



Public Procurement Conference

centralization and new trends

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Centralising procurement in the EU: The case of the new Health Emergency Preparedness and Response Authority (HERA)



Joint cross-border and centralized procurement in times of crisis

(an ongoing research)

- The case of the Joint Procurement Agreement (JPA)
- Introduced by Decision No 1082/2013/EU, now replaced by Regulation (EU) 2022/2371)
- Voluntary scheme for participating countries to jointly procure countermeasures against serious crossborder health threats



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Il modello europeo degli acquisti congiunti nella gestione degli eventi rischiosi per la salute pubblica

The European joint procurement agreement (JPA) for coordinating responses to serious cross-border health threats

G. Sdanganelli, <u>Il modello europeo degli acquisti congiunti nella gestione degli eventi rischiosi per la salute pubblica</u>, in DPCE online, n. 2/2020, 2323-2346



An evaluation of the effectiveness of the JPA model

- Advantages: improved cooperation between MS, third countries and EU, favorable prices and flexibility (e.g., PPEs)
- Risks: lack of coordination, duplication of procedures and disruption of supply chain
- Poor data quality: little data available on TED (only notices awarded without publication, due to urgency), concerns about lack of transparency



Subject:

Study on assessing the functioning of the Joint Procurement Agreement for purchasing medical countermeasures for crossborder health-threats – Consultation activities and treatment of personal data

The study (2022) also involved a team of researchers from the University of Turin



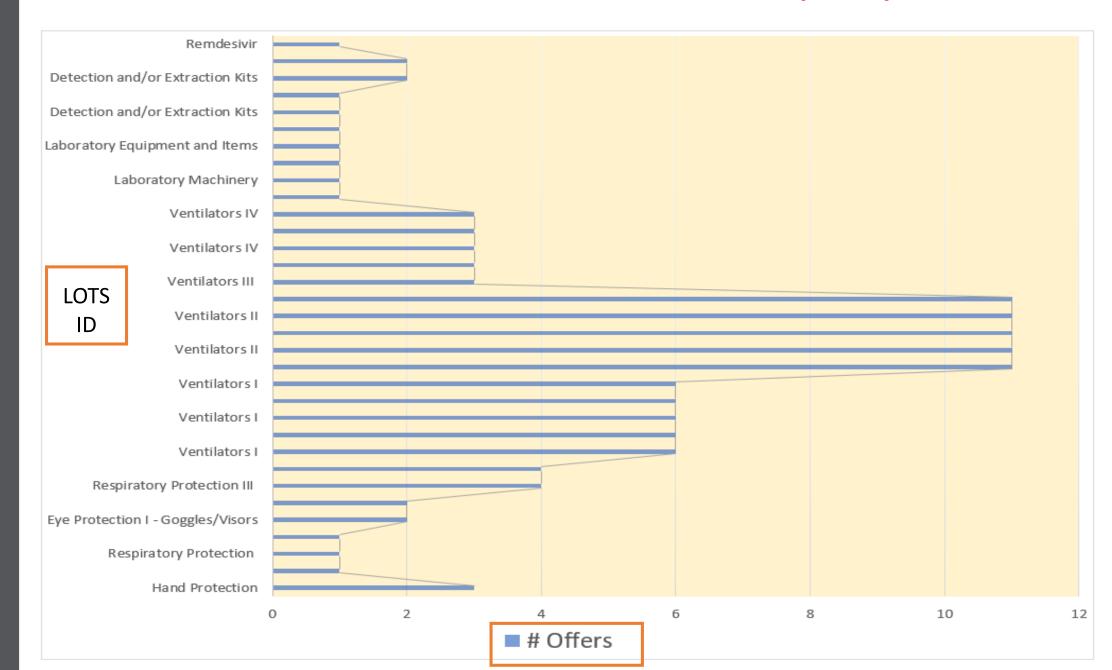
TED data (2020-2022)

Contract notices of procurement awarded by the DG Sante under the JPA:

- Personal protective equipment (SANTE/C3/2020/015; SANTE/2020/C3/017; SANTE/2020/C3/025; 2021/S 092-237152)
- Ventilators (SANTE/2020/C3/018), Laboratory Equipment (SANTE/2020/C3/019)
- Remdesivir (SANTE/2020/C3/038; SANTE/2020/C3/048; HERA/2022/NP0001; 2022/S 142-405075)
- Monoclonal antibodies (SANTE/2020/C3/091; SANTE/2021/C3/04, SANTE/2021/C3/021, SANTE/2021/C3/014; HERA/2022/3/NP002)
- Medical Equipment for Covid-19 Vaccination (SANTE/2020/C3/055)
- Rapid antigen tests (SANTE/2020/C3/064)
- Intensive care products (SANTE/2020/C3/029)
- Monkeypox vaccine (2022/S 142-405075)
- Nirmatrelvir (2022/S 231-667110)
- Heterodimer (2022/S 139-395984; 2022/S 239-688348)

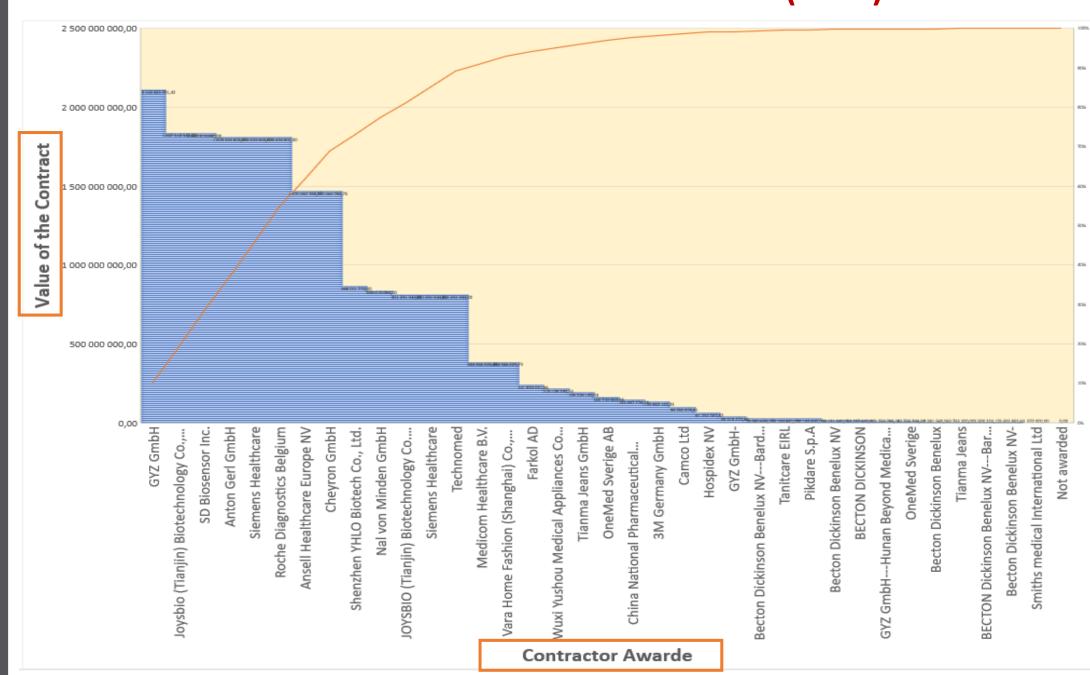


DG Sante – TED Contract notices (2020)





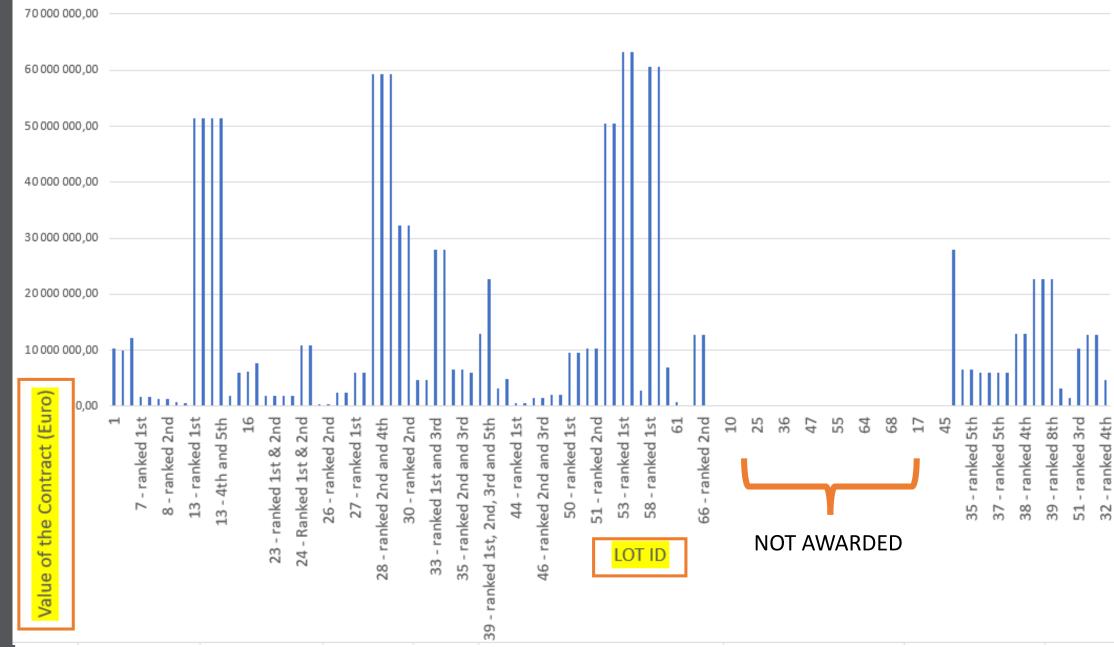
DG Sante – TED Contract notices (2021)





DG Sante - TED Contract notices (2022)

SANTE/2020/C3/029 FA – Medicinal Products for Intensive Care Patients – 68 lots (published 01.04.2022)





HERA

The new European Health Emergency preparedness and Response Authority (HERA)



Brussels, 16.9.2021 COM(2021) 576 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE EUROPEAN COUNCIL, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS

Introducing HERA, the European Health Emergency preparedness and Response Authority, the next step towards completing the European Health Union



The role of centralised procurement and HERA in response to the pandemic crisis



- HERA's mission and scope: to improve the EU's ability to respond to natural and/or man-made threats (nuclear threats, infectious diseases, risks by global population growth, climate change, pressures on land use, food production and agriculture...)
- HERA activities include <u>addressing market challenges</u> and improving the EU strategy for the procurement and distribution of essential medical countermeasures
- HERA will operate in two modes: 1) preparedness mode and 2) crisis mode



HERA's preparedness mode

- HERA's preparatory phase includes the stockpiling of crisis medical countermeasures at EU level and an inventory of production facilities
- Stockpiling strategies require cooperation between the EU and the Member States, as well as private-public collaboration
- HERA will develop advanced technological tools and digital platforms for the accurate identification of the needs of the health supply chain (physical and virtual stockpiling)





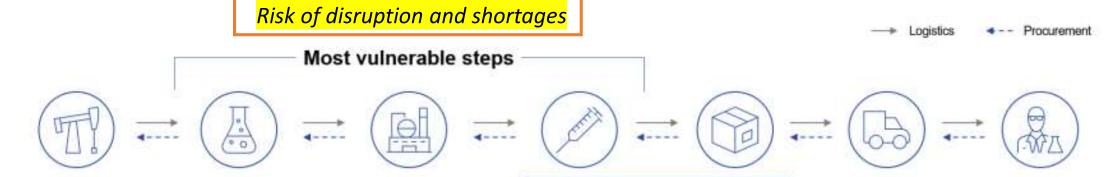
HERA's preparedness mode

- Physical and virtual stockpiling models already tested in the past (eg., implementation of the Virtual Stockpile Pooling by the WHO 2009 during swine flu pandemic)
- Key benefits of stockpiling: real-time information on medicines availability; transparency in supply chain management against the risk of disruption and shortages due to emergencies and/or unforeseeable events (e.g., pandemic / other events: the blockage of the Suez Canal in March 2021)
- Possible solution: combination of virtual and physical stockpiling **and public-private partnerships**, supported by EU data monitoring and redistribution mechanisms





Antibiotic supply chains and potential stockpiling options



Commodities

Simple molecules, reagents and solvents. Produced in continuous processes at high volumes. Low cost compared to other steps

Intermediates

Precursor to APIs. Can be divided into "far" and "advanced" intermediates. The latter require GMP¹ compliance

API manufacturing

Active pharmaceutical Ingredients (APIs) refer to portion of finished drug to have pharmacological effect or other impact on body function. Requires cGMP¹ compliance

Formulation/ filling

Formulation:
Powders, liquids,
suspensions,
emulsions
Filling:
Consumable
capsules, tablets
or vials

Secondary pack

Drug product manufacturing

Packaging into stock-keeping unit (SKU), this can be a box of vials, blisters in a carboard box with leaflet in country language

Wholesale distributors

Wholesalers buy the drugs from manufacturers or suppliers in large quantities and sell them at wholesale prices to pharmacists

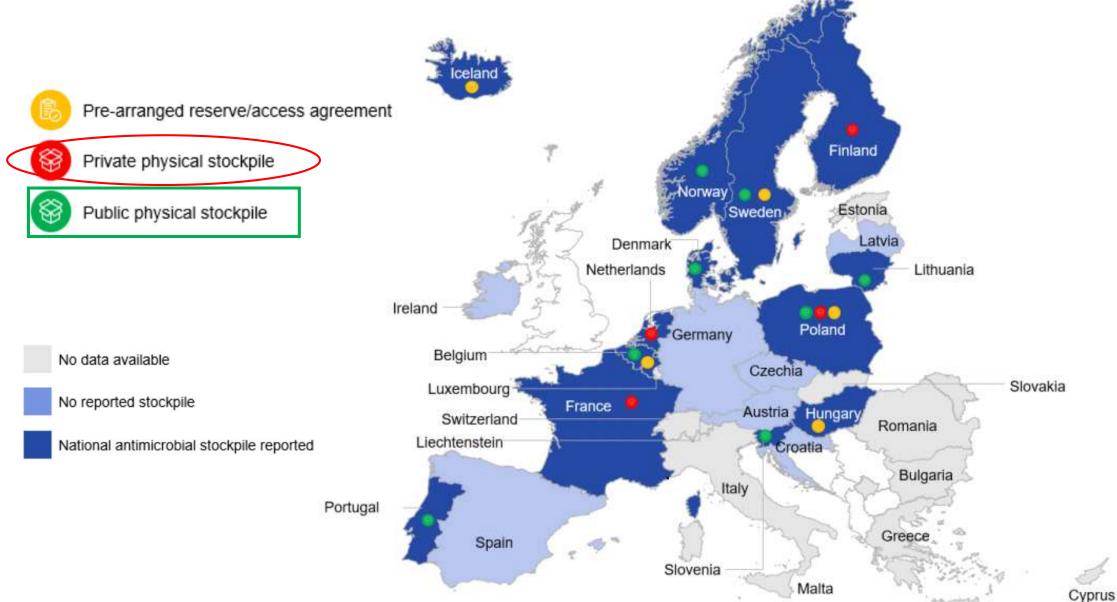
Community/ hospital pharmacy

Pharmacies sell to the end customer and can be community or hospital

Source: EU Commission, European Health and Digital Executive Agency (2022) <u>HERA AMR feasibility</u> <u>study on stockpiling: D1-D5 Final report</u>, Publications Office of the European Union



Antibiotic supply chains and potential stockpiling options



Source: EU Commission, European Health and Digital Executive Agency (2022) <u>HERA AMR</u> <u>feasibility study on stockpiling: D1-D5 Final report</u>, Publications Office of the European Union



HERA's crisis mode

- During the crisis mode, HERA will act as a <u>central purchasing body</u>, on behalf of the participating countries under the **JPA model**, as amended by the new Regulation on serious cross-border threats (Regulation (EU) 2022/2371)
- Aim: to overcome fragmented efforts at EU level and allow the timely access to crisis medical countermeasures
- HERA 2022 awards based on TED data (notices following negotiated procedure without calling for competition):
 - 'HIPRA' vaccine for Covid-19 variants (ref. 2022/S 139-395984 and 2022/S 239-688348)
 - o 'Remdesivir' drug for Covid-19 treatment (ref. 2022/S 142-405075)
 - Smallpox Vaccine (ref. 2022/S 230-663924)
 - o 'Nirmatrelvir' drug for Covid-19 treatment (ref. 2022/S 231-667110)





2022
CONTRACT
NOTICES

Contract Nº	Publication date	Title of the notice	Contracting Authority name	Procurement type	Framework agreement?	# Offers	Contractor awarded	Value of the Contract
HERA-PN-2022- 0002	21/07/2022	Framework Contract for the Supply of a Bivalent Variant Vaccine, Recombinant Protein (Heterodimer Rbd) – HIPRA	HERA	Negotiated procedure without a call for competition	Yes	1	HIPRA Human Health SL	2 375 000 000,00
HERA/2022/NP /0001	26/07/2022	Framework Contract for the Supply of Veklury (Remdesivir) for the Treatment of COVID-19	HERA	Negotiated procedure without a call for competition	Yes	1	Gilead Sciences (Ireland, Slovakia, Belgium, Denmark, Finland, Hellas, Norway)	776 250 000,00
HERA/2022/NP /0004	29/11/2022	Framework Contract for the Supply of Modified Vaccinia Ankara—Bavarian Nordic (MVA-BN*), a Third- generation, Non- replicating Smallpox Vaccine	HERA	Negotiated procedure without a call for competition	Yes	1	Bavarian Nordic A/S	1,00
HERA/2021/3/ 002	30/11/2022	Framework Contract for the Supply of the Protease Inhibitor PF-07321332 (Nirmatrelvir) that is Co- packaged and Co- administered with the Pharmaceutical Product Ritonavir	HERA	Negotiated procedure without a call for competition	Yes	1	Pfizer Incorporated	1,00
HERA-PN-2022- 0002	12/12/2022	Framework Contract for the Supply of a Bivalent Variant Vaccine, Recombinant Protein (Heterodimer Rbd) – HIPRA	HERA	Negotiated procedure without a call for competition	Yes	1	HIPRA Human Health SL	2 375 000 000,00



HERA's new DPS-PPEs

In June 2022, HERA launched a pilot **Dynamic Purchasing System (DPS)** for a rapid and agile procurement of PPEs



EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH EMERGENCY AUTHORITY

The Director General

- The DPS is based on a fully digital process that enables economic operators to pre-qualify and register within the system (pre-qualification will remain open for 4 years)

Based on the results of the pilot, the EU Commission may consider extending the DPS to other medical countermeasures

Subject:

Invitation to participate Dynamic Purchasing System for the supply of Personal Protective Equipment (DPS-PPE)/Phase I; HERA-2022-3-001

> Source: EU Commission (https://health.ec.europa.eu/latestupdates/european-health-union-hera-sets-dynamic-purchasingsystem-more-effective-joint-procurement-ppe-2022-10-04 en)

Brussels



Aggregation of demand and digitalisation for a better dialogue with the industry

- Administrative cooperation and aggregation of public demand are crucial to face current and future cross-border threats (one health approach)
- **Data and digitalisation** are the key for better procurement outcomes (better management of procurement data and spending, transparency and accountability)
- Better dialogue with industry is needed, as at present operators sometimes resist procurement aggregation and related data, fearing a loss of influence on pricing
- The **Public Procurement Data Space** and the European Health Data Space can play a key role in supporting data sharing and coordination for facing future crisis (environmental, nuclear, digital...)



THANK YOU

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