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SUMMARY

Third Health Programme - Work Programme for 2016

The annexes to Commission Implementing Decision C(2016) 1158 of 01 March 2016 concerning the work programme for 2016 in the framework of the third Programme of the Union's action in the field of health (2014-2020) and the EU financial contribution to the WHO Framework Convention on Tobacco Control, serving as a financing decision set out the priorities and actions to be undertaken, including the allocation of resources (Annex I). The other annexes cover the eligibility, exclusion, selection and award criteria as well as criteria for assessing the independence from industry, commercial and business or other conflicting interests, and exceptional utility criteria (Annexes II to VIII). The allocation of resources (including EFTA) for the year 2016 is as follows: for grants (implemented under direct management): EUR 36 300 000; for procurement (implemented under direct management): EUR 60 000 and for other actions: EUR 6 719 000. The total available budget is established at EUR 57 992 112 for 2016.

The full version of the annexes after adoption of the Work Programme 2016, will be available only in English and accessible at http://ec.europa.eu/health/programme/policy/index_en.htm

ACTIONS PROPOSED FOR FUNDING (ANNEX I)

Annex I of the Implementing Decision sets out the details of the various actions scheduled for 2016.

GRANTS

The total amount earmarked for this section is EUR 36 300 000.

- <u>Grants for projects</u>: Under the overall operational budget reserved for grants, EUR 13 050 000 are allocated to projects. The maximum rate for EU co-financing is 60 %. However, this may be up to 80 % if a proposal meets the criteria for exceptional utility set out in Annex VII. Annex II contains the eligibility, exclusion, selection and award criteria for project grants.

In 2016, the following actions are identified for funding:

- Best practices in care provision for vulnerable migrants and refugees;
- Knowledge and best practices on reducing underage drinking and heavy episodic drinking
- Knowledge and best practises to on measures to prevent illicit drug use
- Addressing the chronic disease challenge

- European Reference Networks
- Rare diseases support for new registries
- Donor selection and protection.
- <u>Grants for actions co-financed with Member State authorities</u>: EUR 13 800 000 will be reserved for grants for actions co-financed with Member State authorities. The maximum rate of EU co-financing is 60 %. This may be up to 80 % if a proposal meets the criteria for exceptional utility set out in Annex VII. Annex IV contains the eligibility, exclusion, selection and award criteria for these actions.

In 2016, the following actions are identified:

- Quality of HIV/AIDS/STI, viral Hepatitis and tuberculosis prevention and linkage to care
- Action on chronic diseases
- Tobacco control
- Antimicrobial resistance and Health Care Associated Infections
- Authorisation of preparation processes in blood and tissues and cells.
- Financial contribution to the functioning of non-governmental body (Operating grants): Under the overall operational budget reserved for grants, EUR 4 800 000 are reserved for operating grants. Operating grants are calculated based on eligible costs incurred. The maximum rate for EU co-financing is 60 %. However, this may go up to 80 % if a proposal meets the criteria for exceptional utility set out in Annex VII. Annex III contains the exclusion, eligibility, selection and award criteria for operating grants. Annex VI contains the criteria for assessing the independence from industry, commercial and business or other conflicting interests.

In 2016, no call for proposals will be organised as a result of the conclusion of framework partnership agreements (FPA) for a duration of maximum three years based on the work programme for 2014 – covering the operating years 2015, 2016, 2017. FPA recipients are eligible for a specific grant agreement. In 2016 they will be invited to submit an application for a specific grant agreement for 2017. This will include the annual work programme and the budget. Having received an FPA does not guarantee annual co-funding.

- <u>Presidency conference grants</u>: Presidency conferences, which are highly political in nature and involve representation at the highest national and European levels, are to be organised exclusively by the Member State holding the Presidency of the European Union. Two conferences organised by the Presidencies of the European Union may receive up to EUR 100 000 each, the maximum rate of EU co-financing being 50 % of eligible costs incurred. The conferences supported under this work plan are a conference on 'Prevention of chronic non-communicable diseases and healthy lifestyles' and a conference on 'Alzheimer's

disease - the epidemic of the third millennium - are we ready to face it' planned under the Slovakian Presidency and a conference on 'Structured Cooperation between Health Care Systems' under the Maltese Presidency.

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- <u>Direct grant agreements with international organisations</u>: The overall budgetary allocation reserved for actions implemented via direct grants to international organisations amounts to EUR 4 450 000. The maximum EU co-financing rate is 60 %, up to 80 % in case of exceptional utility. Funding for actions with international organisations will be allocated through grant agreements without a call for proposals on topics specifically identified in this work plan.

In 2016, activities supported will address:

- EU contribution to the WHO Observatory on dementia (grant to the World Health Organization (WHO))
- Grant to the WHO/FCTC (grant to the World Health Organization (WHO))
- European Observatory on Health Systems and Policies: country specific knowledge and anti-microbial resistance (grant to the World Health Organization (WHO))
- Best practices in care provision for vulnerable migrants and refugees (grant to the World Health Organization (WHO))
- Preparation of EU Health Report 'State of health in the European Union' and country specific analysis (Grant to the OECD);
- The European Pharmacopoeia (Grant to the Council of Europe).

PRIZES

The overall budgetary allocation reserved for prizes in 2016 amounts to EUR 60 000. In the context of the Health Policy Forum, a Health Award will be organized. The overall objective is to raise awareness of the vital role non-governmental bodies play in strengthening participative democracy and active citizenship for a healthier EU and fairer access to healthcare.

The award will reward and highlight good practices of European, national and/or sub-national non-governmental bodies which have made a significant contribution towards promoting a healthier EU and fairer access to healthcare for EU citizens, preventing diseases and protecting EU citizens' health.

PROCUREMENT

For procurement (implemented under direct management), the total amount earmarked is EUR 14 913 112. It covers activities such as the evaluation and monitoring of actions and policies; studies; provision of advice, data and information on health; scientific and technical assistance; communication, awareness-raising and dissemination of results; and information

technology applications in support of policies. New and existing framework contracts and new service contracts will be used following tendering procedures for public procurement on TED. An overview of actions considered in this section is provided below:

- Monitoring of EU Platform for Action on Diet, Physical Activity and Health and the stakeholder commitments concerning reduction of alcohol related harm;
- EU Health Policy Forum or similar cross cutting stakeholder activities;
- Support to the report to the Council on the implementation of the Action Plan on Childhood Obesity
- EU framework for national initiatives on selected nutrients: feasibility study
- Assessment of the socio-economic impact of the future initiatives on HIV/AIDS, viral hepatitis and tuberculosis
- Baseline study on dementia and other neurodegenerative diseases in EU Member States
- Pilot specific training modules for health professionals, border guards and trainers in migrants' and refugees' health;
- Provision of technical and scientific input to support the implementation of the new Tobacco Product Directive and further development of existing tobacco control measures on the EU level;
- Training programme for first-line health professionals, border officers and trainers working at local level with migrants and refugees;
- Capacity building against health threats in Member States;
- Healht innovation and Health Technology Assessment;
- Health innovation and e-Health;
- Support for the health workforce planning and forecasting expert network;
- EMP database (management of marketing authorisations for medicinal products and of maximum residue limits of veterinary medicinal products) and IT systems;
- Maintenance and development of the existing EUDAMED;
- Development of the future EUDAMED following the adoption by the legislators of new Regulations on medical devices;
- Communication and publication actions to promote the understanding and correct implementation of the requirements and risks relating to medical devices;
- Overview of certain transposition measures of the Falsified Medicines Directive
- Clinical trials database;
- Study on cross-border cooperation;
- Study on enhancing information provision to patients;

- Conference of National Contact Points for Cross-border healthcare;
- Scientific and technical assistance for scientific committees and the Expert Panel on effective ways of investing in health and public health policies;
- European Reference networks: assessment of applications of network and membership proposals, support to the IT platform and a conference

Horizontal activities

- Communication, promotion and dissemination of information on EU health policies and the results of the Health programmes;
- Information technologies in support of public health policies;
- Review of implementation of and follow-up to the 2010 Commission Communication and subsequent Council Conclusions on Global Health including a stakeholder consultation on next steps

OTHER ACTIONS

The overall budgetary allocation for other actions in 2016 amounts to EUR 6 719 000. This section covers contributions paid by the EU as subscriptions to bodies of which it is a member, administrative agreements with the Joint Research Centre (JRC), system inspections on medicinal products, and special indemnities paid to experts for participating in meetings and for work on scientific opinions and advice on health systems.

Actions considered under this action will address:

- An administrative agreement with the Joint Research Centre on the European initiative on breast cancer and a cancer information system;
- Risk assessment:
- Expert Panel on effective ways of investing in Health Indemnities paid to experts;
- Technical and scientific opinions and advices regarding medical devices (administrative agreement with the JRC);
- Support of International Conference for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH);
- Reimbursement of experts' expenses for joint assessments;
- EU experts in ICH Development of EU requirements for the placing on the market of medicinal products for human use through the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human (ICH):
- Joint Audit Programme on Good Manufacturing Practice inspections

- The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceutical for Veterinary Use (VICH) - reimbursement of experts' expenses;
- Organisation and management of the meetings of the Medical Device Coordination Group (MDCG);
- Active pharmaceutical ingredients: systems inspections;
- Clinical trials on medicinal products for human use Union controls (expert expenses)
- The Commission membership fee to the European Observatory on Health Systems and Policies; and
- Scientific Committees (indemnities paid to experts).