMMISSION

Brussels, 9.9.2026
SWD(2026) 262 final

COMMISSION STAFF WORKING DOCUMENT

Handbook for EU Crisis Procurement of Medical Countermeasures

This document is a staff working document of the European Commission. It does not represent an official position of the Commission and is not legally binding. The views expressed are those of the authors and do not necessarily reflect the official views of the European Commission.

List of abbreviations

APA	Advance Purchase Agreement
ATHINA	Advanced Technology for Health Intelligence and Action IT System
CBRN	Chemical, biological, radiological and nuclear
ECDC	European Centre for Disease Prevention and Control
EMA	European Medicines Agency
EP	European Parliament
ERCC	Emergency Response Coordination Centre
ESI	Emergency Support Instrument
EU-FAB	EU's manufacturing capacity reservation network
EWRS	Early Warning and Response System
HERA	Health Emergency Preparedness and Response Authority
IPCR	Integrated Political Crisis Response
JPA	Joint Procurement Agreement
JPASC	Joint Procurement Agreement Steering Committee
PA	Purchase Agreement
PPE	Personnel Protective Equipment
SPPSC	Specific Procurement Procedure Steering Committee

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1. Introduction

This Handbook is designed to present a comprehensive overview of the different approaches available at EU level for the procurement of medical countermeasures in a health crisis, along with an explanation of some of key features of the framework within which such procurement will take place.

Medical countermeasures ([1]) – including vaccines, therapeutics, diagnostics, medical devices, as well and personnel protective equipment (PPE) – are essential products for Europe to respond to a future public health crisis. The European Commission's medical countermeasures strategy ([2]) set out four major threat categories that can be addressed by means of medical countermeasures:

- respiratory or contact-based viruses with pandemic potential;
- vector-borne or animal-reservoir viruses with epidemic potential;
- antimicrobial resistance; and
- armed conflict related and chemical, biological, radiological and nuclear (CBRN) threats.

During a health crisis, medical countermeasures are critical for the people's lives, basic societal functions and security. During the COVID-19 pandemic, people without access to PPE could not work safely. Access to vaccines was one of the key elements in being able to save lives and remove social and economic restrictions. The medical countermeasures needed to address the COVID-19 pandemic proved to be strategically vital products.

Whilst this document deals with crisis procurement, procurement is also a crucial tool for stimulating or securing production of medical countermeasures during periods of preparedness, so that they are more readily available in the event of a crisis. The Commission's proposal today to revise the EU's public procurement framework is an important step forward in making public procurement simpler and more effective.

Alongside that proposal, the present staff working document covers procurement of medical countermeasures at EU level, carried out by EU institutions on the basis of the EU's Financial Regulations and the relevant sectoral legislation (see section 2 below) ([3]). This Handbook explains the functioning of the framework for procuring medical countermeasures at EU level.

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[1] Defined in Article 3(10) of Regulation 2022/2371 as "medicinal products for human use as defined in Directive 2001/83/EC of the European Parliament and of the Council, medical devices as defined in point 12 of this Article and other goods or services that are necessary for the purpose of preparedness for and response to serious cross-border threats to health."

[2] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Preparing the EU for the next health crisis: a Medical Countermeasures Strategy, COM/2025/529 final of 9 July 2025, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025DC0529

[3] Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union (recast), available at: http://data.europa.eu/eli/reg/2024/2509/oj

The focus of the document is on crisis procurement, and it is structured accordingly, starting with the framework that operates during a public health emergency.

It confirms the strategic role of public procurement as a key instrument for building a more resilient EU in times of crisis as set out prominently in the Niinisto report ([4]), the European preparedness union strategy ([5]), the medical countermeasures strategy ([6]), and the Union prevention, preparedness and response plan for health crises ([7]).

In this context, it should be noted that two of the three procurement approaches set out in the Handbook are also available for use outside of a public health emergency, and can equally be used strategically to build EU resilience during phases of crisis preparedness ([8]).

The legal and administrative framework for procuring medical countermeasures in a crisis at EU level has evolved significantly (see Section 2, below). Establishing a common understanding of how it operates will help to improve both the speed and quality of the EU's response in the early stages of a future crisis.

This document has four sections. Section One provides the historical background of EU-level crisis procurement, along with some considerations on how it may optimally be used at present. Section Two details the overall framework for crisis procurement, including the activation and operation of 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 ([9]), and the identification of targets for procurement. Section Three outlines the operation of the three different potentially available procurement approaches, along with considerations on when they may best be used. Finally, Section Four covers other important aspects relevant to procurement, including funding, the EU's network of ever-warm production facilities (EU-FAB), and transparency.

[4] https://commission.europa.eu/topics/defence/safer-together-path-towards-fully-prepared-union_en

[5] https://commission.europa.eu/topics/preparedness_en

[6] See footnote 2.

[7] https://health.ec.europa.eu/publications/commission-communication-introducing-union-prevention-preparedness-and-response-plan-health-crises_en

[8] These two approaches being 'Commission acting as a wholesaler' and 'joint procurement', both of which are set out in more detail later in this Handbook.

[9] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022R2372

2. EU-level procurement of medical countermeasures over time

The Decision on serious cross-border threats to health ([10]) adopted in 2013 provided the first legal basis for EU institutions and any Member State which so desired to engage in joint procurement of medical countermeasures to address serious cross-border threats to health. The operational framework was established in April 2014 through the Commission Decision approving the Joint Procurement Agreement (JPA) ([11]). The Commission and 14 EU Member States ([12]) signed the JPA in June 2014, and it entered into force in 2015. The JPA has since been used for a number of procurements, for example in 2024 to procure diphtheria antitoxin and in 2022 and 2025 to procure pandemic influenza vaccines.

Participation in the JPA has been expanded over time to include all Member States and the wider EU neighbourhood ([13]).

Early in the COVID-19 pandemic, the Commission proposed a vaccines strategy to support the development and manufacturing of COVID-19 vaccine candidates, and to ensure access to those vaccines for EU Member States. To that end the Commission and Member States agreed to design a specific procurement approach, using as a legal base the Emergency Support Instrument (ESI), which had been activated by Council Regulation (EU) 2020/521 ([14]). This procurement approach (explained in more detail below) was designed to facilitate rapid procurement in a crisis situation, and involved, inter alia, a mandate for the Commission to sign contracts on behalf of Member States than that contained in the JPA ([15]). This approach was then used to purchase COVID-19

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[10] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC, at https://eur-lex.europa.eu/eli/dec/2013/1082/oj

[11] https://health.ec.europa.eu/publications/commission-decision-c2014-2258-final_en

[12] Belgium, Croatia, Czechia, Cyprus, Estonia, Greece, Latvia, Matla, Netherlands, Portugal, Slovakia, Spain, and the United Kingdom(*).

(*) Following the UK's withdrawal from the EU, and in line with the Withdrawal Agreement, the contracting authorities from the UK could participate in specific joint procurement procedures that implement Union programmes and activities committed under the 2014-2020 Multiannual Financial Framework or previous financial frameworks.

[13] EU Member States, Albania, Bosnia and Herzegovina, Iceland, Kosovo*, Liechtenstein, Moldova, Montenegro, North Macedonia, Norway, Serbia, Ukraine.

* This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

[14] Council Regulation (EU) 2020/521 of 14 April 2020 activating emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak.

[15] The Commission was mandated to sign contracts on behalf of Participating Member States who had five working days from the Commission's announcement of its intention to sign a given contract to decide whether or not they wished to participate in it.

vaccines ([16]). At the same time, the JPA was used to procure a range of PPE to protect healthcare workers, and laboratory equipment, medical devices, therapeutics and diagnostics to diagnose and treat patients ill with severe COVID-19 disease, to support participating countries in their efforts to contain and mitigate the pandemic in line with relevant EU policies and strategies ([17]).

Since the end of the pandemic, the countries participating in the JPA have again used the joint procurement mechanism to conclude preparedness contracts for medical countermeasures, such as contracts for pre-pandemic and pandemic influenza vaccines, and for mpox vaccines and therapeutics. Joint procurement has also ensured security of supply of a range of COVID-19 vaccines through contracts for the supply of mRNA and protein-based COVID-19 vaccines.

During the 2022 and 2024 mpox outbreaks, the Commission, acting as a wholesaler under Article 9(1)(c) of Regulation (EU) 2021/522 (the EU4Health Regulation) purchased vaccines on its own account for the first time to donate them to Member States (2022) and partner organisations (2024, to Africa Centres for Disease Control and Prevention (Africa CDC)). This purchase was possible as funds had been set aside for such a purpose under the EU4Health programme.

Two pieces of legislation affecting the EU's crisis procurement framework for medical countermeasures have been adopted within the European Health Union framework:

- 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 (hereinafter: Regulation on serious cross-border threats to health);
- 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 (hereinafter: Emergency Framework Regulation).

[16] Joint procurement was used towards the end of the acute phase of the pandemic for one further COVID-19 vaccine.

[17] https://commission.europa.eu/strategy-and-policy/coronavirus-response/public-health/ensuring-availability-supplies-and-equipment_en#public-procurement-of-medical-and-protective-equipment

Commission Recommendation (EU) 2020/1595 of 28 October 2020 on COVID-19 testing strategies, including the use of rapid antigen tests, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020H1595

Commission Recommendation (EU) 2020/1743 of 18 November 2020 on the use of rapid antigen tests for the diagnosis of SARS-CoV-2 infection, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020H1743

Council Recommendation EU 2021/C 24/01 on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021H0122(01)

Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 6 May 2021 on EU Strategy On Covid-19 Therapeutics, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021DC0355&qid=1784274587748

Corrigendum https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021DC0355R(01)

Furthermore, a recast of the EU's Financial Regulation, which constitutes the basis for all EU-level procurement activity and contains provisions relevant for crisis procurement, has entered into force in September 2024.

Finally, in November 2025, the Commission adopted the Union prevention, preparedness and response plan for health crises ([18]), to promote an effective and coordinated response to cross-border threats to health at EU level. That plan is the EU's blueprint for action on serious cross-border health threats.

3. Procurement at EU level: the strategic dimension

Most crisis-relevant medical countermeasures are likely to be procured at the level of Member States, while procurement at EU level (encompassing three different procurement approaches, set out in section three, below) can complement national efforts in addressing specific crisis situations. To illustrate this, it is worth recalling some of the rationales behind specific procurements that have taken place in the past.

One of these factors is **scarcity of supply**. In a situation where there is limited supply of a given medical countermeasure, there is a need to avoid competition between Member States and ensure equity of access.

Security of supply is also an area where the EU's scale can make a difference. Incentivising manufacturers to invest in EU-level production may be easier to do on the basis of orders at scale, which the EU can do by aggregating Member State demand in a procurement process.

Another factor is the need to maximise the possibilities for Member States to have rapid access to a successful product where the **medical countermeasures needed are still under development**. This is best illustrated by the approach taken during the COVID-19 pandemic. As it was not known which of the candidate vaccines, if any, would be successful, it was judged best to take a 'portfolio' approach, signing procurement contracts for a number of candidate vaccines on behalf of all Member States. If the EU-level procurement had not taken place, it is doubtful whether all Member States would have been able to put a similarly broad portfolio approach in place, meaning that some would have risked undersupply (or even not having a successful vaccine at all).

The EU may also be able to leverage its scale to secure better **terms and conditions** in negotiations, for example on price, favourable delivery schedules, or rapid access to adapted versions of a given medical countermeasure.

The **negotiating capacity of manufacturers** must also be considered. There have been situations where a given manufacturer would not have been able to negotiate procurement contracts with all EU Member States simultaneously. In this case, EU-level procurement enables the manufacturer to deliver to all Member States via one procurement process.

[18] See footnote 7.

This is a non-exhaustive list based on previous experience, which points to the type of situations where EU-level procurement could be a viable option.

The choice of whether to use one of the procurement approaches at EU level will also take into account the nature and severity of the threat the EU is facing. In particular, EU-level procurement would be a useful tool to address any of the priority threats to health: pandemic viruses, epidemic viruses, antimicrobial resistance, armed conflict and CBRN-related threats.

While this staff working document focuses on procurement during a health crisis, this section could also be taken into consideration in non-crisis periods to improve the EU's ability to respond to a future health crisis.

Section Two: Crisis procurement of medical countermeasures: general framework

This section sets out the overall framework within which crisis procurement is most likely to take place. Whilst it is not a 'given' that the emergency framework under the Emergency Framework Regulation would be activated, it can be activated if there is a public health emergency at Union level where that is appropriate to the economic situation, taking into account the need to ensure a high level of protection of human health. Since this will significantly affect both the governance of procurement and, potentially, the number and type of procurement approaches available, this Handbook sets out the activation and operation of that Regulation in detail.

The section also sets out how potential procurement targets will be identified.

4. Activation of the emergency framework under the Emergency Framework Regulation

The following section sets out the activation process in some detail.

Institutional steps for activating of the Emergency Framework Regulation

A pre-condition for activating the Emergency Framework Regulation is the recognition of a public health emergency at Union level through an implementing act adopted by the Commission, under Article 23 of the Regulation on serious cross-border threats to health.

Subsequently, following the recognition of a public health emergency at Union level by the implementing act, the Commission may propose that the Council adopt a regulation activating the emergency framework and crisis-relevant measures, where that is appropriate to the economic situation (Article 3(1) of the Emergency Framework Regulation).

In accordance with Article 3(3) of the Emergency Framework Regulation, the proposal for a Council regulation must specify which of the following Emergency Framework Regulation measures should be activated ([19]):

- a mechanism for monitoring crisis-relevant medical countermeasures (Article 7);
- the procurement, purchase and manufacturing of crisis-relevant medical countermeasures and raw materials (Article 8);
- the emergency research and innovation aspects of the preparedness and response plans and the use of clinical trial networks and data-sharing platforms (Article 9);
- an inventory of crisis-relevant medical countermeasure production and production facilities (Article 10);
- an inventory of crisis-relevant raw materials, consumables, medical devices, equipment and infrastructure (Article 11);
- measures to ensure the availability and supply of crisis-relevant medical countermeasures (Article 12);
- emergency funding (Article 13).

The proposal for a Council regulation may contain any or a selection of these measures, depending on the situation. For the procurement of medical countermeasures, Article 8 and potentially Article 13 of the Emergency Framework Regulation are the most relevant.

Once the Commission has put forward a proposal for a Council regulation, the timeliness of the Council adoption of that regulation is key for the EU's ability to respond to the crisis, not least as there are further steps to be taken once the Emergency Framework Regulation has been activated – most notably the conclusion of a framework agreement between Commission and Member States that is necessary for the Commission to act as a central purchasing body for crisis-relevant medical countermeasures on behalf of the Member States in accordance with Article 8(2) of the Emergency Framework Regulation.

It is important to note that neither the implementing act, nor the proposal for a Council regulation will arrive in a vacuum. In practice, the epidemiological situation, the implications in terms of the required medical countermeasures and the probable needs of Member States will have been discussed between the Commission and the Member States in the relevant fora (the Health Security

[19] The order of the Articles is as per the Regulation 2022/2372 and does not represent an order of priority or sequencing.

Committee, the HERA Board ([20]), the Steering Committee of the JPA, potentially also the Integrated Political Crisis Response (IPCR)([21]) mechanism) before these formal steps are taken. Where necessary, depending on the type of incident, consultations with the relevant security mechanisms, and particularly NATO and the European External Action Service, would take place.

Point 7 below contains more detail on the identification of potential targets for procurement in these early stages.

These measures may be proposed for a maximum period of six months with the possibility of prolonging them for another period of maximum six months, following a report from the Commission (Article 4(1) of the Emergency Framework Regulation) and a corresponding proposal from the Commission. There are no limits as to how many times the Commission may propose such a prolongation.

If the Council does not activate all potential Emergency Framework Regulation measures in one regulation, it may decide to activate additional measures at a later stage on the basis of a proposal from the Commission.

5. The Health Crisis Board

Composition and role

Where the Council activates one or more of the Emergency Framework Regulation measures set out above, Article 5 of the Emergency Framework Regulation requires the Health Crisis Board to be set up for coordinating action by the Council, the Commission, relevant EU bodies and Member States to ensure the supply of and access to crisis-relevant medical countermeasures.

The Health Crisis Board will consist of representatives from the Commission and one representative from each Member State. The Director of the European Centre for Disease Prevention and Control (ECDC), a representative of the Advisory Committee on public health emergencies, and a member of the Health Security Committee will also be invited as observers to the Health Crisis Board. Other relevant experts may be invited as appropriate.

The Health Crisis Board will be co-chaired by the Commission and the Member State holding the rotating presidency of the Council.

The Health Crisis Board assists and guides the Commission in preparing and implementing measures to be taken pursuant to Articles 7 to 13 of the Emergency Framework Regulation (when

[20] https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/overview/hera-board_en

[21] https://www.consilium.europa.eu/en/resources/publications/the-eu-integrated-political-crisis-response-ipcr-arrangements/

activated). It is thus the forum in which Member States give their advice on all matters relating to ensuring the supply of and access to medical countermeasures for responding to the public health emergency. This includes in particular the following aspects:

- identifying the medical countermeasures which are relevant in the specific crisis;
- selecting medical countermeasures to be procured at EU level, either by activating or expanding existing contracts, or by negotiating new contracts;
- choosing the EU-level procurement approach for each identified medical countermeasure;
- drawing up the provisions of the framework agreement between Member States and the Commission where the establishment of the approach 'Commission acting as a central purchasing body on behalf of Member States' under Article 8(2) of the Emergency Framework Regulation is envisaged (see below);
- providing support to the Commission in preparing procurement procedures as well as negotiating the purchase agreements; in practice this may include advising on the priorities and needs in any given procurement procedure and negotiation;
- providing advice to the Commission on sensitive horizontal issues affecting procurement, for example on an overall approach to indemnification and liability, where this is appropriate.

The Health Crisis Board will act in close coordination with the Health Security Committee to facilitate prompt and efficient information sharing. It will also coordinate and exchange information with the IPCR structures, and the Emergency Response Coordination Centre (ERCC).

Member States' representatives

One of the critical early arrangements that Member States will need to put in place is the nomination of their representative to the Health Crisis Board and the provision of supporting staff. These arrangements could have a major impact on the effective functioning of any crisis procurement activity at EU level.

For the Health Crisis Board to function effectively, it will be important that Member States' representatives are nominated quickly and equipped with a mandate covering the above matters. This mandate will be a critical factor for the Board's ability to act swiftly.

Past experience from EU-level procurement procedures suggests that a mix of expertise from Member States, covering procurement, medical, legal, logistical, pharmaceutical, research and regulatory aspects will be optimal. In the event of a health crisis where both civilian and military capabilities are engaged, there may be security aspects that need to be covered. As well as ensuring that the Health Crisis Board member has expertise or knowledge of at least one relevant area, Member States could therefore consider what human resources they will make available to support their Health Crisis Board member, and thereby the Health Crisis Board as a whole, in performing its tasks.

The Commission may decide to set up working groups within the Health Crisis Board dealing, for example, with scientific aspects of the medical countermeasures in question. In this case, nominated national officials could provide direct input via these working groups.

Where joint procurement is used during a period of crisis, the Health Crisis Board will liaise closely with the Joint Procurement Agreement Steering Committee (JPASC) and/or the respective Specific Procurement Procedure Steering Committee(s) (SPPSC) (see below).

Procedural aspects

The Health Crisis Board secretariat will be provided by the Commission. The Board will adopt its own rules of procedure in the first Board meeting, on the basis of a proposal provided by the Commission.

Either of the Board's co-chairs can convene a meeting, either on their own initiative, or at the request of a Member State. Joint meetings of the Board with other fora (e.g. the Health Security Committee) may be convened to discuss matters falling within their respective areas of responsibility and to ensure rapid exchange of information.

The Health Crisis Board may issue opinions upon the request of the Commission or on its own initiative. This should be done by consensus where possible. If consensus cannot be reached, the Board will deliberate by a two-thirds majority of the Member State representatives.

The Health Crisis Board and any working groups it has set up will cease to operate when all of the Emergency Framework Regulation measures that have been activated expire or are de-activated by the Council, or when there is no longer a public health emergency at Union level ([22]). Procurement contracts signed during the Board's period of operation may continue past this point; the Commission and Member States will need to put in place appropriate arrangements for ongoing governance of those contracts where this will not be undertaken under the respective/appropriate standing/existing mechanisms.

6. Identification of medical countermeasures as potential targets of EU-level procurement

As part of its intelligence gathering functions, the Commission, in cooperation with the ECDC and the European Medicines Agency (EMA), continuously reviews its threat prioritisation ([23]), and identifies suitable medical countermeasures to address the most serious cross-border health threats for the EU.

[22] This being confirmed by the Commission terminating its previous recognition of such an emergency; see Article 23 of Regulation 2022/2371.

[23] https://health.ec.europa.eu/document/download/147630e7-835a-40cc-96d4-e0dc44707396_en?filename=hera_wd-health-treat-prioritisation-assessment_en.pdf

The medical countermeasures strategy sets out that an EU list of medical countermeasures for priority threats will be drawn up in 2026 in collaboration with Member States. The EU list of medical countermeasures for priority threats is intended to cover both marketed and medical countermeasures in development (including but not limited to medicinal products) to address specific threats with the potential to create a public health emergency. The list complements the Union list of critical medicines which identifies human medicines whose continued supply is considered a priority in the EU. The list of medical countermeasures for priority threats may serve as the basis for defining the specific list of crisis-relevant medical countermeasures that may be established to monitor supply and demand under the Emergency Framework Regulation (Article 7). Depending on the nature of the public health emergency, the specific list may need to be reviewed and updated.

Once a signal of a potential serious cross-border threat to health is detected through public health intelligence or notified through the Commission's early warning systems (e.g. the Early Warning and Response System EWRS ([24]), or, for radiological and nuclear incidents, ECURIE ([25])), it will be assessed to determine whether specific actions should be taken (See the Union prevention, preparedness and response plan for health crises ([26])). Notably, the Commission will assess the need to coordinate the medical countermeasures response at EU level. If EU-level action on medical countermeasures is needed, the Commission will seek advice from the HERA Board, where relevant. Depending on the event and the availability of medical countermeasures (including in the rescEU ([27]) Medical and CBRN Stockpiles), an ad hoc meeting of the HERA Board can be convened to assess the demand for and availability of crisis-relevant medical countermeasures and to discuss the actions (e.g. EU-level procurement) that the Commission and/or the Member States could take to support the availability of and equitable access to those medical countermeasures.

Early coordination via the HERA Board and other relevant structures such as the Health Security Committee will ensure that the Commission and Member States have sufficient information about the supply and demand of the products deemed to be relevant for the crisis at hand, also in view of considering any potential purchase pursuant to Article 8 of the Emergency Framework Regulation. The discussions would also aim to establish Member States' current and future needs, which may be similar or divergent (depending on, for example, existing procurement arrangements and stockpiles in place), thus ensuring a shared understanding of the state of the market and supply chains for the medical countermeasure under discussion.

[24] Article 19 and Article 23 of Regulation (EU) 2022/2371 on serious cross-border threats to health.

[25] 87/600/Euratom: Council Decision of 14 December 1987 on Community arrangements for the early exchange of information in the event of a radiological emergency, at https://eur-lex.europa.eu/eli/dec/1987/600/oj/eng

[26] See footnote 7.

[27] https://civil-protection-humanitarian-aid.ec.europa.eu/what/civil-protection/resceu_en

The Commission may request information gathered by EMA on Marketing Authorisation Holders, manufacturers, and distributors of medicinal products, where relevant, in the context of crisis preparedness according to Article 126 of Directive 2001/83/EC, which forms part of the revised pharmaceutical legislation. Moreover, according to Article 117 of Regulation (EU) 2017/745 under the revised pharmaceutical legislation, the Commission may request the marketing authorisation holder to provide this information when it is not available to EMA or the Member State (including for instance, information producers located in a given Member State or existing national procurement contracts). This would allow the Commission and Member States to build a shared market analysis regarding the availability of those medical countermeasures which may be of most relevance and to use this to inform subsequent decisions on procurement. According to the information provided by the available intelligence gathering tools and systems (e.g. ATHINA([28]), the EMA's European Shortages Monitoring Platform etc.) the Commission will seek to collect additional data to inform procurement decisions under the mechanism for monitoring crisis-relevant medical countermeasures provided for under Article 7 of the Emergency Framework Regulation, where this mechanism is activated.

Section Three: Approaches to crisis procurement

There are three different procurement approaches which may be available for EU-level procurement in a public health crisis: 'procurement by the Commission acting as a wholesaler', 'joint procurement' and 'procurement by the Commission on behalf of Member States'. To be available for use in procurement, the third of these must be activated in a Council regulation activating the Emergency Framework Regulation (see Part 4, above).

This section sets out the operation of those three procurement approaches in detail, and, drawing on previous crisis procurement experience, concludes with some considerations on when and how each of them may best be deployed.

7. Procurement by the Commission acting as a wholesaler

Legal basis: Financial Regulation Article 168(3), last paragraph

Article 9(1)(c) of Regulation (EU) 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 ('EU4Health Regulation') *(*[29])

[28] Advanced Technology for Health Intelligence and Action IT System (ATHINA), https://athina.ec.europa.eu/home

[29] In principle, any programme which includes objectives aligning or covering medical countermeasures, and which provides implementation under direct management, could also fund procurements of medical counter measures by the Commission.

At present the funding programme which has been used under the multiannual financial framework 2021–2027 has been the EU4Health programme ([30]). The possibility for and operation of this procurement approach may be different in the next period of the multiannual financial framework starting in 2028.

Article 9 of the EU4Health Regulation provides that the pre-conditions for using the EU4Health programme to purchase medical countermeasures are either a notification from one or more Member States in the EWRS of the emergence or development of a serious cross-border threat to health, or the recognition of a public health emergency under the Regulation on serious cross-border threats to health ([31]). Using this mechanism, the Commission can purchase medical countermeasures using funds from the EU4Health budget and then donate or resell them to Member States or partner organisations selected by the Commission ([32]).

In purely procedural terms, it is the most straightforward and quickest of the procurement approaches, simply because it is carried out directly by the Commission with no formal involvement of other parties.

The allocation and distribution of the purchased medical countermeasures should be agreed before the launching of the procurement procedure as it may have a direct impact on the contract terms (e.g. on quantities and delivery modalities). If demand is likely to exceed supply, the Commission would consult Member States (e.g. via the HERA Board or the Health Crisis Board) on the allocation mechanism or principles that could be applied.

Before the recast of the EU Financial Regulation, an earlier version of this procedure was used for the Commission's initial purchases of mpox vaccines in 2022 and 2024. Those purchases were only possible because funds had been allocated for emergency purchases of medical countermeasures in the relevant EU4Health annual work programmes. There was therefore a contingency fund which the Commission was able to draw on in this particular emergency.

[30] In principle, other funding programmes which permit the use of funds for the purchase of medical countermeasures could have been used, such as the EU Civil Protection Mechanism.

[31] Article 9 of the EU4Health Regulation refers to Decision No 1082/2013/EU, which was repealed by Regulation 2022/2371

[32] This has included, in the past, non-EU countries.

8. Joint procurement

Legal basis: Article 12 of Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health in conjunction with *Article 168(2) of the Financial Regulation.*

Geographical coverage as of June 2026: 38 countries that are parties to ([33]).

Under the current JPA ([34]), the Commission is mandated to organise a procurement procedure on behalf of a minimum of four countries ([35]) following a proposal from any member of the JPASC.

Strategic oversight of activities under the JPA is carried out by the JPASC, in which all signatories to the JPA are represented. The Commission shall, in liaison with the Member States, ensure coordination and the exchange of information between the different entities participating in any action relating to medical countermeasures at Union level, in accordance with Article 12(4) of the Regulation on serious cross-border threats to health.

When the JPASC decides that a new joint procurement procedure should be prepared, a SPPSC is set up, consisting of representatives of the participating countries (i.e. countries that are JPA signatories and that have decided to participate in the specific procurement procedure).

The JPA was used as a purchasing mechanism for a significant number of contracts during the COVID-19 pandemic, (see section 2, above). Since the end of the pandemic, it has been used either for crisis-related purchases (mpox) or to set up preparedness contracts (pre-pandemic and pandemic influenza vaccines/antivirals, COVID-19 vaccines, respiratory syncytial virus vaccines). It is therefore a mechanism with which the Commission, Member States and other participating countries (in particular their representatives in the JPASC) collectively have considerable experience.

Before the launch of the JPA procedure, the Commission prepares an assessment note indicating the general envisaged conditions of the joint procurement procedure which is sent to the JPASC. Based on this assessment note, countries must take a decision on whether to launch and participate in the procurement procedure ([36]).

Participation in a specific joint procurement procedure is done on a voluntary basis and does not, in principle, prevent countries from carrying out bilateral procurement procedures for the same medical countermeasure in parallel. However, while this non-exclusivity is the default

[33] See footnote 9.

[34] https://health.ec.europa.eu/system/files/2016-11/jpa_agreement_medicalcountermeasures_en_0.pdf

[35] Any procurement requires a minimum of five contracting authorities, of which the Commission is always one.

[36] Depending on the circumstances, this may also involve Member States checking that their own national legislation permits them to take part in the given procedure.

arrangement, Article 12 of the Regulation on serious cross-border threats to health allows the Commission, subject to a joint procurement assessment and agreement by the participating countries, to propose that procurement under the JPA include restrictions on parallel procurement and negotiation activities ('exclusivity') where necessary to ensure security of supply. If Member States agree to such exclusivity before launching the procedure, participating countries would not be able to carry out national procurements in parallel for the same products. These restrictions apply only to the countermeasure in question and only for the duration of the specific joint procurement procedure. This approach was used successfully in the later stages of the COVID-19 crisis for the joint procurement of vaccines from a single manufacturer.

Once the JPASC has taken the decision to launch a procedure, the Commission consults participating countries via the SPPSC on each subsequent step. The consultations include approval of tender documents, evaluation, negotiations, and approval of the final terms of the contract. A positive opinion of the SPPSC on each of those steps is needed for the process to continue.

The Commission leads the negotiations with the manufacturer, with the input and oversight of participating countries. Specifically, in terms of evaluation and negotiations, a representative from at least one participating country must take part in the evaluation and negotiations team (though usual practice is to have at least two such representatives), which in turn informs the other participating countries of the outcome via the SPPSC.

To finalise the contract, the Commission must receive explicit written prior approval from all participating countries on the final text of the contract. Only once the participating countries have granted their explicit approval is the contract then awarded by the Commission.

In urgent situations, the SPPSC may authorise the Commission to sign the framework contract on behalf of and for the account of all the participating countries once the award decision is adopted, as laid down in Article 22(5) of the JPA.

Participating countries may use and benefit from the solidarity mechanisms embedded in the JPA, such as the reallocation of quantities, the redirection of orders, resale and donations, including to third parties and international organisations. This can help promote the optimal use of the available contracts and more equitable access to medical countermeasures among participating countries and beyond.

9. Procurement on behalf of Member States

Legal basis: Article 8(2) of 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 in conjunction with Article 168(3) of the Financial Regulation.([37])

Geographical coverage: EU Member States

When the Emergency Framework Regulation has been activated (see above) and the activating regulation specifies that the procurement measure (Article 8) of the Emergency Framework Regulation has been activated, then Member States can mandate the Commission to conclude advance purchase agreements (APAs) or purchase agreements (PAs) on their behalf.

To this end, a framework agreement must be concluded between the Commission and Member States before a procurement activity can begin ([38]). Under Article 8(3) of the Emergency Framework Regulation, the framework agreement must cover:

- procedural rules for initiating and preparing procurement procedures;
- practical arrangements for Member States' participation, including the conditions and time frames for Member States to opt in and opt out of specific contracts;
- practical arrangements for the involvement of participating Member States throughout the procurement process;
- procedures for allocating procured crisis-relevant medical countermeasures.

While it is not possible to say in advance exactly what this agreement will contain, the general concept of this procurement approach is based on the experience of the EU and its Member States under the EU's COVID-19 vaccines strategy.

This Strategy was implemented on the basis of an agreement ([39]) between the Commission and the Member States, with the ESI Regulation ([40]) as the legal basis and funding source.

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[37] Furthermore, there is another legal basis in Article 9(1)(b) of the EU4Health Regulation.

[38] Member States will need to explicitly and formally indicate their adherence to this Agreement; the Commission will adhere to the Agreement via a College Decision.

[39] The text of this agreement can be found here: https://commission.europa.eu/strategy-and-policy/coronavirus-response/public-health/eu-vaccines-strategy_en#documents

[40] See footnote 14.

10. Considerations when choosing a procurement approach

The choice of the procurement mechanism has implications for the organisation and relative complexity of the procedure and the level of control retained over the procedure by the Member States. It also affects the negotiation dynamics and may have a significant impact on the outcome of these negotiations.

Commission acting as a wholesaler

The possibility of carrying out procurement in this way, and the possible scale of that procurement, will depend, inter alia, on the funds allocated in the EU budget prior to a crisis, or on there being sufficient remaining unallocated funds elsewhere in the EU budget to be reassigned to procuring medical countermeasures in a crisis.

For reference, in 2022 EUR 46 million had previously been allocated for such a purpose and were thus available from the EU4Health programme. EUR 20 million were available from the same programme in 2024. It should therefore be assumed that any funds pre-allocated in the EU budget to such a contingency would allow procurement of medical countermeasures on a limited scale only.

This type of procurement is therefore likely to be an option where the total value of the procurement is relatively low. It is rather unlikely to be a viable option for large-scale procurement in a major health crisis affecting the EU.

Joint procurement

There are three features of joint procurement that should be taken into account when considering it for use.

The first feature is the speed of the process. The need for each participating country to sign off the various stages of the process – and particularly the final contract – means that the process can only go as fast as the slowest country at each stage. Experience has shown that this can significantly increase the time to conclude a contract compared with the kind of ‘procurement on behalf of Member States’ approach that was used for COVID-19 vaccines.

This procurement approach may therefore not be best suited to situations where there is considerable time pressure.

The second feature is the geographical extent of the process. As noted above, joint procurement can potentially cover a wider range of countries than procurement on behalf of Member States, namely all countries that are a party to the JPA.

The third feature concerns exclusivity. Participation in a specific joint procurement procedure is voluntary and in principle does not prevent countries from carrying out bilateral procurement procedures for the same product in parallel. This 'non-exclusivity' is the default arrangement.

Experience has shown that non-exclusivity affects the EU's collective negotiating leverage, with manufacturers able to play one procedure off against another. Non-exclusive joint procurement therefore works best for products that are not in particularly short supply.

Consideration should therefore be given early in the process as to whether a given joint procurement should be done on the basis of exclusivity or non-exclusivity, since this can have a major impact on the negotiation process and outcome.

Commission acting as a central purchasing body on behalf of Member States

Procurement by the Commission acting as a central purchasing body on behalf of Member States will be possible if the procurement measure of Article 8 of the Emergency Framework Regulation has been activated ([41]), and if a framework agreement has been concluded between the Commission and Member States on the terms and conditions of such a procurement scheme.

Until such an agreement is in place, any considerations on the use of this procurement approach must therefore be based on hypotheticals. To understand what procurement whereby the Commission is acting as a central purchasing body on behalf of Member States might look like, some key considerations from the setting up of the procurement scheme for COVID-19 vaccines can be recalled.

(1) It was considered important to ensure that Member States were not competing with each other, in a context where there was considerable global competition for medical countermeasures that did not yet exist and which, when they did exist, would be available only in relatively small quantities for some time.

    The issue was addressed through an exclusivity clause: participating Member States agreed not to pursue any discussions with manufacturers outside the Commission-led procurement process. This greatly increased the EU's leverage, as manufacturers wanting to sell within the EU had to engage with the Commission and all Member States through the centralised approach and could not play Member States or the EU process off against each other. All Member States would thus gain access to a given countermeasure and on the same terms and conditions.

[41] It would also be possible on the basis of Article 9(1)(b) of the EU4Health Regulation.

(2) It was considered essential to leverage the combined weight of the EU so that manufacturers wishing to sell to any country in the EU had to do so via the Commission-led approach.

The issue was also addressed by the exclusivity clause.

(3) Speed was also considered to be of the essence, in the context of global competition for scarce resources and the very considerable impact of the pandemic on human health, and on social and economic life.

This challenge was addressed by mandating the Commission to sign contracts and amendments that legally bound Member States, along with a clear time-bound mechanism for opting-out of those contracts. This considerably speeded up the process of agreeing and signing contracts. Member States were involved in the process via the Vaccines Steering Board, on which all Member States were represented.

This experience indicates that this procurement approach is most likely to be attractive where (i) the EU and its Member States have objectives similar to those set out above in the future; (ii) the structure of the JPA makes it unsuitable for attaining these objectives; and (iii) Member States are therefore prepared to give the Commission a significantly stronger mandate than that contained in the JPA to conduct procurement on their behalf.

Section Four: Other aspects of procurement

11. 'Up-front payments' under either joint procurement or 'procurement on behalf of Member States"

Both joint procurement and procurement by the Commission on behalf of Member States imply that the Member States, in principle, order and pay for the medical countermeasures they procure upon delivery. There may however be situations where the terms of the contract include an up-front payment to the manufacturer after the conclusion of the agreement, for example to engage in risk-sharing for products under development where there is no guarantee of success, to accelerate the ramping up of manufacturing capacity, or to secure supply chains of essential components. This may be of particular importance given the overall need to minimise supply chain risks, including through ensuring that manufacturing takes place in the EU.

This was the case for the COVID-19 vaccines strategy. The Commission's Communication of 17 June 2020 ([42]) noted that delivering a successful vaccine *requires running clinical trials in parallel*

[42] Communication from the Commission to the European Parliament, the European Council, the Council and the European Investment Bank, EU Strategy for COVID-19 vaccines, at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0245

with investing in production capacity and securing raw materials so that production can start as soon as those trials are concluded, or even earlier. The need to deliver quickly, the high up-front costs, and the high failure rate make investing in a COVID-19 vaccine a high-risk decision for vaccine developers. The use of up-front payments ([43]) for vaccines under development was therefore *an insurance policy, which transfers some of the risk from industry to the public authorities in return for assuring Member States equitable and affordable access to a vaccine, should one become available*.

Where vaccine candidates were successful, the amount of the up-front payments was deducted from the price of the vaccine as paid by Member States.

In the case of the COVID-19 vaccines strategy, funding was made available to support the procurement by activating Council Regulation (EU) 2016/369 (ESI). Under Article 13 of the Emergency Framework Regulation, activating the ESI and providing funding in this way would be a possibility in the case of future health emergencies

The decision to activate emergency support under that Regulation is to be taken by the Council on the basis of a proposal by the Commission. Compared with other programmes, the ESI's simplified legal framework allows for a swifter implementation of procurement initiatives.

It should be noted that in this legal framework the ESI funding can be used only for procurement which benefits Member States, whereas procurement based on the JPA may include non-Member States that are parties to the JPA. Using ESI funding in this way may therefore only be an option where no non-EU countries participate directly in a given procurement. Member States would, however, be able to resell or donate the medical countermeasure to non-EU Member States, provided that the contract includes provisions for resale and donation.

An alternative option would be to use funding from ongoing EU programmes, subject to its being available to support such procurement activity. Depending on the specific situation, other sources of funding, such as the European Defence Fund, may be relevant and available.

Another potential approach would be for Member States to make up-front payments directly themselves upon the signature of the contract, for example by paying a percentage of the cost of every dose purchased. While this saves the need to identify and make operational a single source of funding at EU level like the above-mentioned ESI, this approach makes the process of paying and collecting the up-front payments more onerous for Member States and contractors respectively, which may not be ideal if time is of the essence in providing funding to support a product.

[43] In the COVID-19 vaccines strategy, the terms 'up-front payment' and 'downpayment' were used interchangeably.

12. Network of ever-warm production capacities for vaccines and therapeutics manufacturing (EU-FAB)

EU-FAB is a vaccine manufacturing capacity reservation network set up by the Commission to provide the EU with vaccine manufacturing capacity in the event of future public health emergencies. The network consists of facilities with manufacturing capacities across three vaccine technology platforms (mRNA, viral vector and protein) that are 'ever-warm' in the sense of providing direct access to a contract manufacturing organisation able to produce vaccines that have been procured by the EU.

The EU-FAB network was set up via a framework contract that became operational in June 2023 ([44]). The total capacity reserved is 325 million vaccine doses per year across the three platforms.

EU-FAB contractors can be obliged to manufacture a given vaccine where that vaccine's Marketing Authorisation Holder does not have the capacity to meet the EU's demands, or where no capacity exists (e.g. products under development) subject to a number of conditions (set out below).

This could be done in a number of scenarios:

(1) to supply a single product in high volumes
(2) to ensure a supply of multiple products to mitigate the risk of reduced efficacy to a novel pathogen
(3) to ensure a supply of multiple products to hedge against the risk of products in development failing

EU-FAB in preparedness mode

During the preparedness phase, the facilities are used by the manufacturers and function as a standard vaccine production facility. Previously identified critical materials are stockpiled, preparedness plans are drafted, and generic technology transfer plans are prepared by the manufacturers.

The level of preparedness is regularly monitored by the Commission and assessed by annual updates and reviews of the preparedness plans, third party audits and ongoing discussions between the EU-FAB stakeholders. EU-FAB's ways of working and capacities are kept under continuous review and modified where necessary to take advantage of new technologies or developments.

[44] The current EU-FAB framework is covering vaccines. Future arrangements might be extended to other medical countermeasures.

EU-FAB activation in a crisis

In case the emergency framework under the Emergency Framework Regulation is activated, the Health Crisis Board may advise the Commission as to which vaccines, and in what quantities, should be produced under EU-FAB.

EU-FAB can be activated where a procurement contract is in place for a given medical countermeasure that the EU-FAB contractor can produce. To facilitate the smooth activation of EU-FAB, such a procurement contract should include the possibility of technology transfer from the Marketing Authorisation Holder to the EU-FAB contractor. While EU-FAB can be activated before the product in question has received an EU marketing authorisation, the EU-FAB contractor's facilities can supply the product to the market only once this authorisation has been granted.

Once the decision has been taken to activate EU-FAB, the Commission would contact the EU-FAB manufacturers and instruct them to seek the appropriate manufacturing licences and agreements from the Marketing Authorisation Holders. It is important to note that, while EU-FAB contractors have a contractual obligation to manufacture in response to this instruction, the manufacturing costs are not covered by the EU-FAB contract.

In terms of the timelines needed for EU-FAB, there are a number of factors involved, some of which will be beyond the control of the Commission or Member States:

- the broad scope of potential products that EU-FAB could manufacture (the swiftness of any given technology transfer being impacted by the particular technology involved, as well as the particular actors);
- the level of demand from Member States;
- the timelines for regulatory approval for the EU-FAB contractor's facilities to produce the vaccine in question;
- the timelines for regulatory approval for the EU-FAB manufactured vaccine to be considered as equivalent to that produced by the Marketing Authorisation Holder (where relevant).

Once both a supply agreement (between procuring authorities and the Marketing Authorisation Holder) and a licence agreement (between the Manufacturing Authorisation Holder and the EU-FAB contractor) are in place, technology transfers can begin and the EU-FAB companies are contractually obliged to supply 50% of the procured quantities within six months, and 100% of the procured quantities within 12 months – up to 325 million vaccine doses per year across the three platforms (mRNA, viral vector, protein).

The allocation of EU-FAB-produced vaccines to Member States will be determined by consultation between the Member States participating in the procurement with, where necessary, expert guidance from the Commission, ECDC, EMA and other agencies and will consider the prevailing medical advice and epidemiological circumstances of the outbreak.

The significant lead time from the activation of EU-FAB to the actual supply of products, which is unavoidable given the factors set out above - should be noted and taken into account in planning when considering whether and how to deploy EU-FAB in support of any vaccine procurement or production strategy.

Depending on the circumstances, EU-FAB contractors may be asked to participate in specific steps of the manufacturing process, rather than take on end-to-end manufacturing. An example might be a situation where a Marketing Authorisation Holder has excess drug substance manufacturing capacity but requires additional fill/finish capacity from EU-FAB contractors in order to use that excess capacity to deliver finished product.

13. Transparency

In the specific context of procuring medical countermeasures at EU level, these procurement processes are subject to established rules for transparency and accountability towards EU institutions other than the European Commission and the general public. Those rules balance the need for transparency with the recognition that certain information needs to be protected. They therefore allow access to confidential, information, including business-sensitive information, to be restricted. Any such restrictions have to be proportionate and duly justified.

The European Parliament (EP) can raise questions or ensure accountability in the same way as in other areas of the Commission's activities – as was the case with the regular in-camera meetings with EP Members on the negotiations for the COVID-19 vaccines. For joint procurement under the Regulation on serious cross-border threats to health, Article 12(5) of that Regulation requires that the Commission informs the Parliament about the joint procurement procedures and, upon request, provides for access for the EP to contracts concluded, subject to the adequate protection of business secrecy, commercial relations and the interests of the Union.

There may also be particular considerations where the EU budget is involved in the procurement, since the EP has a role in budgetary oversight. In this case, as with COVID-19, the relevant EP committee can be provided with certain information on the use of the budget.

Any crisis procurement procedure is likely to involve national governments spending funds on medical countermeasures. As a result, there are also questions of transparency and accountability within Member States, concerning access to information by, for example, national parliaments and audit institutions.

Therefore, the general approach for any future crisis procurement should be to ensure the maximum level of transparency possible towards the public from the outset, as well as specific arrangements to ensure that those institutions that need to access some of the more confidential information can do so where appropriate and under appropriate security arrangements.

This section of the Handbook sets out a number of considerations in that regard.

Confidential information and public access to Commission documents

Procurement contracts sometimes include confidentiality clauses, which outline the obligations of parties to safeguard sensitive information, limit its use to the purposes of the agreement, and prevent unauthorised disclosure to third parties. Such clauses may not, however, prevent full or partial disclosure of the contract where this is required by law and, in particular, Regulation (EC) No 1049/2001 ([45])([46]).

Regulation (EC) No 1049/2001 establishes the general principle that the institutions are required to provide access to documents to the furthest extent possible. Only in exceptional situations (Article 4) can the institutions deny access to documents, where this is duly justified.

Under Article 4(2), first indent, of Regulation No 1049/2001, access to (parts of) a document shall be refused when its disclosure would undermine the protection of commercial interests of a natural or legal person unless there is an overriding public interest in disclosure (see above). However, as demonstrated in a number of legal actions linked to public access to the COVID-19 procurement and contracts, there can be disagreement over exactly what constitutes a legitimate commercial interest.

The Court of Justice of the EU has observed that 'Regulation No 1049/2001 does not define that concept, except in so far as it states that those interests may cover the intellectual property of a natural or legal person. Moreover, it should be noted that, in order to justify refusal of access to a document the disclosure of which has been requested, it is not sufficient, in principle, for that document to fall within a commercial activity, but it is for the institution concerned to explain how disclosure of that document could specifically and actually undermine the commercial interests and to demonstrate that the risk of the interest being undermined is reasonably foreseeable and not purely hypothetical' ([47]).

The Court has also observed 'that protection may cover commercially sensitive information, such as information on the commercial strategies of the undertakings, their sales figures, market shares or customer relations' ([48]).

Experience during the COVID-19 pandemic suggests that companies have quite different approaches to exactly what they consider to be commercially sensitive information. Some were

[45] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, at https://eur-lex.europa.eu/eli/reg/2001/1049/oj/eng

[46]Judgment of the General Court of 12 October 2022, *Saure / Commission*, T-524/21, paragraph 64, at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62021TJ0524

[47] Judgment of the General Court of 17 July 2024, *Auken and Others v Commission*, T-689/21, paragraph 31, at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62021TA0689

[48] See paragraph 33 in the judgment referenced in footnote 47.

more cautious or conservative than others. Some believed some information to be confidential during the early stages of the pandemic, but not at later stages.

In addition to commercially sensitive information originating from companies, it may also be necessary to consider certain information originating from institutions or Member States as confidential where one of the exceptions in Article 4 of Regulation (EC) No 1049/2001 applies.

The assessment of whether public disclosure of business information would harm the commercial interest of an undertaking requires a case-by-case analysis by the Commission of the given circumstances and may require consultation with the companies concerned.

A further consideration is that, for certain procurement activities – for example those relating to CBRN threats – some of the information related to the procurement may be subject to security classification. This does not prejudice assessment under Regulation (EC) No 1049/2001, but obliges the Commission to follow the additional procedural warranties in Article 9 of Regulation (EC) No 1049/2001.

Considerations for contracting authorities

In the context of EU procurement procedures, it is essential that all contracting authorities maintain suitable records of all documentation related to procurement activities to facilitate national and EU-level audits, respond to requests from governmental authorities, and address enquiries from the public.

The obligation to retain records extends, but is not limited, to documents such as order forms (or signed specific contracts), invoices, delivery notes or other logistical documentation. This requirement is particularly relevant with respect to documents concluded bilaterally between companies and contracting authorities, as such documents are not held by the Commission.

To evaluate a request for the potential disclosure of documents such as the procurement contracts, it is essential to consider the specific confidentiality provisions specified in the procurement contracts alongside the obligations in EU and national laws.

The following procedures for providing access to documents at the national level may be distinguished, based on the category of document at issue.

a. *Correspondence between Member States and the European Commission*: a potential disclosure should be considered under the relevant national legislation, and the Commission should be consulted before the disclosure as provided for in Article 5 Regulation (EC) No 1049/2001.

b. *Correspondence between Member States and companies:* a potential disclosure should be considered under the relevant national laws, and the company concerned should be informed about the request. Where the documentation concerned contains confidential information, it is generally considered necessary to consult the companies and obtain their approval before disclosure.
c. *Correspondence between the European Commission and companies*: any request must be forwarded to the Commission, which will assess the potential disclosure under the applicable EU laws and ensure compliance with the obligation to inform and/or consult the companies concerned.

In the case of national audits or requests for disclosure by a governmental authority under applicable law in connection with any legal or administrative proceeding, Member States should consult the specific contract to check their obligations. These can relate to the need to consult the Commission and the companies concerned about the request as soon as practicable. These obligations are also likely to govern the type of information that can be made available, and the confidentiality to be requested from the receiving body.

It is also important to assess each request in light of the applicable national legislation to determine whether specific safeguards are required for authorities to access the confidential information. Such safeguards may include, for example, the establishment of a secure reading room, the signing of a confidentiality declaration, or any other guarantees required under national law.

14. Dispute resolution

Experience from previous procurement exercises indicates that consideration should be given at an early stage to how the Commission and Member States wish to handle disputes with contractors that arise in the performance of a procurement contract.

As a general remark, procurement contracts signed at EU-level, whilst subject to EU law, are typically constructed such that, should formal disputes arise, they will be dealt with according to the legislation and within the legal system of one named Member State. It has hitherto been standard practice to make performance of the contracts subject to the legislation of Belgium.

It is common practice for contracts to contain clauses on dispute resolution. In the event that a dispute arises, contracts commonly require parties to initiate an informal dispute resolution mechanism to attempt to resolve the dispute, before moving to formal dispute resolution via legal action.

Consideration should already be given at an early stage to the role of the Commission in any dispute resolution mechanism, including any informal process. If it is deemed desirable for the

Commission to be able to participate such a mechanism – either on behalf of or alongside Member States, then this should be taken into account when drafting the dispute resolution clauses.

In the event of an initiation of a dispute resolution procedure, where the Commission would be acting in a dispute on behalf of or in the name of Member States, it would need to obtain an explicit mandate from those Member States who are parties to the contract in question. It would not need to seek such a mandate where it is acting solely on its own name and on its own behalf.

Annex 1 – Comparison of procurement approaches

Mechanism	Legal structure and basis	Geographical coverage	Mandate agreement needed	Negotiation team	Modalities of Member States' opt-in and opt-out	Key points
Procurement by the Commission acting as a wholesaler	Article 168(3) last paragraph of the Financial Regulation *Article 9(1)(c) of Regulation (EU) 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*	Determined by the coverage of the funding programme. Currently EU4Health participants - EU Member States, and associated countries (Bosnia and Herzegovina, Iceland, Moldova, Montenegro, Norway, Serbia and Ukraine).	No	Commission	n/a The Commission purchases the goods and distributes them to Member States or partner organisations selected by the Union institutions. Coordination with Member States generally takes place via the HERA Board/Health Crisis Board (if the Emergency Framework Regulation has been activated).	Requires funding to already be allocated (or for there to be unallocated funding elsewhere in the budget that can be reassigned)

	(’EU4Health Regulation’)					
Joint procurement	Article 168(2) of the Financial Regulation Article 12 of Regulation 2022/2371 If necessary to implement a joint action between a Union institution/ body or an executive agency and one or more contracting authorities from Member States Article 12 of Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health.	EU Member States and EEA EFTA States (Switzerland is not included) and Union candidate countries and potential candidates if that possibility has been specifically provided for in a bilateral or multilateral treaty, or with other non-EU countries if such a possibility is specifically provided for in the applicable basic act Currently: EU Member States, Albania, Bosnia and Herzegovina, Iceland, Kosovo*, Liechtenstein, Moldova, Montenegro, North Macedonia,	In the JPA	Commission plus maximum five Member State representatives (from the SPPSC for that procurement)	Member States have to confirm their final participation in the contract explicitly in writing	Procurement can be done under exclusivity, but it is not the default. Need for explicit approval from all participating countries can slow the procurement process considerably. Contains embedded flexibility and solidarity provisions, allowing for reallocation of quantities, resale, redirection of orders and donations, including to third countries and international organisations. This is important in promoting more equitable access to medical countermeasures among participating countries and globally.

		Norway, Serbia, Moldova, and Ukraine. * This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo Declaration of Independence.				
Procurement by the Commission on behalf of Member States	Article 168(3), first paragraph, of the Financial Regulation. Article 8(2) of 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	EU Member States	Yes	To be defined in the mandate agreement.	To be defined in the mandate agreement.	Allows for a streamlined process to be set up in a time-sensitive crisis situation. Allows for exclusivity to be made the default rule. The Emergency Framework Regulation establishes a governance framework for Member States to coordinate and contribute to the procurement work.

	Another legal basis is in Article 9(1)(b) of the EU4Health Regulation.					

Annex 2 – Step-by-step procurement

Commission acting as a wholesaler

1. *Needs identification and potential supply sources*

Once the medical countermeasures of potential interest for procurement have been identified, the Commission will conduct an informal survey to establish the relevant countries' level of interest in the procurement.

This will generally be done via the Health Crisis Board (if set up) or the HERA Board.

Exploratory talks, led by the Commission, with producers of medical countermeasures may take place at this stage to identify critical points, e.g. the state of play of clinical development, manufacturing capacity and timetable, and likely requests for financing or up-front payments. Where Member States have information about a given product from their own contacts with the producer, it would be very helpful if they shared it, to the extent they feel able, with the Commission and other Member States at this stage.

Where the same product can be supplied by multiple producers ('multiple sourcing'([49])), and the procurement will take place under a competitive tender, the Commission's contacts with producers at this stage will be limited to what is strictly necessary and legally feasible, to avoid prejudicing the procurement procedure.

For defining the needs of the contracting authority, specific considerations regarding the geographical location of manufacturing may also need to be considered namely, if they have an impact on the security of supply of the given medical countermeasure.

2. *Drafting tender documents*

The Commission will draft the tender documents, as set out in Point 16 of Annex I to the Financial Regulation.

[49] Multiple sourcing may be used where it is necessary to avoid over-reliance on a single provider for critical supplies, works or services, or where it is necessary to have identical or quasi-identical services, supplies or works performed in parallel by different contractors

3. *Publication of the call for tenders*

The Commission publishes the call for tenders on the Commission's Funding and Tenders portal ([50]), which is either open to the public or limited to invited organisations, depending on the type of procurement procedure.

The deadline for submission depends on the type of the procedure and the complexity of the call ([51]). Usually, it is between two weeks and a month. However, Article 167(1)(d) of the Financial Regulation and point 11.1(c) of Annex I to the Financial Regulation allow, under certain crisis conditions set out in that Article, for negotiated procedures to be used such that there is no minimum deadline for submission, only that it has to be reasonable considering the complexity of the call for tender. Shorter timelines could be considered if the specific situation allows.

During the submission phase, the members of the evaluation/negotiation team will be appointed: these will be composed of Commission officials.

To streamline the process, it is common practice to have the same colleagues performing both the evaluation and the negotiations, however, this is not compulsory.

4. Evaluation and negotiations

After the expiry of the deadline for submitting the tender, the evaluation committee evaluates the tender(s). The evaluation committee might contact the tenderer to request the clarification and correction of application documents. The negotiation committee negotiates the tender and the terms and conditions of the contract. Negotiations are started once the tenders have been evaluated and selected tenderers have been invited to negotiate. Each contact with the tenderer is duly documented and archived by the Commission in line with article 172 (2) of the Financial Regulation.

Given the time constraints associated with this procedure, internal experts should be considered, except in cases where the subject matter is highly specialised and expertise is not available in-house.

5. *Finalisation and signature of the contract*

After finalising the negotiations, the evaluation committee evaluates the final submitted offer against the procurement documents requirements and completes the evaluation report ([52]). This

[50] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home

[51] See Point 24 and 26 of Annex I of the Financial Regulation

[52] See point 30.2 of Annex I of the Financial Regulation regarding the content of the evaluation report.

report describes the committee's assessment of the tender received and contains an overview of the negotiation steps.

Once the evaluation report has been finalised the contract(s) can be awarded to the successful tenderer(s).

In non-crisis situations, in the case of competitive procedures with more than one candidate and negotiated procedures there is a standstill period of 10 calendar days before the FWC can be signed. In crisis situations this standstill period does not apply.

Usually, the contractor signs the contract first, followed by the Commission.

Joint procurement (the process below is described on the basis of the current JPA)

1. *Needs identification and potential supply sources*

Once the medical countermeasures of potential interest for procurement have been identified, the Commission will conduct an informal survey among the countries participating in the JPA to establish the level of interest in procuring those countermeasures.

This will be done via the JPASC.

Exploratory talks led by the Commission with medical countermeasure producers may take place at this stage to conduct a market analysis and identify critical points e.g. the state of play of clinical development, the producers' available manufacturing capacity and timetable, and likely requests for financing or up-front payments. Where JPA countries have particular information about a given product from their own contacts with the producer, it would be very helpful if they share it, to the extent they feel able, with the Commission and other JPA countries at this stage.

Where no medical countermeasures are currently available, or where they are only in the early stages of development, the EU may call for interested parties with projects of interest to make contact and provide information on their product.

Where the same product can be supplied by multiple producers ('multiple sourcing'([53])), and the procurement will take place under a competitive tender, the Commission's contacts with producers at this stage will be limited to what is strictly necessary and legally feasible, to avoid prejudicing the procurement procedure.

[53] Multiple sourcing may be used where it is necessary to avoid the over-reliance on a single provider for critical supplies, works or services, or where it is necessary to have identical or quasi-identical services, supplies or works performed in parallel by different contractors

For defining the needs of the contracting authority, specific considerations regarding the geographical location of manufacture may also need to be considered, namely, if they have an impact on the security of supply of the given medical countermeasure.

2. *Assessment note*

For procurement under the JPA, referred to in Article 12(2) of the Regulation on serious cross-border threats to health, Article 12(3)(c) of that Regulation requires the Commission to prepare an assessment note on the planned joint procurement, based on which participating countries can take an informed decision about their participation in a particular joint procurement.

The assessment note contains information gathered from the market analysis and also includes the general envisaged conditions of the proposed joint procurement procedure, i.e.

- the reasoning behind the launch of the joint procurement, the technical specificities of the medical countermeasure (e.g.: shelf life, presentation, estimated lead time for delivery,);
- the type of the procurement procedure that is envisaged, where the two most frequent procedures within the JPA so far are:
    - negotiated procedures, which are one-step procedures, where the tender is restricted to specific companies/organisations. This procedure can be used only in certain exceptional situations, e.g. where there is a technical monopoly, or where it is justified by an emergency situation,
    - competitive procedures with negotiations, which are two-step procedures. The first step is open to any economic operator. Only those who fulfil the exclusion and selection criteria, will be invited to submit a tender in the second phase. This procedure is used in non-emergency situations and when there are several economic operators providing the same product. The negotiations are necessary due to the complexity of the purchase;
- any particular conditions of the procurement e.g. whether or not exclusivity is proposed, and why;
- the characteristics of the planned procurement contract: duration, binding/flexible/non-binding, the expected price.

The assessment note is shared with participating countries via the JPASC, using a collaborative space ([54]).

Countries participating in the JPA will be asked to communicate whether or not they are participating in this particular joint procurement alongside their expected needs at this stage.

[54] https://circabc.europa.eu/ui/welcome

It should be noted that the assessment note sets out what is known at this stage, before detailed negotiations begin. The terms and conditions on offer may change and participating countries' assessments of their needs may evolve.

3. *Preparation of the procurement procedure*

If there is sufficient interest from participating countries on the basis of the assessment note, the Commission can start preparing the procedure. Sufficient interest is defined in the case of the JPA as being four countries ([55]).

Where a joint procurement procedure is implemented, an SPPSC is created to manage the specific procurement. Interested countries have to nominate member(s) to the SPPSC. The members have to sign a declaration of absence of a conflict of interest. Once this is done, the Commission will create an SPPSC mailing list and a collaborative space, where documents can be shared securely with the members.

4. *Drafting tender documents*

The Commission will draft the tender documents as set out in Point 16 of Annex I to the Financial Regulation

Once the Commission has finalised the draft procurement documents, they will be shared with the members of the SPPSC, who need to approve them.

In a non-crisis situation, this is the final point at which a country can join a procurement procedure. After that a contracting authority may no longer be added (when the call for tender is officially published, either publicly or sent to the sole tenderer in the case of a monopoly). However, if an EU-level emergency has been recognised, the Financial Regulation allows for more flexibility on this point (see Annex 3).

5. *Publication of the call for tenders*

The Commission publishes the call for tenders on the Commission's Funding and Tenders portal ([56]), which is open to the public or limited to invited organisations depending on the type of procurement procedure.

The deadline for submission depends on the type of the procedure and the complexity of the call. Usually, it is between two weeks and a month. However, Article 167(1)(d) of the Financial Regulation and point 11.1(c) of Annex I to the Financial Regulation allow, under certain crisis conditions set out in that Article, for negotiated procedures to be used such that there is no

[55] Technically, five contracting authorities, but the Commission is always one of these.

[56] See footnote 50.

minimum deadline for submission, only that it has to be reasonable considering the complexity of the call for tender. Shorter timelines could be considered if the specific situation allows.

During the submission phase, the members of the evaluation/negotiation teams will be appointed. These committees are composed of Commission officials and also of representatives from the participating countries (see section 8, above).

To streamline the process, it is common practice to have the same colleagues performing both the evaluation and the negotiations, however, this is not compulsory.

While it will be the prerogative of the Commission and the participating countries to nominate their respective members of the negotiation team, previous experience has shown the importance of the team being able to draw (either directly, via supporting officials, or via the SPPSC) on:

- high-level negotiation and procurement expertise
- legal expertise, particularly in the matter of contracts
- an understanding of the operating and commercial constraints and realities of the sector in question
- regulatory expertise, in terms of product safety but also e.g. clinical trials and marketing authorisation (where relevant)

6. *Evaluation and negotiations*

After the expiry of the deadline for submitting tenders, the evaluation committee evaluates the tender(s). The evaluation committee might contact the tenderer to request the clarification and correction of application documents. Negotiations are started once the tenders have been evaluated and selected tenderers have been invited to negotiate. Each contact with the tenderer is duly documented and archived by the Commission.

The negotiations are considered as concluded once all the participating contracting authorities explicitly approve in writing the final version of the evaluation results, including the contract.

7. *Finalisation and signature of the contract*

After concluding the negotiations, the evaluation committee evaluates the final submitted offer against the requirements in the procurement documents and completes the evaluation report ([57]). This report describes the committee's assessment of the tender received and contains an overview of the negotiation steps.

[57] See point 30.2 of Annex I to the Financial Regulation regarding the content of the evaluation report.

Once the evaluation report is finalised and the participating countries have approved the result and the terms and conditions of the procurement contract, the contract(s) can be awarded to the successful tenderer(s).

In non-crisis situations, in the case of competitive procedures with more than one candidate and negotiated procedures there is a standstill period of 10 calendar days before the contract can be signed. In crisis situations this standstill period does not apply ([58]).

Usually, the contractor signs the contract first, followed by the Commission and contracting authorities from participating countries. The JPA lays down that each participating country must sign the contract. However, to ease the process, the Commission can, in case of urgency, request written confirmation (via email is sufficient) from each participating country allowing it to sign on behalf of all contracting authorities.

Procurement by the Commission on behalf of Member States

Regarding this procurement approach, it should be noted that the detail of the procedure will depend to a certain extent on the provisions stipulated in the framework agreement that is to be concluded between the Commission and the Member States under Article 8(2) of the Emergency Framework Regulation (see Section III(c) above).

1. *Needs identification and potential supply sources*

Once the medical countermeasures of potential interest for procurement have been identified, the Commission will generally conduct an informal survey via the Health Crisis Board (unless the Health Crisis Board specifically advises that this should be done via another body, such as the JPASC) of the level of Member States interest in procuring those countermeasures.

Exploratory talks led by the Commission with producers of medical countermeasures may take place at this stage to conduct a market analysis to identify critical points e.g. the state of play of clinical development, manufacturing capacity and timetable, and likely requests for financing or up-front payments. Where Member States have particular information about a given product from their own contacts with the producer, it would be very helpful if they shared it, to the extent they feel able, with the Commission and other Member States at this stage.

Where no medical countermeasures are available, or where they are only in the early stages of development, the EU may call for interested parties with projects of interest to make contact and provide information on their product for the consideration of the Health Crisis Board and the Commission.

[58] Other exceptions to the standstill period are described in point 36.2 of Annex I to the Financial Regulation, e.g.: in the case of a dynamic purchasing system

Where the same product can be supplied by multiple producers ('multiple sourcing ('[59])), and the procurement will take place under a competitive tender, the Commission's contacts with producers at this stage are limited to what is strictly necessary and legally feasible, to avoid prejudicing the procurement procedure.

Specific considerations regarding the geographical location of manufacture may also need to be considered at this stage, if they have an impact on the security of supply of the given medical countermeasure.

2. *Launch of the procurement procedure (all procurement mechanisms)*

The modalities of the Member States' involvement will need to be dealt with in any framework agreement under Article 8(2) of the Emergency Framework Regulation. This will need to cover the conditions under which a procurement procedure can be launched (e.g. the minimum number of Member States participating).

3. *Drafting tender documents*

The Commission will draft the tender documents as set out in Point 16 of Annex I to the Financial Regulation. Once the Commission has finalised the draft procurement documents, it will share them with Member States for comments.

In a non-crisis situation, this is the final point at which a country can join a procurement procedure. After that a contracting authority may no longer be added (when the call for tender is officially published, either publicly or sent to the sole tenderer in the case of a monopoly). However, if an EU-level emergency has been recognised, the Financial Regulation allows for more flexibility on this point (see Annex 3).

4. *Publication of the call for tenders*

The Commission publishes the call for tenders on the Commission's Funding and Tenders portal ([60]), which is open to the public or limited depending on the type of procurement.

The deadline for submission depends on the type of the procedure and the complexity of the call. Usually, it is between two weeks and a month. However, Article 167(1)(d) of the Financial Regulation and point 11.1(c) of Annex I to the Financial Regulation allow, under certain crisis conditions set out in that Article, for negotiated procedures to be used such that there is no

[59] Multiple sourcing may be used where it is necessary to avoid the over-reliance on a single provider for critical supplies, works or services, or where it is necessary to have identical or quasi-identical services, supplies or works performed in parallel by different contractors

[60] See footnote 50.

minimum deadline for submission, only that it has to be reasonable considering the complexity of the call for tender. A shorter timeline could be considered if the specific situation allows.

During the submission phase, the members of the evaluation/negotiation team will be appointed.

The membership of the negotiation team will be defined in the agreement setting up the system.

To streamline the process, it is common practice to have the same colleagues performing both the evaluation and the negotiations.

While it will be the prerogative of the Commission and the Member States to nominate their respective members of the negotiation team, previous experience has shown the importance of the team being able to draw on:

- high-level negotiation and procurement expertise
- legal expertise, particularly in the matter of contracts
- an understanding of the operating and commercial constraints and realities of the sector in question
- regulatory expertise, in terms of product safety but also e.g. clinical trials and marketing authorisation (where relevant)

5. *Evaluation and negotiations (all procurement mechanisms)*

After the expiry of the deadline for submitting tenders, the evaluation committee evaluates the tender(s). The evaluation committee might contact the tenderer to request the clarification and correction of application documents. Negotiations are started once the tenders have been evaluated and selected tenderers have been invited to negotiate. Each contact with the tenderer is duly documented and archived by the Commission.

6. *Finalisation and signature of the contract*

After finalising the negotiations, the evaluation committee evaluates the final submitted offer against the requirements in the procurement documents, and completes the evaluation report ([61]). This report describes the committee's assessment of the tender received and contains an overview of the negotiation steps.

Once the evaluation report has been finalised and participating countries have approved the final contract, the contract(s) can be awarded to the successful tenderer(s).

[61] See point 30.2 of Annex I of the Financial Regulation regarding the content of the evaluation report.

In non-crisis situations, in the case of competitive procedures with more than one candidate and negotiated procedures there is a standstill period of 10 calendar days before the contract can be signed. In crisis situations this standstill period does not apply ([62]).

Usually, the contractor signs the contract first, followed by the Commission.

[62] Other exceptions to the standstill period are described in point 36.2 of Annex I to the Financial Regulation, eg.: in the case of a dynamic purchasing system

Annex 3 – Simplifications of procurement rules in times of crisis

A new package of simplified rules for procurement in crisis situations was introduced with the recast of the Financial Regulation, which entered into force on 30 September 2024.

These rules aim to address the lessons learned from the COVID-19 crisis and ensure swift implementation in situations of extreme urgency resulting from a crisis.

They allow the contracting authorities (EU bodies, not national contracting authorities) to:

i) use the negotiated procedure without prior publication of a contract notice, but only under the circumstances laid down in the last paragraph of point 11.1(c) of Annex I to the Financial Regulation: *Following a crisis declaration referred to in Article 163(6), the authorising officer responsible may only rely on such crisis declaration if the specific procurement procedure is justified by a situation of extreme urgency that is resulting from the crisis;*

ii) add new contracting authorities after the launch of a procurement procedure and before the contract is signed in the case of interinstitutional or joint procurements, or following a modification to the contract;

iii) contact in writing all invited candidates or tenderers with the sole purpose of clarifying their intention to submit a request to participate or a tender;

iv) change a contract or a framework contract, beyond the applicable thresholds;

v) receive evidence on exclusion and selection criteria from the presumed tenderer after the award decision and before the contract is signed.

Before applying the above rules, the contracting authorities must ensure that the following conditions are met.

✓ The situation falls under the scope of a crisis as defined in Article 2(22) of the Financial Regulation, meaning:

(a) a situation of immediate or imminent danger threatening to escalate into an armed conflict or to destabilise a country or its neighbourhood;

(b) a situation caused by natural disasters, man-made crises such as wars and other conflicts or extraordinary circumstances having comparable effects related to, among other things, climate change, public and animal health, food security and food safety emergencies, and to global health threats, such as epidemics and pandemics, environmental degradation, privation of access to energy and natural resources or extreme poverty.

✓ A declaration of a crisis has been adopted by the College of Commissioners in line with the Internal Rules. Article 55 of the Internal Rules of the Commission provides the

procedural steps required to adopt, by delegation procedure, the declaration that is based on the proposal prepared by the authorising officer. Such a declaration is not required for procurement in the field of external action. It is important to note that the declaration of a crisis for the purposes of the Financial Regulation is not the same as the declaration of a public health emergency at EU level.

✓ The Authorising Officer has justified that there is a situation of extreme urgency resulting from the declared crisis in each case in which the simplified rules are used. In other words, the subject matter of the procurement procedure or the contract must cover needs that are created by the situation of extreme urgency because of the crisis. For example, in a declared health crisis, the above flexibilities allowed by the procurement rules may not be used by the contracting authority (namely, EU bodies, not national contracting authorities acting independently) to purchase goods not directly linked to the emergency (e.g.: office supplies for health workers).

While it is envisaged that, for the reasons set out above, a declaration of a public health emergency at EU level will be accompanied by a declaration of a crisis for the purposes of procurement under the Financial Regulation, it is in principle possible for the Emergency Framework Regulation to be activated without such a declaration of a crisis.

In this case, the Emergency Framework Regulation provides several simplifications to procurement procedures that may be used:

- point ii) as described above;
- point v) as described above;
- the possibility that any contract amendment may deviate from the Financial Regulation's standard rules ([63]), which includes increasing the contract value by more than 50%, as described in point iv) provided that this is justified as strictly necessary to respond to the evolution of the crisis; and
- the possibility to request that the delivery of goods or services start as soon as the contract is sent to the contractor following the award decision but before it has been signed (under normal circumstances, the performance of the contract can start only once it has been signed by both parties).

[63] According to Article 175(5) of the Financial Regulation, and as a derogation of Article 175(3) of the same Regulation.

Annex 4 – Legal and other official texts referenced in this Handbook

Documents are listed in the order of appearance in the Handbook

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
https://eur-lex.europa.eu/eli/reg/2022/2371/oj/eng

Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Preparing the EU for the next health crisis: a Medical Countermeasures Strategy, COM/2025/529 final of 9 July 2025
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52025DC0529

Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union (recast)
https://eur-lex.europa.eu/eli/reg/2024/2509/oj

Safer together – Strengthening Europe's Civilian and Military Preparedness and Readiness. Report by Sauli Niinistö.
https://commission.europa.eu/topics/defence/safer-together-path-towards-fully-prepared-union_en

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
https://eur-lex.europa.eu/eli/reg/2022/2372/oj/eng

Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC
https://eur-lex.europa.eu/eli/dec/2013/1082/oj
https://health.ec.europa.eu/publications/commission-decision-c2014-2258-final_en

Council Regulation (EU) 2020/521 of 14 April 2020 activating emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak
https://commission.europa.eu/strategy-and-policy/coronavirus-response/public-health/ensuring-availability-supplies-and-equipment_en#public-procurement-of-medical-and-protective-equipment

Commission Recommendation (EU) 2020/1595 of 28 October 2020 on COVID-19 testing strategies, including the use of rapid antigen tests
https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020H1595

Commission Recommendation (EU) 2020/1743 of 18 November 2020 on the use of rapid antigen tests for the diagnosis of SARS-CoV-2 infection https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32020H1743

Council Recommendation EU 2021/C 24/01 on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021H0122(01)

Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 6 May 2021 on EU Strategy On Covid-19 Therapeutics https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021DC0355&qid=1784274587748

Corrigendum https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021DC0355R(01)

Commission Staff Working Document Comprehensive 2025 Health Threat Prioritisation Assessment for Medical countermeasures https://ec.europa.eu/transparency/documents-register/detail?ref=SWD(2026)1&lang=en

https://health.ec.europa.eu/document/download/147630e7-835a-40cc-96d4-e0dc44707396_en?filename=hera_wd-health-treat-prioritisation-assessment_en.pdf

Council Decision 87/600/Euratom of 14 December 1987 on Community arrangements for the early exchange of information in the event of a radiological emergency https://eur-lex.europa.eu/eli/dec/1987/600/oj/eng

Joint Procurement Agreement to procure medical countermeasures https://health.ec.europa.eu/system/files/201611/jpa_agreement_medicalcountermeasures_en_0.pdf

EU Vaccines Strategy https://commission.europa.eu/strategy-and-policy/coronavirus-response/public-health/eu-vaccines-strategy_en

Communication from the Commission to the European Parliament, the European Council, the Council and the European Investment Bank, EU Strategy for COVID-19 vaccines https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0245

Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents https://eur-lex.europa.eu/eli/reg/2001/1049/oj/eng

Judgment of the General Court of 12 October 2022, *Saure / Commission*, T-524/21 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A62021TJ0524

Judgment of the General Court of 17 July 2024, *Auken and Others v Commission*, T-689/21 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62021TA0689