EDF-2021-MCBRN-D: Defence medical countermeasures

Defence medical countermeasures (MCMs) must be kept up-to-date, available and able to respond to the continuously changing and novel health threats posed by CBRN. MCMs may include any medicines or medical devices aimed to combat CBRN threats. This extends to countermeasures that prevent or treat the threat, but also to countermeasures that combat novel modes of delivery of such threats.

Proposals should focus on innovation and development of MCMs or an additional integration into military intelligence and information systems and corresponding civil capacities. Proposals are encouraged to provide for an analysis into novel MCMs and related technology, analysis of gaps and recommendations to ensure baseline preparedness standards and indicators, mapping of CBRN MCM capacities across EU, as well as options for ensuring EU's access and availability of MCMs.

Proposals are invited against any of the following topic:

EDF-2021-MCBRN-D-MCM: Development of defence medical countermeasures.

Budget

The Union is considering a contribution of up to EUR 50 000 000 to support proposals addressing the abovementioned topic and its associated specific challenge, scope, targeted activities and main functional requirements.

Several actions, addressing different topics, may be funded under this call.

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Specific challenge

In recent years, chemical, biological and radiological threats have been continuously rising. For example, one cannot ignore the fact that groups/nations in the future might use disease-promoting microbes and viruses to damage a country's society or weaken its defence. The objective of proposals under this call is to update and/or develop medical countermeasures (MCMs) for the armed forces of EU and – wherever applicable - related civil/health protection to respond to the continuously changing and novel health threats posed by CBRN. It thus aims at developing shared capabilities for EU armed forces against CBRN crises generated by a natural or provoked event, and to treat pathologies or injuries of significant impact. It will thus

contribute to responding more efficiently to conflicts, crises, or isolated events involving CBRN situations. Such MCMs should continue to be bolstered by both academia and industry within the EU due to:

- Their specificity;
- The large funding to be engaged for r&d and poor market prospects;
- The low occurrence of such threats even though proliferation is increasing worldwide (thus increasing operational risks for armed forces);
- The large funding to be engaged for preclinical and clinical trials;
- The large scope of threats to be considered and final demand of the medical countermeasure.

Scope

Proposals should focus on innovation and development of MCMs against CBRN threats as well as their integration into armed forces. Proposals may also provide for analysis of the relevance and feasibility of novel MCMs and related technology, mapping of CBRN MCM capacities across EU, as well as options for ensuring EU's access and availability of MCMs.

MCMs[1] may include any medicines or medical devices that are aimed at combating CBRN threats. This extends both to countermeasures that prevent or treat the threat.

For MCMs to be updated, available and able to respond, this entails a large scope covering innovation, development and analysis.

Targeted activities

The proposals must cover the following activities as referred in article 10.3 of the EDF Regulation, not excluding possible upstream and downstream activities eligible for development actions if deemed useful to reach the objectives:

- Studies, such as feasibility studies to explore the feasibility of new or improved technologies, products, processes, services and solutions.
- The design of a defence product, tangible or intangible component or technology as well as the definition of the technical specifications on which such design has been developed which may include partial tests for risk reduction in an industrial or representative environment.

Generating and integrating knowledge, testing, qualification, and certification of MCMs, as defined below, are desirable. Given that they concern CBRN MCMs, these activities are specific and should be understood, *e.g.* for immunotherapies, as:

- Generating knowledge: choice of pharmacological target, antigen, or physiological process; target or antibody validation; elucidation of mechanism of action.

[1] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health defines MCMs as medicines, medical devices and other goods or services that are aimed at combating serious cross-border threats to health, a life- threatening or otherwise serious hazard to health of biological, chemical, environmental or unknown origin, which spreads or entails a significant risk of spreading across countries, OJ L 293, 5.11.2013.

- Integrating knowledge: development of industrial production under GMP conditions; demonstration of the stability of MCMs (GMP) in bulk and distributed form (ICH Stability testing of new drug substances and drug products).
- Studies: In vitro assays, in aerosol particles, in vivo proof of concept studies, and mapping of defence industrial CBRN MCM capacities.
- Design: Preclinical trials (DRS, safety, efficacy) on relevant animal models, quality control tests, validation of industrial production process under GMP conditions. Pivotal efficacy studies on animal models as close as possible to humans (authorization under exceptional circumstances).
- Testing: phase I clinical trial with most advanced MCM candidates.
- Qualification: finalization of a dossier for marketing authorization.
- Certification: New drug application (NDA) delivered by the regulatory authority (EMA) or early access program.

Innovative disruptive technologies, like MCMs that limit the development of resistance (*e.g.* broad-spectrum MCMs), and platforms for local production of MCMs on-demand, are warranted.

Functional requirements

It is essential that the development activities in this topic generate new or improved medical countermeasure capabilities that are in alignment with requirements from the Member States (MS)' armed forces themselves, or in combination with the operational needs of related civil protection or health authorities. According to the recommendations of national or European regulatory agencies, efficacy of the MCMs should be demonstrated on animal models as close as possible to humans -such as swine or non-human primates - during preclinical studies.

MCMs may be developed from early technology readiness levels and, for most advanced products, up to GMP production, clinical trials, and certification for use in humans. Safety must be demonstrated in human volunteers during phase I clinical trials. The final product should be able to be administered in field conditions by trained medical personnel.

MCMs address the three letters C, B, and R, in the CBRN term:

- **Chemical threat (C)** MCMs against severe poisoning by any chemical agent as indicated in the Chemical Weapons Convention, especially nerve agents.
- **Biological threat (B)** MCMs against B agent for which classical treatments (*e.g.* antibiotics) are not available or not sufficiently efficient.
- **Radiological threat (R)** MCMs against ionizing radiation effects like Acute Radiation Syndromes.

Expected impact

Proposals are expected to:

- Provide substantial improvements to the CBRN defence domain for EU armed forces with consistent CBRN medical protections against a large panel of threats currently not covered by drugs produced within EU;
- Facilitate the development of CBRN defence capabilities that each Member State, individual government or industry cannot face alone;

- Develop EU autonomous industrial segments;
- Contribute to the EU strategic autonomy

Even if the main objective of the project is to contribute to the armed forces, its results can also be of interest for the civilian sector.

Esta call está disponível no site da Comissão Europeia aqui