

Briefing for Patient Groups on core funding opportunities within the 3rd Health Programme 2014-2020 and new eligibility criteria for non-governmental organisations

What is the Third Health Programme?

In April 2014, the European Parliament and the Council adopted the [3rd Health Programme](#) for the period 2014-2020. Although health is a competence of Member States, the EU can complement, support and add value to their policies. Built on the experience of the previous two EU programmes for health (2003-2008 and 2008-2013), the 3rd Health Programme should serve as the main tool to support the implementation of EU legislation on health and will finance activities, projects and not-for-profit organisations aimed at enhancing health in Europe.

The budget of the [3rd Health Programme](#) has increased by almost 30% compared with the previous programme (in total, EUR 449.5 million for the period 2014-2020), but it is still only less than 1% of the EU's budget. The funding covers four general thematic priorities:

1. Promote health, prevent diseases and foster supportive environments for healthy lifestyles taking into account the "health in all policies" principle;
2. Protect Union citizens from serious cross-border health threats;
3. Contribute to innovative, efficient and sustainable health systems;
4. Facilitate access to better and safer healthcare for Union citizens.

The 3rd EU Health Programme is the main instrument the European Commission uses to implement the EU health strategy. It is implemented by means of annual work plans which set out specific priority areas for funding actions under the programme.

The funds are managed by the European Commission through the Directorate-General for Health and Food Safety (DG SANTE), responsible for work plans and actions, and the Consumers, Health and Food Executive Agency (CHAFEA) implements the programme and manages grants.

Operating grants

In order to achieve the objectives of the programme, the European Union provides financial contributions for:

- **joint actions** having a clear EU added value, co-financed by Member States' competent authorities working in the field of health;
- **projects** having a clear EU added value and co-financed by other public, non-governmental and/or private bodies;
- **operating grants** for the functioning of non-governmental bodies, where financial support is necessary for the pursuit of the programme's specific objectives;
- **direct grants to international organisations**, such as the WHO;
- public procurement (e.g.: **tenders** and **framework contracts** for specific studies/service).

The operating grants for the functioning of non-governmental bodies can be awarded if the applicant fulfils all the following **criteria**:

- they are non-governmental, non-profit-making and independent of industry, commercial and business or other conflicting interests;

- they work in the public health area, play an effective role in civil dialogue processes at the EU level and pursue at least one of the specific objectives of the programme;
- they are active at EU level and in at least half of the Member States, and have a balanced geographical coverage of the Union.

Grants paid by the Union shall not exceed 60% of eligible costs. In cases of “exceptional utility”, the contribution by the Union may be up to 80% of eligible costs. This concerns also operating grants.

The call for proposals 2014 provides operating grants to the functioning of non-governmental bodies, including networks, through the conclusion of framework partnership agreements (FPA) for a duration of maximum three years – covering the operating years 2015, 2016, 2017 – and, subsequently, of specific grant agreements for the financial year 2015. As of 2014, it is obligatory to apply within FPA. The FPA includes a multi-annual work programme for the period 2015-2017 as an annex, including a budget plan. Applicants who receive a FPA are eligible for the specific grant agreement. They are invited to submit a simplified grant application. This will include an annual work programme and budget. Signing a FPA does not guarantee annual co-funding. On the one hand, introduction of multi-annual framework contributes to a greater sustainability of non-profit organisations that fulfilled eligibility criteria for funding. On the other hand, it is likely that it will preclude organisations that were not granted funding from applying for another 3 years.

This programme could offer a great opportunity for patient groups to access public funding for health promotion and strengthening, as well as for ensuring that the voice of vulnerable groups is represented at the EU level. Furthermore, European level patient groups and public health, wellbeing and prevention NGOs have no other known possibilities to apply for core-funding from public or non-corporate sources. In addition, their member organisations are not in a position to pay for high membership fees.

How the independence from industry is judged?

To be eligible to receive funding for core activities from this programme, organisations are required to be financially independent from industry: **they cannot receive more than 20% of their core funding from corporate sources**, as this is judged to represent a conflicting interest. This requirement concerns only core funding, an organisation can receive unlimited project funding from corporate sources.

Under the previous health programme, in the calls for proposals in 2011, 2012 and 2013, organisations had to commit to respect this criterion during the financial year covered by the grant, this being subsequently checked by auditors. This criteria was implemented by the European Commission thanks to the advocacy actions performed by the patients’ and community and as acknowledgement of the contribution of patient groups in the EU health policy.

In 2014, the European Commission changed this requirement back to what it was before 2011, by judging independence **retrospectively**, based on the annual accounts of the last financial year, 2013, for which the accounts were closed.

In other words, the criteria is exactly the same, but the time of evaluating is changed.

Why is it an issue?

Due to this change, most European level patients’ and health NGOs groups are at risk of being ineligible to apply indefinitely during the current programme, yet those who have received operating grants several consecutive years are not, as they already fulfil the 20% rule. Paradoxically, this reinforces patient groups’ and health NGOs need to survive on industry funding and prevents them from being

able to diversify their funding sources. This new (old) interpretation may lead to unjustified limitations of patients and other vulnerable groups' (children, women, elderly, migrants etc.) representation in EU decision-making processes. It is also in contrast with the EU's goal to increase patients' involvement and empowerment, as declared in the [3rd Public Health Programme](#).

What changes we would like to see?

- (1) Getting back to the previously valid rule of evaluating financial independence by looking to the accounts during the financial years covered by the grant.
- (2) Whereas we warmly welcome the European Commission's decision to introduce a three year framework agreement allowing organisations to have some long-term financial planning, we still think that separate annual calls should be launched to provide organisation, who were refused funding in the initial launch of three years call, with a possibility to reapply shortly and/or allow organisations to apply when they are ready to do so (it is a long process and organisations need to prepare for it).
- (3) Sufficient funding allocated in the programme to support not-for-profit organisations (currently, the programme is very focused on supporting Member States, international organisations and various service agreements to the Commission)

Strategic vision

When it comes to the whole issue of judging the independence of patient organisations or indeed patient experts, this is an issue in which the patient community needs to advance together.

While doing a preliminary research on other EU funded programmes (e.g.: EuropeAid, Citizenship, LIFE), it appears that the financial independence of non-profit organisations is not considered an eligibility criteria, although other criteria in terms of independence from other entities apply, such as the independence from governments and other public authorities.

During the initial discussions between the European patients' organisations and health NGOs, it was suggested that financial independence of these organisations should be evaluated based on the diversity of funding sources rather than based on an arbitrary ceiling of 20%.

Patient organisations who are active at the European level and who are working with the European Medicines Agency (EMA) are fulfilling a public service, and these organisations are assessed by the Agency every two years. Therefore, the criteria on who is eligible for receiving public support and funding by the Commission should be in line with the assessment performed by the EMA.

As by being involved in EMA's work, patient organisations and health NGOs are performing a public service duty, the organisations should also be considered eligible for support with public funds. Patient organisations and health NGOs play an important and increasing role interacting with the EMA. It is in interest of both the European Commission and EMA to keep patient organisations and health NGOs which render their services to EMA, independent and sustainable to enable them to train their patients/members to get involved with the EMA.

Public funding of patient organisations helps ensure the sustainability of the organisation, ensures a diversity of funding sources and avoids dependence on industry partners. In order to engage effectively and to highlight to the EP and EC the importance of public funds, European patient organisations need to work together to develop a long term strategy for engagement. This strategy must be developed, and driven by patient organisations themselves.

What has already been done?

The new implementation of the funding eligibility criteria was informally discussed by some of the patient organisation representatives during the meeting of the European Medicines Agency (EMA) Patient and Consumer Working Party (PCWP) in early June 2015. As an outcome of the first discussions it was agreed that there is a need to collectively present our position to the European Commission and the Parliament and ask for corresponding actions.

In June 2015, Member of the European Parliament Claudia Monteiro de Aguiar (Portugal, EPP) submitted a written question through to the European Commission on the challenges posed by the new funding eligibility criteria and whether it is planned to change it back. The following answer was given by the Health and Food Safety Commissioner Andriukaitis on behalf of the Commission:

The regulation on the third Health Programme (1) specifies in Article 7 that grants may be given to support the functioning of non-governmental bodies, if they comply with the criteria defined in Article 8(2). Thus applicants must be independent when applying. The financial independence is assessed based on the latest available financial information i.e. the last year for which the applicant organisation's accounts have been approved and related information is included in the financial independence form, as laid down in paragraph 4 of Annex VI of the Work Plan 2014.

A different procedure was applied for Operating Grants under the Second Health Programme, where financial independence was assessed retrospectively for the year covered by the grant, thereby creating a risk for applicants and the Commission that grants would have to be recovered retroactively if the criterion were found not to be fulfilled.

In 2014 three-year framework partnership agreements were concluded (2). Among the current grant holders(3), patient groups are well represented.

(1) <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0282&from=EN>

(2) http://ec.europa.eu/chafea/documents/health/award-fpa-agreements-2014_en.pdf

(3) http://ec.europa.eu/chafea/documents/health/specific-grant-agreements-2014_en.pdf

On the 16th of October, representatives of EPF and EFA met with DG SANTE and CHAFEA. Please see the meeting minutes below.

Meeting minutes

- Date of meeting:* 16th of October 2015 – 11:30-12:15 CET
- Present:* JRy John Ryan (European Commission Directorate-General for Health and Food Safety, DG SANTE)
MH Michael Huebel (DG SANTE)
JRe Jacques Remacle (Consumers, Health, Agriculture and Food Executive Agency, CHAFEA)
PDA Paola D’Acapito (CHAFEA)
NB Nicola Bedlington (European Patients’ Forum, EPF)
SP Susanna Palkonen (European Federation of Allergy and Airways Diseases Patients’ Associations, EFA)
RS Roberta Savli (EFA)
- Apologies:* CT Christoph Thalheim (European Multiple Sclerosis Platform, EMSP)

NB opened the meeting by identifying the main problem: with the new rules regarding the assessment of financial independence (retroactively and not prospectively anymore) set down in the Third Public Health Programme, several European patients’ organisations are not being eligible to apply. She underlined that paradoxically, this reinforces their need to survive on industry funding, and prevents them from diversifying their funding sources.

SP added that the topic was raised within the members of the European Medicines Agency (EMA) Patients and Consumers Working Party (PCWP), where the discussions focused on the wider definition of financial independence of patients’ organisations.

JRy replied by saying that the rules are specified in the programme and that, therefore, it is not possible to change them without the European Parliament and the Council going through the normal legislative procedure and that this, even if feasible, would require a couple of years. This means that the rules setting down financial independence of non-profit organisations would remain as such for the next 5 years (until the end of the programme that covers the period 2014-2020): applicants must be independent when applying. He also mentioned that the article on financial independence was requested both by the Parliament and the Council.

MH emphasised that patients’ organisations as such are not excluded from applying and getting the grants, as demonstrated by grants given to Eurordis, EPF and Alzheimer Europe. He stated that the Commission is fully aware of the problem with the financial independence, but he also explained that the room for manoeuvre is extremely small. Indeed, the review clause in the programme only concerns the list of thematic priorities annexed to the programme itself. In addition to the legal problem, also the availability of funding can represent an issue.

JRy highlighted that the Commission introduced a long-term perspective and the continuity of funding with the establishment of Framework Partnership Agreements (FPA), as requested by non-profit organisations. He also mentioned the possibility for patients' organisations to apply for projects' grants in their field of activities.

SP specified that the three patients' organisations mentioned by MH will also be the only ones able to apply for future grants within this programme and that this may lead to unjustified limitations of patients' representation in EU decision-making processes. She understands that the rule might have been included in the programme without realising what the overall consequences would be for the patients' community and she asked whether the Commission is planning/willing to change the criterion to what it was after 2011, when it was opened up to patients' groups, these being obliged to respect the financial independence criterion during the financial year covered by the grant.

JRe explained that the change in the criterion, checking the financial independence of organisations in advance and not at the end of the grant's period, was particularly important with this programme, as there would have been a too high risk with FPAs. This would have created a risk both for applicants and the Commission that grants would have to be recovered retroactively if the criterion were found not to be fulfilled and for the entire duration of the FPAs.

NB clarified that patients' organisations welcomed the introduction of the FPAs as they clearly recognise the importance of the continuity of funding. She also however mentioned that she is not aware of any occasion in the past where non-profit organisations have been asked to give the funds back because in breach of the financial independence criterion.

JRy proposed that this topic might feed into the discussions for the final evaluation of the third public health programme, if it was found out that certain groups were excluded and therefore the new programme, if any, could present a changed criterion regarding financial independence.

SP concluded that on the one hand projects grants are not sufficient for patients' organisations as they do not cover their core activities and on the other hand she mentioned that EMA has its own way of evaluating the independence of patients' organisations collaborating with the Agency and that this system is well accepted and functioning.

Next steps

Establishment of the patient-/public health organisations driven group to develop a strategic action plan.

It is unlikely that the European Commission will change any funding-related criteria for patient and public health organisations in the upcoming years, before 2020, when the new Health Programme will be adopted. Despite inflexible approach of the Commission, patient and public health organisations still need to take action, as public funding of patient organisations helps ensure the sustainability of the organisations/patients groups, ensures a diversity of funding sources and avoids dependence on industry partners. The focus of action should shift from highlighting exclusion of certain patient groups by not supporting them financially, to a broader approach, emphasising a need to support general patient and public health organisations movement. The action should be taken on a political level, both through the European Parliament and the European Commission.

To engage effectively and to emphasise the importance of public funds, European patient and public health organisations need to work together to develop a long term strategy for engagement. This strategy must be developed, and driven by patient and public health organisations themselves.

This briefing was drafted by Jelena Malinina, Policy and Membership Officer at the European Federation of Allergy and Airways Diseases Patients' Associations (jelena.malinina@efanet.org).