

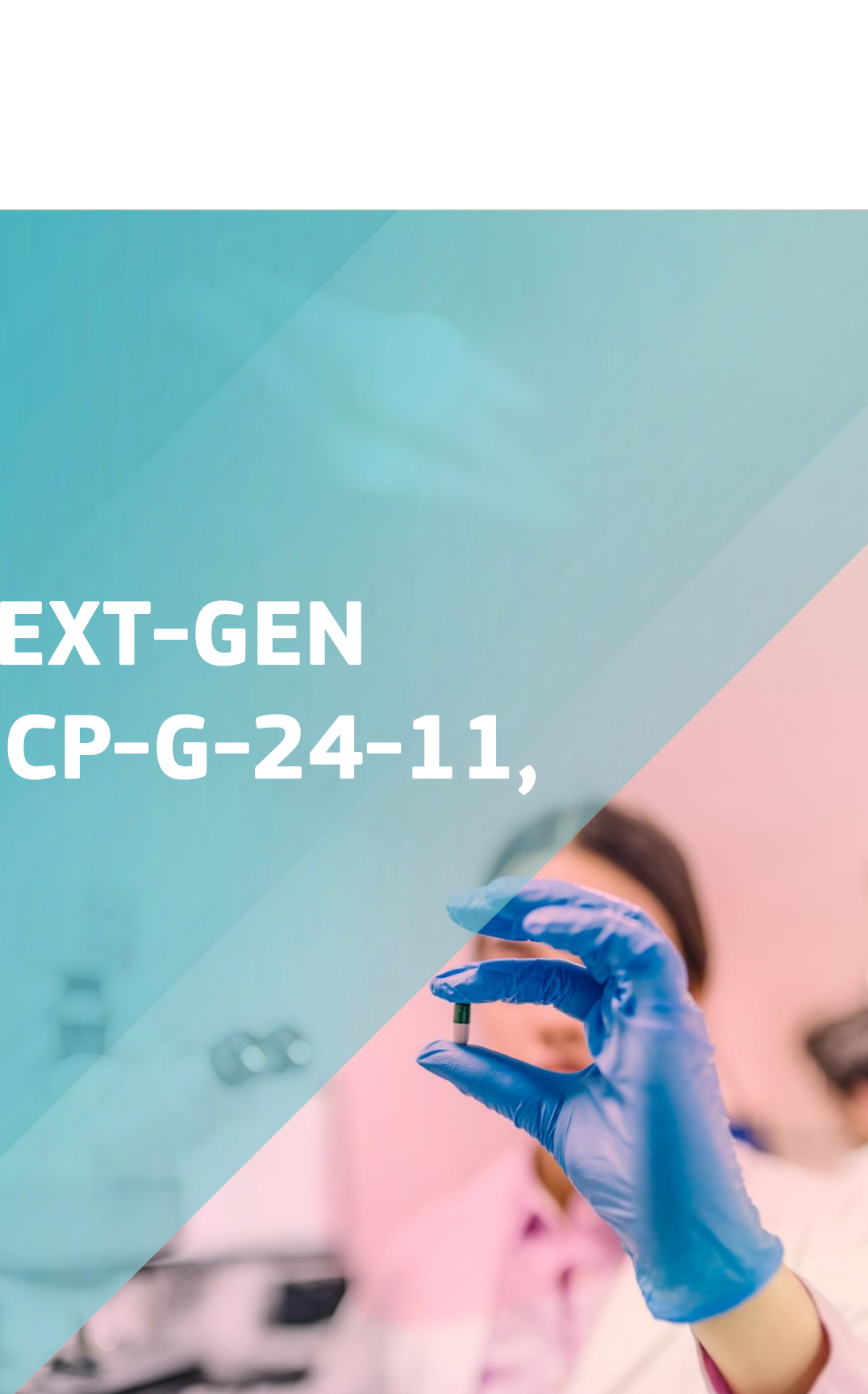
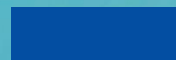


HERA HEALTH EMERGENCY
PREPAREDNESS AND
RESPONSE AUTHORITY

#HealthUnion

CALL FOR PROPOSALS ON NEXT-GEN RESPIRATORY PROTECTION, CP-G-24-11, EU4H-2024-PJ-01-2

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PRESENTATION OUTLINE

- Call overview & policy context
- Innovation targeted – overview of implementation options
- Mandatory deliverables, indicators and expected results

Call for detailed proposals, incl. timeline and cost overview, of:

- **Development**
- **Certification**
- **Uptake:** healthcare settings, critical workers, stockpiling
...of next-generation respiratory protection

Budget: **€20 million** (expectation of **4 grants**)

- 60-80% cost reimbursement
- Open to applicants from EU and associated third countries

- Respiratory protection **critical in saving lives** in health emergencies
 - Particularly in early pandemic phase, before vaccines developed
- Significant drawbacks of respiratory protection used in Covid-19 (surgical, FFP2 masks)
 - Initial shortages
 - Protection against highly transmissible pathogens
 - Fit-testing
 - No comfortable multi-hour use

- Reusability
 - Environmental impact
 - Risk of supply chain disruptions
- Affordability
- Comfortable multi-hour use
- Highly protective
- 'Universal' fit
- Optimised for stockpiling
 - Minimum space requirements
 - Long shelf life



OPTION 1: ELASTOMERIC HALF-MASKS

- Stress-test for 100 cycles of hospital-grade hygienic reprocessing
- Filter lifecycle of at least 100 8h-shifts
- Either of the following:
 - Scalable production with supply chains in Europe
 - Optimised for long-term storage (shelf life, space requirements)



OPTION 2: POWERED FILTERING DEVICE ('PAPR')

- Unit price < EUR 200 (at scale production)
- Low lifecycle cost (e.g. reusable and durable hoods, filters and components)
- Desirable attributes:
 - Low communication barriers (e.g., by reducing fan noise)
 - Source control
 - Easy disinfection and reprocessing
 - Compatible with UV-disinfection
 - Increased comfort
 - Compatibility with standard rechargeable batteries
 - Scalable production in EU *OR* optimised for stockpiling



OPTION 3: OTHER INNOVATION

- Enhanced communication
- Improved aesthetic appeal
- Better breathability or thermal comfort (e.g. advanced materials)
- Sensors for real-time fit assurance or leakage detection
- Low risk of self-contamination during doffing
- Universal fit (95% of adult population) without fit-testing
- Maintain fit and user compliance during extended periods of use
- Long shelf lives (12 years or more)



- Proposals need to detail plan for market and uptake in preparedness times:
 - Active use to protect healthcare and other critical workers
 - Stockpiling
- Significant percentage of budget funds testing and distribution of product
 - Consortia may include **hospital management, stockpiling organisations, critical workers**
 - Option to establish user-managed inventory (supply bubbles close to end users)
 - Plan to generate **sufficient demand to set up production**

OPTION 4: MANUFACTURING INNOVATION

- Innovative manufacturing processes for rapid scale-up in emergencies
 - Novel automation technology to minimise need for human labour
 - Best practices for stockpiling raw materials
 - Distributed manufacturing solutions
- Availability in emergencies ensured through rapid scale-up
 - No focus on distribution in preparedness times



MANDATORY DELIVERABLES SET EXPECTATIONS

- Development activities, studies and tests
- Consultations with user base (essential workers in- and outside of healthcare)
- Detailed analysis of costs (material, personnel, manufacturing, etc.) and resale price
- Testing and trial results
- Engagement with notified bodies and regulatory authorities

- Resale price and lifetime cost of devices
- Projected shelf life
- Number of distributed units (projection in offer)
 - For manufacturing innovation: potential for rapid scaleup within first months of emergency
- Number of consultations with user base (essential workers in- and outside of healthcare)
- Number of individuals evaluated for fit
- Quantitative user satisfaction levels

YOUR PROPOSALS ENABLE BETTER PREPAREDNESS

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- More choice for personal protection:
 - Healthcare workers
 - Other essential workers
 - General public
- Next-gen respiratory protection slowly replaces existing devices
 - Wide Incorporation into clinical practice



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Thank you!

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