



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Council Recommendation on strengthened cooperation against vaccine preventable diseases

Factual report of the online public consultation

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FACTUAL REPORT

1. INTRODUCTION

This report covers data and input received in the context of an open public consultation (OPC) and a Targeted Stakeholders' Consultation on the European Commission's initiative developed by DG SANTE, as a Proposal for Council Recommendation on strengthened cooperation against vaccine preventable diseases.

The consultation took place altogether between 21 December 2017 and 15 March 2018¹.

The stakeholders' consultation, launched on 17 January 2018 until 14 February 2018, was open only upon invitation to selected stakeholder groups and available in English; The OPC, which ran from 21 December 2017 to 15 March 2018, addressed citizens and any other organisations with an interest in vaccination, available in 23 official EU languages².

The two consultations received replies by 8927 participants in total: 239 stakeholders (33 to the stakeholders' consultation and 206 to the open public consultation) and 8688 citizens (representing 97.3% of all respondents). 127 contributions to the public consultation have been unpublished (10 due to duplication and 117 due to anonymity). Besides, 3 respondents uploaded additional feedback documents, in PDF format.

The stakeholders represented a great variety of sectors. Almost a quarter of respondents were NGOs, followed by health administration, research and academia, and professional associations (Annex – Graph 1). The majority of them is based in Belgium (19.6%), followed by France (12.1%) and Italy (11.2%). 22 of them are based in non-EU countries.

As for the citizens, 8494 came from the EU Member States (except Malta and Slovakia), while 194 came from other 53 non-EU countries. The vast majority of citizens is from France (81%), followed by Belgium (3.6%) and Germany (3.1%).

As a consultation instrument, the results are not statistically representative due to the high geographical imbalance of contributions, but with the large response received, the consultation gives strong indications of the preferences and concerns of citizens and other organisation on the initiative. However, around 50% of citizens answered the public consultation with the '*no opinion*' option, leading to boycotted and biased results. It is highly likely that they were encouraged to do so through online campaigns, as over 60% of total contributions were registered in one single day. As these contributions provided no opinion, they were not analysed further for the scope of this report.

Concerning the respondents' work experience in different areas³, citizens mostly indicated the healthcare and education sectors, while stakeholders the healthcare and vaccination sectors. (Annex – Graph 2). 1522 respondents (17%) affirmed being healthcare professionals.

All respondents consented to the European Commission to publish their replies: 2251 (25.2%) with no restrictions⁴ and 6676 (74.8%) only anonymously⁵.

¹ The cut-off date is 15 March 2018. Contributions received by the European Commission after that date could not be taken into account in preparing this report.

² The questionnaire is not available in Gaelic.

³ More than one answer was possible to this question

⁴ Yes (I consent to the publication of all my replies and any other information I provide, and declare that none of it is subject to copyright restrictions that prevent publication)

The consultation aimed at collecting input on the 3 main pillars of the initiative: (1) tackling vaccine hesitancy; (2) sustainable vaccine policies in the EU; and (3) EU coordination, including the promotion of stakeholders' dialogue and contribution to global health.

This report summarises the contributions received. Based on the analysis of data, it puts forward the main priorities and concerns for the respondents in the area of vaccination.

2. PILLAR I: TACKLING VACCINE HESITANCY

The consultation sought to examine which actors and actions with a strong EU added value for Member States would be most appropriate to tackle vaccine hesitancy effectively. Stakeholders and citizens answered questions, which examined possible courses of action. They were also invited to propose further actions, in response to open questions.

Interestingly, 50% of respondents attributed the highest impact on vaccine hesitancy to the confidence in the effectiveness of vaccines, the fear of side effects, the lack of information on risks and the potential introduction of mandatory vaccination (Annex – Graph 3).

One stakeholder pointed out that the determinants of vaccine hesitancy, grouped into contextual, individual, and group influences as well as vaccine specific issues, should be considered at all national, regional and local levels. Affordability is also a rather important issue for socially disadvantaged families, as well as the fact that public discourse often differs depending on which vaccine is discussed.

2.1. BETTER COMMUNICATION BY THE HEALTH AUTHORITIES

In terms of communication about vaccine safety and effectiveness, the respondents considered that health authorities should make use of a multi-component approach, involving different communication instruments. In the case of communicating to the general public, the most impactful tools identified were national campaigns, provision of online information and social media (Annex – Graph 4). In addition, trainings at the workplace and at university were considered highly effective for the healthcare workers (Annex – Graph 5).

Stakeholders and citizens made further suggestions, specifying their answer '*other*'.

In the case of the health authorities' communication to the public, the negative comments included no need for further communication, unless it is a transparent, lobby-independent one.

Instead, positive contributors emphasised the need of face-to-face interaction at the local level:

- Supporting better primary healthcare professionals, including nurses, through trainings on communicating all the important information on vaccines (e.g. risks, benefits, safety, herd immunisation et.) to more hesitant people;
- Providing a patient-centred approach in the dialogue between the general public/patients and the healthcare professionals, with more time dedicated to discussion and the promotion of vaccines in combination with other preventive care services;
- Making transparent studies and data on vaccine safety more easily accessible to the public, including quick and easy ways of communication (infographics, short films etc.);

⁵ Yes, only anonymously (My replies can be published, but not any information identifying me as respondent)

- Accepting responsibility for vaccine damages and giving the opportunity to report side effects directly to a common EU database;
- Providing information and awareness-raising programmes locally, in relation to the specificities of the territory, during open days in GP practices (e.g. display of material, flyers, one-page leaflets etc.), engaging with local schools, churches, famous influencers, business enterprises, etc;
- Introducing trusted mediators in vulnerable groups (e.g. Roma communities, refugees etc.);
- Providing periodic and proactive fact checking on fake news and conflicts of interest;
- Stimulating the public to read vaccine products package insert;
- Engaging with the internet search engines to limit the anti-vaccine search results;
- Opening the debate for supporters and opponents, to give a balance of benefits and risks;
- Communicating directly with parents, with a bottom-up approach, in which the public's queries and anxieties are answered by qualified and updated experts;
- Organising healthcare conferences and events about the importance of vaccination, taking into account the diversity principle, in which vaccine information is adapted to local linguistic diversities, sensory impairment or existing levels of (health) literacy, etc.;
- Engaging with patient groups, healthcare professionals, health-related international organisations and NGOs in the communication on vaccination, instead of including the political authorities and the political debate in a scientific and public health issue.

In relation to the communication of health authorities to the healthcare workers, the main concern of citizens was the lack of studies on the effectiveness of vaccines. They believed that all suggested method could be used, but only within a *“balanced pro and contra information”* that allows parents to choose freely on vaccination and informed consent.

The provided suggestions focused on the transparency of information, communication and research:

- Providing healthcare professionals with materials containing reliable, independent and verifiable information on the safety of vaccines;
- Funding and engaging more in transparent research, independently from vaccine industry (with free online access, through a respectable authority, such as the WHO, the EMA etc.);
- Encouraging doctors to recognize known risks and potentially vulnerable groups, and keep record of the undesirable side effects after vaccination;
- Organizing meetings, consultations, discussion panels and roundtables, based on open research and where all views are exchanged in an open professional discussions;
- Creating evidence-based discussion platforms, where to promote also specialized accredited online courses and professional conferences;
- Providing healthcare workers with tangible data on the use and achievements of vaccines globally and recommendations on what should be done to eradicate other diseases (e.g. HPV-related illnesses);
- Imposing mandatory vaccination to healthcare workers and sanctions for breaking this professional requirement;

2.2. BETTER COMMUNICATION BY THE EUROPEAN UNION

The communication of the EU to citizens and to other relevant stakeholders aiming at increasing trust about the benefits of authorised vaccines was considered overall inadequate by stakeholders (respectively 58.5% and 67.7%) and citizens (respectively 26% and 25%, although over 60% expressed no opinion).

Stakeholders⁶ further considered that communication is not adequate to healthcare professionals either (73%). They justified their answers, motivating that:

- The information is available by EMA, ECDC and WHO-Europe, but it is fragmented, not diffused or accessible enough, and mostly disconnected from the national level;
- The ECDC should provide and promote evidence-based information on one single platform, on the model of the US CDC website;
- The EU should establish national websites and handbooks, with explanations, examples and best-practise cases on vaccine hesitancy (on the model of EAAD);
- An interactive EU campaign on vaccination would be beneficial to overcome the lack of information updates at national level and to tackle vaccine hesitancy;
- The establishment of a pan-European vaccine surveillance database coordinated by the ECDC would allow efficient communication on vaccine programmes' effectiveness and the benefits of authorised vaccines;
- Communication should come from ECDC information, translated into (sub-)national sources and media or communication campaigns;
- The EU should proactively engage with healthcare professional organisations, ensuring adequate training and communicating throughout the year on the benefits of life-course vaccination and leveraging opportunities during the European Immunisation Week;
- Information campaigns should be targeted and personalised by population groups.

2.3. BETTER COOPERATION OF ACTORS IN TACKLING VACCINE HESITANCY

As regards to the contribution against vaccine hesitancy, respondents called for a cross-sectorial approach, in which different actors promote the use of recommended vaccination in different measures. The most welcomed actors were healthcare providers and family members, by both citizens and stakeholders (Annex – Graph 6 and 7).

The role of civil society to overcome vaccine hesitancy⁷ was strongly supported by stakeholders⁸, particularly to establish information sessions at schools (73.79%), respond to fake news (63.59%) and promote routine checks of vaccination status at school (62.62%).

Besides, 62.59% of citizens and 40% of total stakeholders suggested further actions that the civil society should undertake against vaccine hesitancy, putting the focus on the need of educating the general public. These actions include:

⁶ Answering the stakeholders' consultation only.

⁷ More than one answer to this question was possible

⁸ Answering the public consultation only

- Differentiating essential vaccines (e.g. polio) from voluntary vaccines (e.g. seasonal influenza) in relation to different vulnerable groups and limit the discrepancies in the recommendations by healthcare professionals, in order to tackle distrust;
- Engaging with respected people within local communities with a professional attitude and knowledge on vaccines to interact and demonstrate confidence in the effectiveness of vaccines, by giving personal examples and vaccinating themselves and their families;
- Involving famous people (media, actors, artists) in vaccine advocacy activities;
- Showing images of the damages of vaccine-preventable diseases publicly across the EU, on the model of cigarette packs;
- Explaining the concept of herd immunity to the general public, as a form of responsabilization of individual actions for the benefit of the entire community;
- Involving women, as the main carers of children and ageing parents, in the development of positive vaccine messaging;
- Providing the general public with more factual proofs, scientific materials and statistical facts about vaccines and educating them about the manufacturing process and ingredients of vaccines;
- Putting in place a mechanism of denunciation of those, who divulge fake news;
- Putting in place a mechanism of blood testing before receiving the vaccine shots;
- Targeting friends and family through social media and events (e.g. World Immunisation Week), as these are the groups that usually have an impact on vaccine hesitancy;
- Giving space to a transparent open debate about benefits and risks of vaccines;
- Introducing vaccination in health education in schools;
- Reporting more responsibly on vaccine issues on the media (improve risk communication);

However, the vast majority of citizens commented with a vaccine hesitant feeling, rejecting the need for the civil society to engage in any further action. They were concerned in particular about the lack of a balanced information including both benefits and risks of vaccination. They feel that only “*biased, unilateral information*” in the financial interests of the vaccine industry are shared, more than about personal and public health.

Stakeholders⁹ also identified the role of the vaccine industry, as:

- Providing transparent information on the benefits and safety of vaccines, based on trials, prices and compositions of vaccines;
- Prioritizing public health over commercial gains, including with the support to campaigns;
- Improving the quality of vaccines, as well as the supply production, by investing in research and development;
- Developing more social responsibility programmes, affordability and good governance principles in the vaccine supply chain;

In terms of concrete, cooperative activities at EU level to increase vaccine coverage rates and reduce vaccine hesitancy, citizens considered most helpful that Member States exchange best practices in vaccine injury compensation programmes (2489, 28.6%).

Stakeholders instead endorsed the setting-up of an information website with user friendly, evidence based, up to date and factual information on safety and effectiveness of vaccines

⁹ Answering the stakeholders’ consultation only.

(62%), that Member States and health professional associations develop and provide together in-service training for health professionals (56.4%) and that Member States evaluate together the impact of intervention strategies to address vaccine hesitancy (53.5%).

2.4. HIGHER VISIBILITY OF SCIENTIFIC EVIDENCE

In order to strengthen the evidence base and effectively tackle vaccine hesitancy, respondents advocated for providing scientific arguments in favour of vaccination programmes. According to citizens, the healthcare professionals (24.55%) and the international organisations (22.8%) are the main actors, who should make the highest efforts in producing scientific evidence. Stakeholders also indicated the international organisations, the European Commission and EU agencies and healthcare professionals, almost in the same extent (Annex – Graph 8).

2.5. BETTER SUPPORT TO HEALTHCARE PROFESSIONALS

Success against vaccine hesitancy depends on efforts from all levels of governance and a multitude of societal actors, among whom healthcare professionals have an extremely important role, due to their first hand contact with patients.

The most accepted activities by stakeholders¹⁰ that the EU should undertake to support the healthcare professionals in advising citizens on their vaccination needs and in strengthening confidence in vaccines, include providing support/training to improve communication on immunisation (82%), online information/training materials (79%), providing scientific materials (70%) and EU campaigns on vaccination (66%).

Besides, 40% of stakeholders suggested:

- Making EMA a regulatory organisation assisting new product development (as FDA);
- Developing hard mandates (e.g. mandatory vaccination for high-risk groups);
- Designing harmonised EU campaigns, including social media;
- Better supporting healthcare workforce to convey credible/coherent information, reaching out to the most vulnerable to meet their vaccination needs, through a wider public health promotion communication effort;
- Ensuring that all healthcare professionals receive the relevant vaccination themselves and improving working hours conditions, a main reason for inadequate patient communication;
- Increasing education standards (e.g. innovative teaching formats at universities and CME events; encouraging Q&A, case studies, role play, as supervised vaccine communications are more effective than lecture formats);
- Creating a large coalition of stakeholders to support national immunisation programmes;
- Creating uniform recommendations, introducing fees for breaching the rules;
- Engaging healthcare professionals in EU initiatives (e.g. Joint Action on Vaccination);

Citizens also believe that healthcare professionals should be better supported in the advocacy for vaccination, mostly with material to explain the benefits and risks of vaccination (81.33%).

¹⁰ Answering the stakeholders' consultation only.

3. PILLAR II: SUSTAINABLE VACCINE POLICIES IN THE EU

The challenge of sustainable vaccine policies is shared across the European Union. Due to the barriers that prevent a facilitated exchange of vaccine products between the countries and long production lead times, vaccine shortages in the EU are a serious concern to the interests of public health. The consultation sought to gather views on possible activities and mechanisms that would allow balancing the vaccine supply and demand, improving vaccine production capacities, bolstering research and increasing overall vaccination coverage rates and the sustainability of vaccine policies in the EU.

Stakeholders¹¹ (81%) also considered developing a common approach to vaccination schedules in the EU as a crucial harmonisation action, motivating that:

- It would be useful for cross-border movements in the EU;
- It would be useful for Member States to elaborate on schedules, monitoring, coordination, supply and demand issues, but bearing in mind the different settings in the Member States and the infectious disease prevalence rates;
- It would bring more coherent information to the public
- It would set a benchmark for all Member States to aspire to and a campaigning tool for NGO's and others to help them raise awareness.

However, the negative considerations include that change is hardly accepted by citizens, especially if cultural beliefs are involved; that child growth and development monitoring would be affected by schedule changes; that vaccination schedules are a national competence.

3.1. INVESTMENT IN E-HEALTH AND DIGITALIZATION

Among the areas of investment to strengthen the monitoring of vaccination programmes, e-health is the most supported by stakeholders¹², especially as far as an electronic vaccination record for each EU citizen is concerned (97%).

Other heterogeneously suggested priority areas of investment in the e-health field include:

- Effectiveness and adverse events register;
- Phone applications reminding individuals about their vaccination schedules;
- Online platform with factual information and figures, room for expression of concerns and evaluation of vaccine sentiment in the EU population;
- Monitoring system for high risk groups (children, pregnant women, refugees etc.);
- Bridging national vaccination registries, creating a common adverse events following immunisation (AEFI) area;
- Sharing patient records with other primary care professionals such as pharmacists to improve inter-professional collaboration;
- Reinforcing a comprehensive pharmacovigilance system to increase public confidence in vaccines and their safety.

¹¹ Answering the stakeholders' consultation only.

¹² Answering the stakeholders' consultation only.

3.2. BETTER COMMUNICATION WITH THE VACCINE INDUSTRY

The main area of communication between public health authorities and the vaccine industry regards the balance of vaccine supply and demand. To promote a better communication on this balance, citizens supported obliging the industries established in the EU to produce and supply the required vaccines (24.55%), while the majority did not provide any opinion (65.93%). Stakeholders¹³ instead supported mapping vaccine demand at EU and national level (70.87%) and establishing national systematic forecasts of vaccines (65.53%).

Other stakeholders¹⁴ further suggested:

- Ensuring accurate quantities of vaccines are ordered and administered;
- Having periodically updated planning and an EU alert mechanisms;
- Changing the EU legislation so that one of the conditions for the marketing authorisation is sufficient production capacity;
- Promoting the cooperation of the vaccine industry with WHO, that would collect the information on supply and demand and collaborate with Member States;
- Creating a shared international portal which (1) has mapped the vaccine landscape and (2) can offer timely inputs on supply and demand needs / issues;
- Creating national and European vaccine producers' federations;
- Having sensitive monitoring systems and trend analysis;
- Creating the vaccination plan according to precise data of the people able to get the vaccine and the percentage of vaccination coverage to achieve.

In addition to the balance between supply and demand, the most important issues (both short-term and long-term) to be addressed with the industry according to stakeholders¹⁵ would be:

- The guarantee of purchase of vaccines produced;
- The increase the vaccine production on EU public investments;
- The issues of transparency, pricing, investment in research and safety;
- The identification of national needs, according to different vaccine schedules and regions;
- The development of long-term planning and emergency preparedness, good manufacturing practices, industry marketing practices;
- The need of ensuring that positive messages to public receptive to being vaccinated continues, through the involvement of the vaccine industry in appropriate, scientifically robust and user-tested communication campaigns;

3.3. BETTER ENGAGEMENT IN FUNCTIONING VACCINATION PROGRAMMES

In terms of a correct and successful functioning of vaccination programs, respondents attributed the responsibility to healthcare professionals (almost 90% in total). Citizens further attributed the responsibility to international organisations (25.7%) and stakeholders to the Member States (85%) (Annex – Graph 9). However, it is necessary to mention that over 45% of contributions expressed no opinion to the question.

¹³ Answering the public consultation only.

¹⁴ Answering the stakeholders' consultation only.

¹⁵ Answering the stakeholders' consultation only.

As healthcare professionals were the highest-rated actors, one of them pointed out the responsibility healthcare professionals have in relation to their professional responsibilities and degree of (de-)centralisation of vaccine demand-supply chains, and in addition to the traditional, decision-making actors. It stressed that good communication and collaboration between all levels is a key to vaccine programmes' success, following a top-down approach. Country obligations towards international organisations are important as they put pressure on countries to achieve and maintain particular goals, but from the operational level perspective, it is local and regional authorities that are responsible for purchasing and for the administration. Lastly, it is the confidence and knowledge of health professionals who administer the vaccine to convince the hesitant parent/patient to accept the intervention.

Despite the fact that NGOs were overall not considered highly responsible, respondents suggested the following actions for grassroots level organisations, including NGOs, patient groups and civil societies, to engage in supporting the sustainability of vaccination policies:

- Forming a stakeholders' alliance, such as in Ireland, to work with the same goals nationally or at EU level and to ensure the patients voice is included in ongoing discussions;
- Researching the barriers to the access to vaccination, in order to suggest solutions to the public authorities and reaching out to vulnerable groups, such as the Roma population;
- Providing grassroots level organisations with higher EU and government financial support;
- Establishing an EU "Vaccination Ambassador" programmes to promote vaccination and to give grassroots level organisations more recognition and visibility at EU level.
- Cooperating with institutional organisations to increase vaccine literacy, the trust in science and in the documented vaccination benefit and risks, and to emphasize responsibility for the community;
- Establishing partnerships with national health care providers to promote and deliver vaccination programmes, fund local programmes, share best practices, monitor vaccine preventable diseases, simplify vaccination calendars and provide decisional support for lacking vaccinations;
- Spreading transparent and scientifically accurate information in a capillary way in schools, in families with financial difficulties, engaging local celebrities with an effective and simplified language;
- Engaging more on social media, responding to fake news;
- Calling for legal and economic responsibility in case of vaccine-driven damages;
- Involving grassroots level organisations in the early stages of policy development, immunisation strategy and programme planning, and in dialogues with the industry;
- Performing independent research on the benefits of multi-shot vaccines, in comparison to single-shots, and creating expert working groups to check the reliability of research and the effectiveness of vaccination;
- Engaging in dialogue with the vaccine industry to proof to the general public that the focus is on public health, instead of financial gains;

One anti-vaccination opinion used multiple times was that *“trying to get grassroots organisations to support vaccination policies is premature when there are inadequate scientific data on which to justify national immunisation programmes”*.

3.4. BETTER PROMOTION OF VACCINATION TO INCREASE COVERAGE RATES

In the interest of public health, increasing the coverage rates of vaccination is the principal purpose in tackling vaccine hesitancy, developing sustainable vaccination policies or harmonising vaccination under the coordination of the EU.

To do so, stakeholders¹⁶ identified improving linkage with patient summaries and electronic health records, including access to patient immunisation (51%) as the most important action.

To promote vaccination as a central part of prevention, they considered necessary:

- Developing better education for citizens through primary school and continuous training for healthcare professionals;
- Developing European, national and regional information campaigns, underlining that vaccination is one of the most cost-effective public health interventions;
- Using the expertise of international organisations, the European Commission and its agencies and Member States to engage public health authorities, NGOs and local actors in the promotion programmes with a focus on vaccination;
- Empowering healthcare professionals and integrating vaccine communication and provision in other, different medical specialities;
- Involving politicians, policy makers, media and the civil society in the diffusion of pro-vaccine messages, financial and political support of vaccination programmes;
- Formulating a robust legal regulation of vaccination, with clear accountability to those involved, starting with the authorities, the medical profession, as well as the legal representatives of the children;
- Increasing the cooperation at EU level, with a European league table, measuring the performance of Member States and exchanging best practices;
- Making vaccination free-of-charge and its access universal.

In terms of integrating vaccination programmes in national health systems, citizens considered no action needed (24.88%) or expressed no opinion (53.84%). Stakeholders¹⁷ instead suggested establishing vaccination programmes linked to health care activities for different age groups (75.73%), increasing awareness of health professionals about vaccination (71.84%) and providing vaccination as part of the routine health care visits (66.99%)

Other stakeholders¹⁸ further identified additional actions, such as:

- Aligning vaccination schedules and policies, providing surveillance methods for specific groups, considering the demographic/migratory dynamics, developing an interoperable immunisation information system at EU level;
- Ensuring that citizens have adequate and free of charge access to vaccination programmes, allowing pharmacists and nurses to prescribe and administer vaccinations;
- Producing targeted action plans, legislation, policies, better funding at the national level, with the involvement of health professionals and school teachers;
- Improving the coordination between the Ministries of Health and ECDC/WHO;

¹⁶ Answering the stakeholders' consultation only.

¹⁷ Answering the public consultation only.

¹⁸ Answering the stakeholders' consultation only.

3.5. REDUCTION OF VACCINE SHORTAGES

According to stakeholders, the policy interventions with the biggest impact on mitigating vaccine shortages at EU level are vaccine forecasting and joint vaccine procurements between countries (Annex – Graph 10). Instead, 36.87% of citizens considered the availability of individual vaccines, instead of multi-shot vaccines, as the most impactful (Annex – Graph 11).

According to stakeholders¹⁹, coordination at EU level to address vaccine shortages can be improved through:

- An industry flag when they anticipate a manufacturing problem, to allow time to source vaccines elsewhere;
- A standardization of packaging;
- Increased price and volume transparency to help Member States in their vaccine procurement and planning of consume and waste;
- A high level political commitment by appointment of a special committee in the European Parliament to regulate vaccine related cross-country actions and mutual sharing across EU;
- A reinforcement of the role of the EU agencies, creating a stable network between national PH institutes, ministries of health and regulatory agencies to improve surveillance, communication and joint notification systems in Member States on forecasting;
- The implementation of the already operational ‘track and trace’ system: vaccine packaging could be fitted with RFID chips to track the batches, but also to scan them to retrieve the appropriate medical information in different languages;
- A reduction in inequalities between countries, by encouraging those with excessive supply of vaccines to help those in demand.

3.6. IMPROVEMENT OF VACCINE PRODUCTION CAPACITIES

In order to increase vaccine-manufacturing capacities and reduce long production lead times, stakeholders²⁰ observed that a number of actions could be taken in the European Union, such as:

- Increase of surveillance and investment in vaccine production/research;
- Change in EU legislation and political commitment;
- Incorporation of new technologies;
- Better joint procurement system;
- Financial incentives to the industry;
- Coordination of EU vaccination schedules
- Harmonisation of vaccine information, including packaging and language (e-leaflet);
- Simplification of marketing authorisations;

To establish and maintain a sufficient production capacity in the EU, they considered most helpful the following incentives:

- Regulation and prioritisation of vaccine production;

¹⁹ Answering the stakeholders’ consultation only.

²⁰ Answering the stakeholders’ consultation only.

- Coordinated planning, systematic forecasting, mapping vaccine demand, joint procurement and legal action, with common funding mechanisms;
- Multiannual budgets for implementation of national immunisation schedules and vaccine-dose planning based on epidemiological studies at least 3 years before the manufacturing orders are placed, at Member State level;
- R&D Infrastructure funding mechanisms, like US BARDA, for vaccines that are health security priorities;
- Avoidance of country specific products and packaging requirements;
- Diversification of the market sector and production sites/methodologies (if possible);

3.7. BOLSTER RESEARCH AND DEVELOPMENT

Stakeholders²¹ expressed clear support for reinforcing cooperation in the areas of research and development, which are essential for supporting innovation in the field of vaccination.

The actions they suggested to speed up R&D and increase its capabilities in the EU are:

- Aligning with the Global Research Collaboration for Infectious Disease Preparedness (GLOPID) and the Coalition for Epidemic Preparedness Innovations (CEPI) for vaccines for emerging infectious diseases;
- Increasing funding in HR, infrastructures, independent researchers, in consortium structures and universities;
- Ensuring the industry's support for public health-led, independent vaccine studies;
- Establishing joint scientific advice groups and regulators at European Commission level;
- Sharing scientific expertise, knowledge and data on innovative approaches to vaccines development among Member States;
- Using financial instruments like Horizon2020 to invest in the development of new vaccines, to improve skills, capacity and knowledge for addressing vaccine hesitancy.

In order for the EU to better support the scientific evaluations for the introduction of new vaccines, in respect of national competences in decision-making, they further identified:

- Collaborating stricter with WHO and the UN, and setting up multinational agreements;
- Supporting and giving bigger visibility to EMA and ECDC;
- Introducing a new health technology assessment (HTA) mechanism and expanding the use of the central authorisation procedure, including the independent testing of vaccines.
- Creating a network of National Immunisation Technical Advisory Groups (NITAGS), EU regulators, HTAs sharing strategies and evidence produced in different countries when deciding to introduce a new vaccine, compiling relevant studies and cost-effectiveness analysis in English, designing an effective EU wide evaluation method;
- Supporting the development of post-marketing studies based on an EU immunisation information system (data are country-specific, but comparability in the EU).

²¹ Answering the stakeholders' consultation only.

3.8. SUSTAINABILITY OF VACCINATION PROGRAMMES

Stakeholders²² identified the areas in which it would be important to support new EU actions to address the sustainability of vaccination programmes, as:

- Improving the access to vaccination by all resources and means;
- Better forecasting of vaccine demand;
- Better vaccination coverage monitoring and infectious disease surveillance systems;
- Exchanging information with authorities outside the EU on the quality of vaccines;
- Stimulating the development of new improved products by SMEs;
- Improve EU legislation with new binding commitments to the vaccine manufacturers;
- Establish an EU fund for vaccine impact studies;
- Fighting fake news, involving the healthcare professionals and the media, focusing on education, improving the access to information;
- Establishing an EU platform with guidance to national implementation programmes, expertise sharing, monitoring on supply and facilitation of cross-border vaccine exchanges;
- Performing pharma-economic evaluations and share the results with all stakeholders.

In terms of establishing independent and sustainable information on vaccine effectiveness, they suggested:

- Circulating ECDC data better;
- Funding public health research and development studies independently from the industry;
- Cooperating with academic institutions to develop evaluation mechanisms;
- Improving existing multinational tools for pharmacovigilance and data sharing;
- Setting up a fund (with mandatory contributions from the vaccine industry) to conduct public health-led vaccine impact studies utilizing available health and vaccine registries;
- Creating and funding an EU Agency able to produce tenders for countries to provide routine data on vaccination effectiveness in order to make this activity sustainable;
- An information and monitoring system at European level, respectful of the specificities of countries, but capable of consolidating the vaccine data collected in each country in order to have a European vision on vaccine effectiveness.

Besides, concerning the independent and sustainable information on vaccination impact monitoring at EU level, stakeholders suggested:

- Encouraging Member States to implement a vaccine recording system to monitor national vaccination rates and produce league tables;
- Having an EU-wide ECDC-coordinated vaccination impact and safety monitoring system;
- Improving coordination and exchange between Member States and public health authorities on vaccination impact, in diverse settings (socio-economic, age and gender groups) to identify inequalities in access and vaccine uptake;
- Supporting projects that bring together stakeholders in industry, NGOs, key opinion leaders and governmental institutions.

²² Answering the stakeholders' consultation only.

4. PILLAR III: EU COORDINATION, INCLUDING THE PROMOTION OF STAKEHOLDERS' DIALOGUE AND CONTRIBUTION TO GLOBAL HEALTH

Cooperation is an essential strategy in fighting vaccine hesitancy and increasing vaccination coverage rates at the EU level. The consultation questions in this section are aimed at gathering opinions and views of stakeholders mainly, but also citizens, on potential actions to strengthen the collaboration of the Member States under the coordination of the European Union in the interests of public health.

Interestingly, stakeholders²³ identified the EU cooperation areas missing for vaccination as:

- A common regulatory framework;
- Visibility, communication and media coverage (relying on ECDC and EMA);
- Cross-border public health campaigns (model of EAAD);
- Aligned vaccine schedules and reliable demand forecast;
- A common digital record system;
- An EU funding platform for studies and research;
- An EU immunisation platform for exchange of information, best practices, etc.

The funding instrument considered most important to support vaccines R&D was the EU framework Programme Horizon 2020 grant scheme (42%). However, answers were extremely heterogeneous in relation to the other funding mechanisms, including a high degree of '*no opinion*', reaching peaks of 30% (Annex – Graph 12).

4.1. PROMOTION OF CROSS-COUNTRY EXCHANGES IN THE EU

Stakeholders²⁴ (97%) called on the European Commission to coordinate and facilitate the sharing of best practices in vaccination policies and the exchange of vaccine medicinal products among Member states in situations of shortages.

In the first case, they explained that:

- Voluntary forums/meetings should provide the opportunity of exchanging best practices, for example the cooperation between health authorities, doctors and health mediators proved to be very successful in Bulgaria in fighting the measles epidemic in 2010;
- It should include (1) establishment of IIS, (2) tailored communication to recommended groups including healthcare professionals, (3) continuous training of healthcare professionals, including in social science and communication;
- Vaccination in community pharmacy should be encouraged in all Member States;

In the second case, they motivated that:

- Most vaccines are centrally authorised through EMA;
- Solidarity is a key value in the EU, especially in the case of public health concerns;
- Harmonisation of specifications and marketing authorisations should be done via OCABR and a change in EU legislation;
- Stockpiling should cover several sites across the EU, also to avoid wastes;

²³ Answering the stakeholders' consultation only.

²⁴ Answering the stakeholders' consultation only.

4.2. STRENGTHENING EU COOPERATION IN PUBLIC HEALTH PREPAREDNESS

Citizens and stakeholders agreed that joint efforts in ensuring vaccine supply and addressing vaccine shortages should be made by different organisations and at different levels. Although between 54% and 60.4% of citizens did not attribute a responsibility to anyone, stakeholders and citizens suggested cooperation between the pharmaceutical industry (respectively 60% and 26.7%) and Member States (respectively 53.5% and 23.5%). Stakeholders further considered that efforts by the European Commission (46%) would be highly effective too.

In order to increase the contribution of vaccination to public health preparedness and help Member States' efforts to ensure vaccine supply, the respondents rated the helpfulness of EU facilitated, cooperative activities. The preferred activity is for Member States to collaborate on the development of a crisis management plan with the industry to anticipate and reduce risks during vaccine manufacturing able to decrease vaccine shortages (48.95% of stakeholders and 18% of citizens). Stakeholders further suggested to assess vaccination needs (50.2%), and citizens considered investigating public perception on the pharmaceutical industry (24%) (Annex – Graphs 13 and 14).

4.3. MAKING RESEARCH MORE GLOBAL AND EFFECTIVE

Respondents were almost unanimous in agreeing that the efforts of the EU regarding vaccine research for fighting infectious diseases should focus on actions both in the EU region and worldwide, despite the fact that, again, 56% of respondents did not provide a view.

In particular, respondents²⁵ observed that engaging in research and development in vaccines would be highly important for the academia (26%), important for the international organisations (10.6%), and slightly important for Member States (8%). Over 48% of respondents did not provide an opinion.

According to stakeholders²⁶, it would be most helpful for Member States to collaborate to develop a roadmap of unmet population needs in terms of vaccination that can be used to inform all future vaccine funding programmes (48%), in order to increase the efficiency and effectiveness of EU funding of vaccine research and development. Identifying common stages and criteria for priority-setting of vaccine research and development needs was also considered very useful (42%). (Annex – Graph 15).

In terms of the most appropriate framework for the collaboration of public health authorities and civil society with the vaccine industry on implementing research, stakeholders suggested:

- Expert networks or platforms, based on transparency and a common agenda and protocol;
- Public universities and multi-stakeholder forums;
- A regulatory framework, especially for anticipating shortages and improve transparency;
- An EU specific agency, which should design the core of action and define the funding of information campaigns and research.
- Join Actions and public-private partnerships to build trust and generate/collect new data;

²⁵ Answering the public consultation only.

²⁶ Answering the stakeholders' consultation only.

5. FURTHER SUGGESTIONS

At the end of the survey, respondents were asked if there were any other policy intervention that they would have liked to add, which was not addressed in the questionnaire.

The majority of comments to the public consultation, especially by French citizens, was negative, supporting that the questionnaire was biased, vaccines are not safe nor effective. They called for a greater independence from the pharmaceutical industry in terms of research, for an open dialogue between vaccine supporters and opponents and for transparent information on vaccination risk and side effects by healthcare providers and public authorities.

Instead, concrete policy interventions suggested in both questionnaires include:

- According to article 114 of Directive 2001/83/EC as amended, Member States have the possibility to test individual batches of vaccines in an Official Medicines Control Laboratory (OMCL) before they reach the patient. This independent public control is essential for the high quality and safety standards for vaccines in the EU and for instilling confidence in patients, as currently any batch is tested in only 1 OMCL and the results are recognised throughout the EU;
- As over 98% of the European population can access a pharmacy within 30 minutes and no appointment or co-payment is needed to consult a pharmacist, they should be able to administer vaccines. In order to do so, pharmacists only need to undergo additional training (with regular refresher training, including managing adverse reactions, anaphylaxis, resuscitation), adhere to protocols, ensure recording, meeting requirements and ensure a private room in the pharmacy is available for this service;
- A robust legal regulation for vaccination is encouraged, with clear accountability to those involved, starting with the authorities, the medical profession, as well as the legal representatives of children. These responsibilities should result in protecting the lives of both children and adults, respecting the basic principles of the exercise of the established medical profession and protecting the physician – patient relationship;
- Establishing an open online platform that it is mandatory for all doctors to register on, which gives a tick or cross for each doctor indicating whether they are up to date on communicable disease vaccines;
- The European Commission should set/extend Mutual Recognition Agreements to 1) inspections of vaccine facilities by EMA and FDA, 2) approvals of post-approval changes by EMA and FDA, 3) batch release by EU OMCLs and non-EU GEON members (as Canada) and FDA;
- To prevent shortages due to repeats of animal tests, delays on lot release or unjustified rejection of conform lots, EDQM should: 1) get a supervisory role on European OMCL network; 2) guarantee the use by OMCL of compendia or product marketing authorisation testing methods; 3) lead harmonisation of methodologies within the EU OMCL network to get better definitions in the Ph. Eur; 4) be appointed for further initiatives to reach harmonisation of testing strategies, methods and specifications, and of pharmacopoeia between EU and other countries/regions;
- A prototype for a vaccine R&D priority-setting framework should be developed in collaboration with the industry and flexibility to enable ongoing innovation should be ensured. The European vaccine R&D Infrastructure should follow the model of US BARDA;

- Establishing at EU level an expert system capable of harmonising vaccination practices and information on vaccination within each country. It would make it possible to personalise and thus increase the impact of information on immunisation and to avoid discrepancies between messages delivered by different health professionals or vaccination actors, thus preventing vaccine hesitancy. It would also enable each Member State to collect data structured in the same way, to improve the quality of the indicators (vaccine coverage, vaccine safety, vaccine effectiveness, vaccine forecast), in real-time;
- Implementing a sanctioning mechanism for those who divulge fake news online and discourage vaccination;
- Prohibiting all lobbying activities to the European Commission by the pharmaceutical companies in particular;
- Making the pharmaceutical industry reliable morally and economically for the vaccine-caused damages, including vaccine injury compensation schemes;
- Allowing free of charge and universal access to the immunisation programmes to the entire population, including migrant populations and vulnerable groups, targeting particularly soon-to-be parents and young girls;
- Introducing a Europe-wide compulsory immunisation (with opt-out possibilities) for the most important vaccines, with exceptions on the basis of clearly defined, medical reasons, and imposing travel restrictions on unvaccinated individuals;
- Introducing mandatory vaccination to healthcare professionals, as a professional requirement, with sanctions in case of non-compliance;
- Mapping which Member States have vaccine information websites (provided by national health authorities, NGOs, academic institutions etc.) that meet the criteria of WHO's Vaccine Safety Net, and which does not, potentially leaving their citizens much more vulnerable to anti-vaccine information;
- Reviewing the available scientific literature on the efficacy and potential side effects of all recommended vaccinations and undertaking a comprehensive study of mapping the known side effect for each vaccine;
- Researching the dangers of vaccinations to individuals with certain pre-existing medical conditions or specific genetic traits, that could constitute a vulnerability to the immunisation programmes.
- Providing an efficient medical response to a major public health incident such as a bioterrorism attack or a rapidly emerging infectious disease, through the establishment of central or regional stockpiles to ensure full preparedness for any potential incident occurring (based on the USA model);
- Making specialist vaccines and countermeasures actively available to first responders, to protect them adequately when they are entering the arena of a possible outbreak or biological attack;
- Disaggregating data and outreach programmes for socio-economic groups, considering the free movement of people and open borders;
- Dedicating more funding and human resources to vaccination programmes, providing incentives to the patients through health insurance schemes;

6. CONCLUSION

Overall, the public consultation revealed a strong polarisation of opinions, between a minority providing concrete suggestions and endorsing the initiative (especially the respondents to the stakeholders' consultation) and a majority supporting vaccine hesitant perspectives. Both groups include stakeholders and citizens, healthcare professionals and non, across the European Union.

A clear country-related trend is visible in the chronological order of submission of comments to the public consultation, suggesting that the respondents, particularly the private citizens and the umbrella organisations, used social media and other online communication tools to spread information within their networks about the opportunity to participate in the consultation. The trends characterised limited numbers of same national respondents in a row (5 to 200) until the 14th March, a day before the closure of the consultation, when almost 6000 new answers were registered from France.

Given the negative nature of these contributions and the identification of online mobilization campaigns against the initiative²⁷, it is highly possible that a link exists between the two actions. In fact, the respondents were encouraged to answer the questionnaire with the 'no opinion' option, leading to boycotted and biased results. As these contributions provided no opinion, they were not analysed further for the scope of this report.

The main concerns for the vaccine hesitant respondents were: the side effects and vaccine ingredients; the perceived lack of safety and effectiveness of vaccines; the imposition of mandatory vaccination; the lack of vaccine-damaged compensation schemes; the perception of the pharmaceutical industry as more interested in financial gains than public health; the lack of a robust, transparent and industry-independent scientific research; the perceived unilateral information received by healthcare professionals on vaccine benefits, but not on risks.

Despite the fact that they represent over half of total respondents, the other contributors endorsed the European Commission's initiative, especially calling for a higher cooperation between Member States and all involved actors in the field of vaccination, including international organisations, healthcare providers, public authorities, civil society and grassroots level organisations.

As far as the first pillar is concerned, the confidence in the effectiveness of vaccines and the related fear of possible side effect were identified as the main vaccine hesitancy determinants. To tackle them and promote simultaneously the use of recommended vaccination, respondents identified a holistic and multi-component approach, in which interventions are dialogue-based, with targeted messages and supported with a range of different means (campaigns, social media, TV, leaflets, events, etc.). The responsible actors are a cross-sectorial team, including healthcare providers, family members, the civil society, the European institutions, Member States, NGOs and others. In particular, the direct communication to the general public was considered most efficient if done by healthcare professionals, as they are in a close relationship with their patients. For this scope, specific trainings in the workplace and during university studies and the provision of information material were considered highly necessary to help healthcare professionals communicate to people that are more hesitant and to be regularly updated on vaccines. A multi-tool approach was identified as effective in communicating to the general public, including national campaigns, user-friendly information with a simple

²⁷ <https://www.ipsn.eu/vaccins-commission-europeenne-demande-avis-15-mars/>, <https://www.ipsn.eu/vaccins-commission-europeenne-demande-avis-15-mars/>

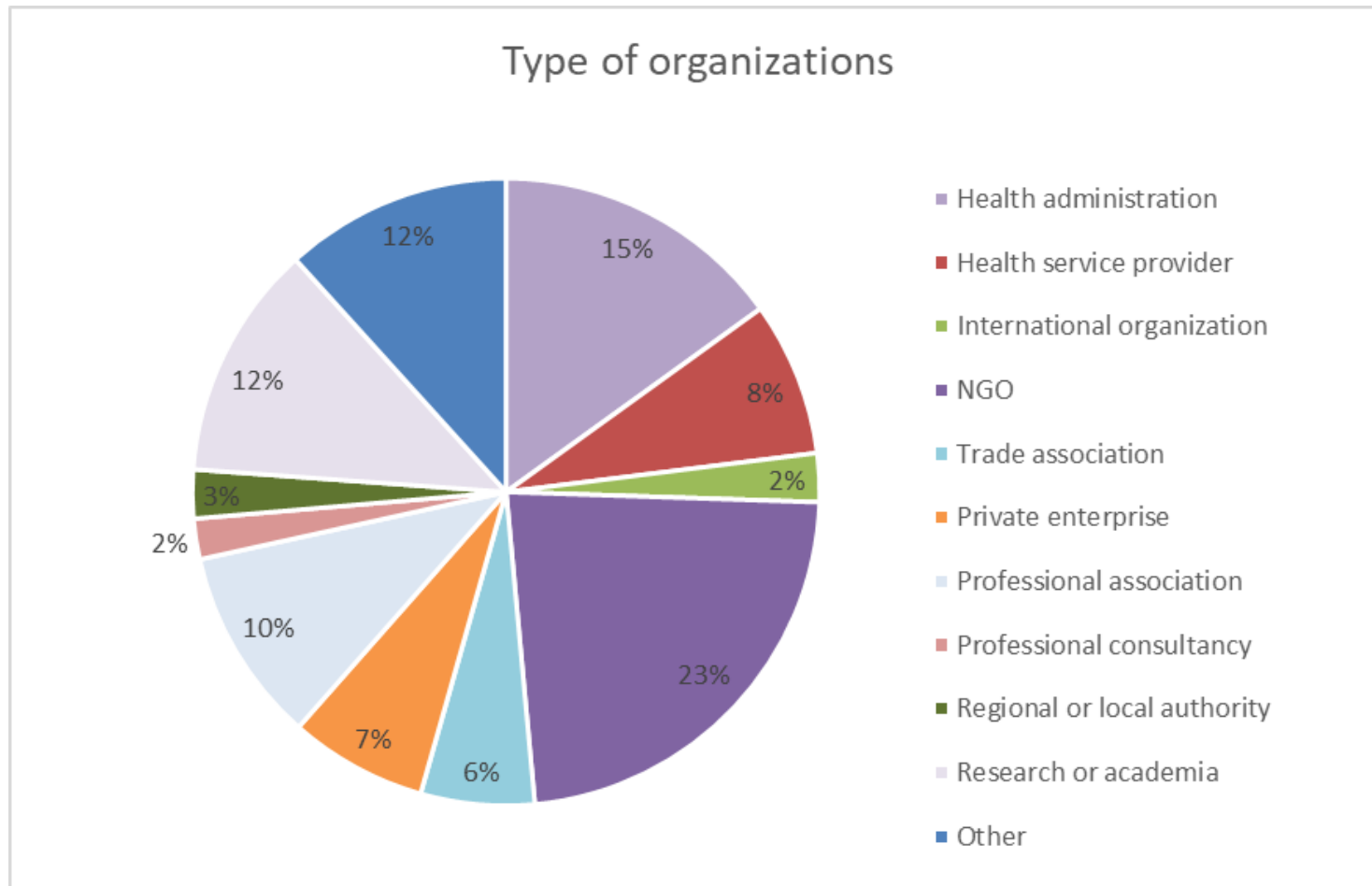
language and relying on infographics and short videos, instead of scientific publications. Importantly, respondents put the focus on the need to educate and inform the general public with a better, holistic, face-to-face approach at the local level, involving schools, churches, famous local influencers, healthcare providers, women etc. The role of the EU in fighting hesitancy by providing adequate communication on vaccine benefits was considered inappropriate, mostly because the information provided by EMA and ECDC are fragmented. The pharmaceutical industry was asked to improve transparency, pricing, research and to develop more social responsibility programs to tackle vaccine hesitancy.

In relation to the second pillar, the well-functioning of sustainable vaccination programmes was also considered a cross-sectorial and holistic responsibility of different actors at different levels. Therefore, good communication and collaboration efforts between the local, regional, national and international levels were of extreme importance. In order to integrate vaccination programmes better in the health system, respondents considered it necessary to include vaccination in a broader public health perspective or in other age-group-related healthcare activities, besides improving the universal access to vaccination programs (e.g. in pharmacies). From the technological point of view, the introduction of an electronic vaccination record was highly supported by stakeholders. To incentivize the vaccines production capacity, address vaccine shortages and improve the communication with the vaccine industry, the respondents suggested carrying out national systematic vaccine forecasts, mapping vaccine demand better, creating joint vaccine procurements and improving surveillance. In terms of bolstering research and development, respondents called for an increase in funding and for ensuring transparent, industry-independent research publications, especially on the safety and effectiveness of vaccines.

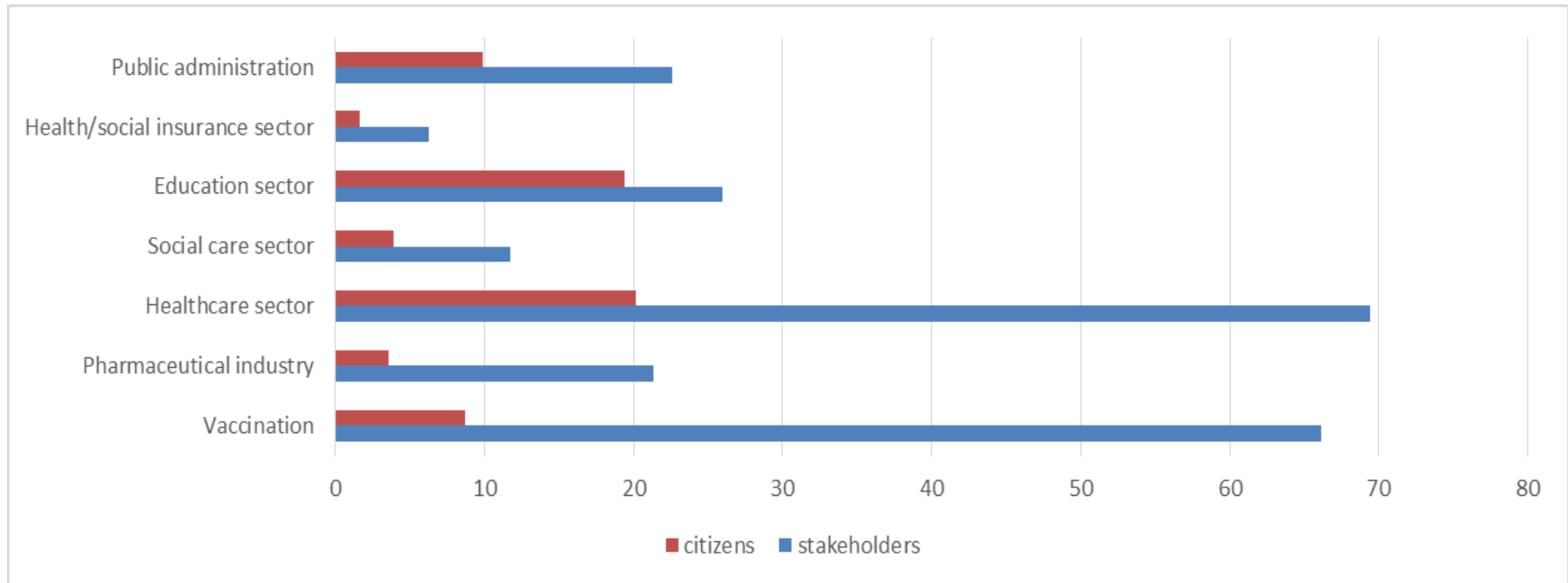
The third pillar regards EU coordination, which, according to respondents, should focus on both the EU region and outside, as far as vaccination research is concerned. Once again, respondents believed that R&D and vaccine supply were fields where a multi-component approach was needed, in terms of actions and responsible actors, principally the pharmaceutical industry and Member States. No clear-cut answer was provided on the funding of R&D, shared among the pharmaceutical industry, Member States, the European Commission and international organisations. However, the most supported funding instruments were the Horizon 2020 grant scheme and PPPs. According to stakeholders, the EU is currently missing a common regulatory framework, besides cross-border public health campaigns, a common digital record system, a common funding for research and online platforms for information exchange and better demand/supply balance preparedness. Respondents accepted the role of the European Commission as facilitator of the exchange of vaccines and best practices among countries. According to them, Member States should focus on the development of a common crisis management plan to anticipate and reduce vaccine manufacturing risks and the assessment of vaccination needs and on the development of a roadmap of unmet population needs in terms of vaccination that can be used to inform all future vaccine funding programmes.

ANNEX

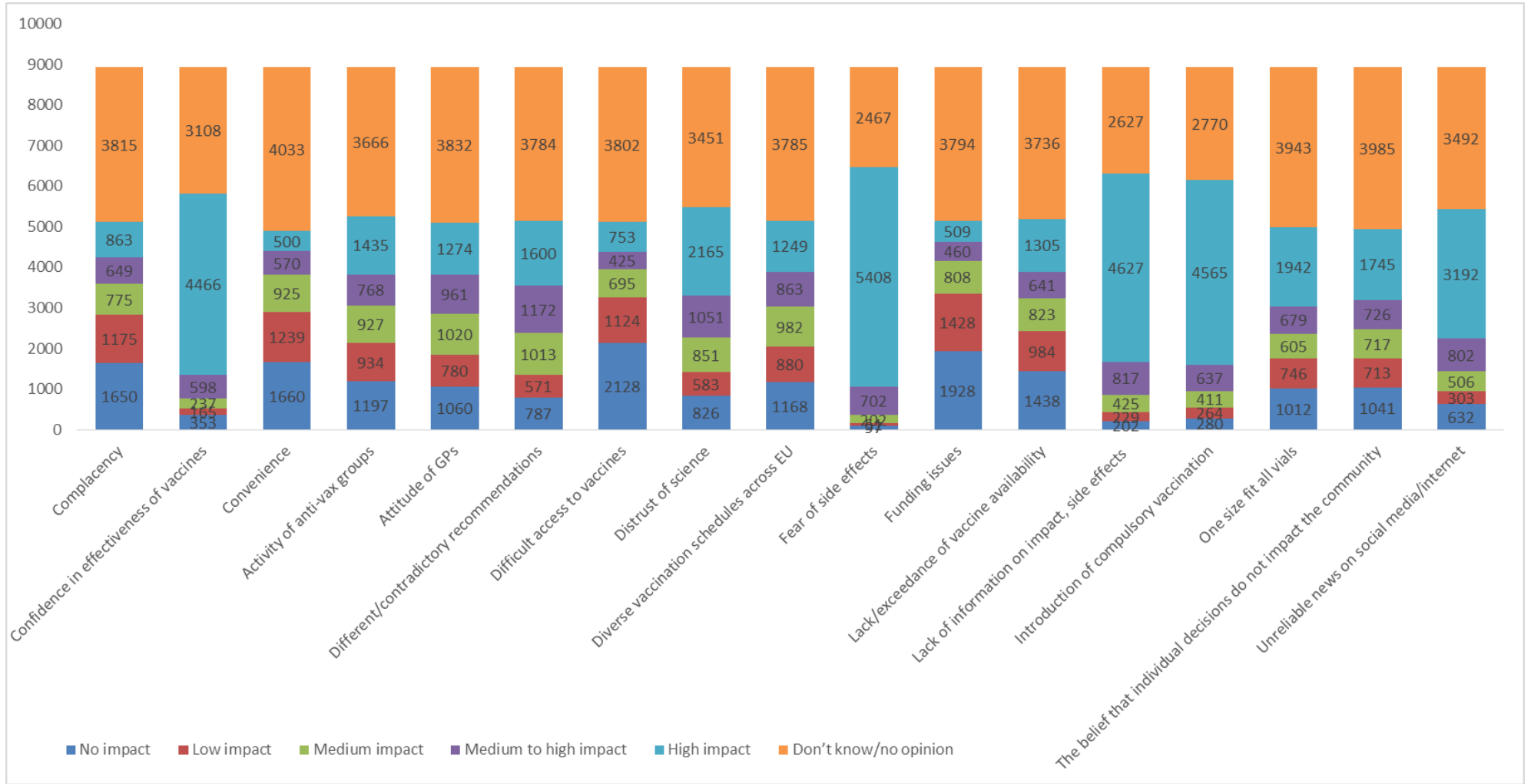
Graph 1 –Stakeholder respondents by type of organisations. N = 239.



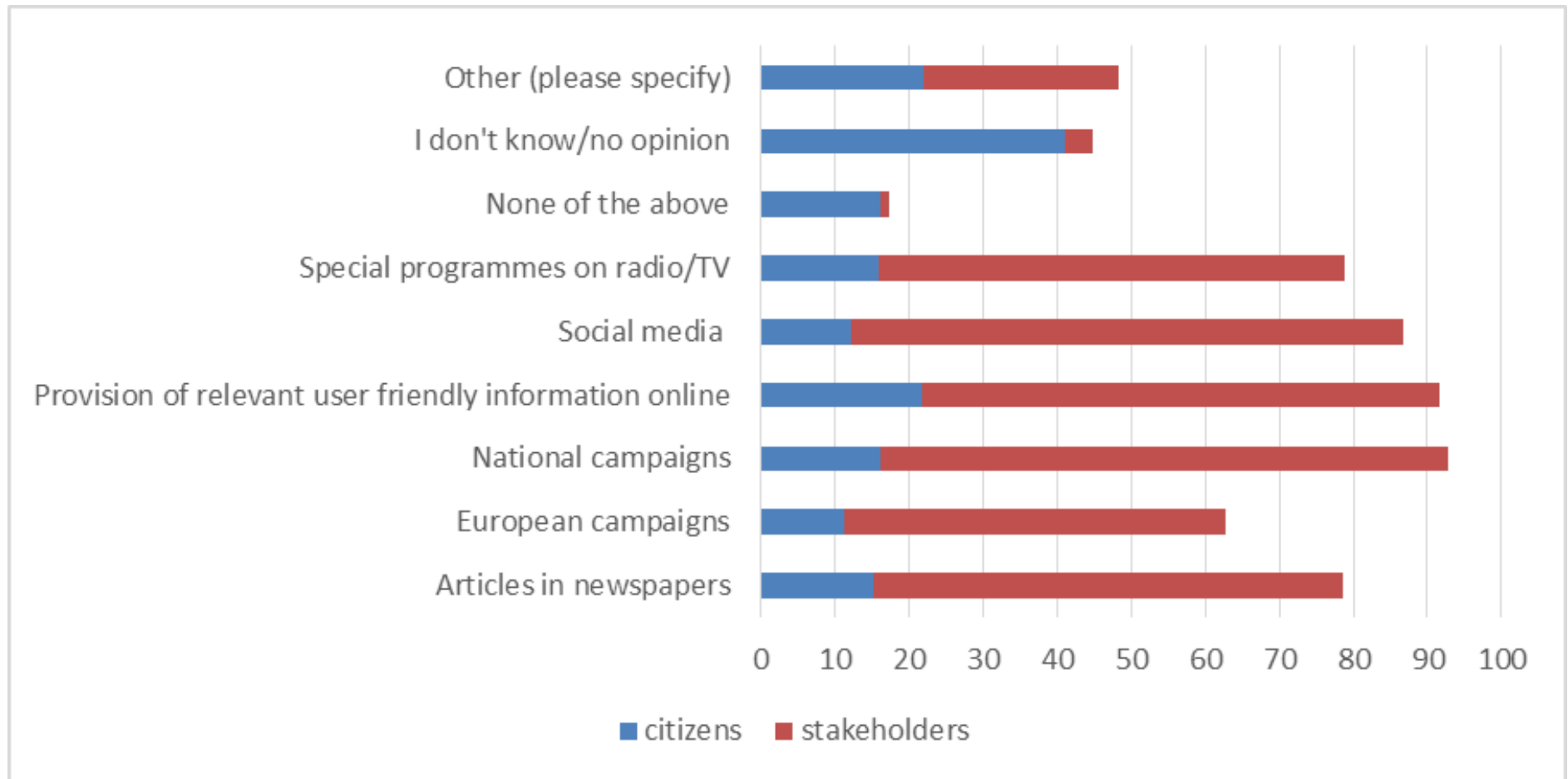
Graph 2 – Declared working experience of citizens (N=8688) and stakeholders (N=239) in specific areas. Statistics in percentage. Multiple answers possible.



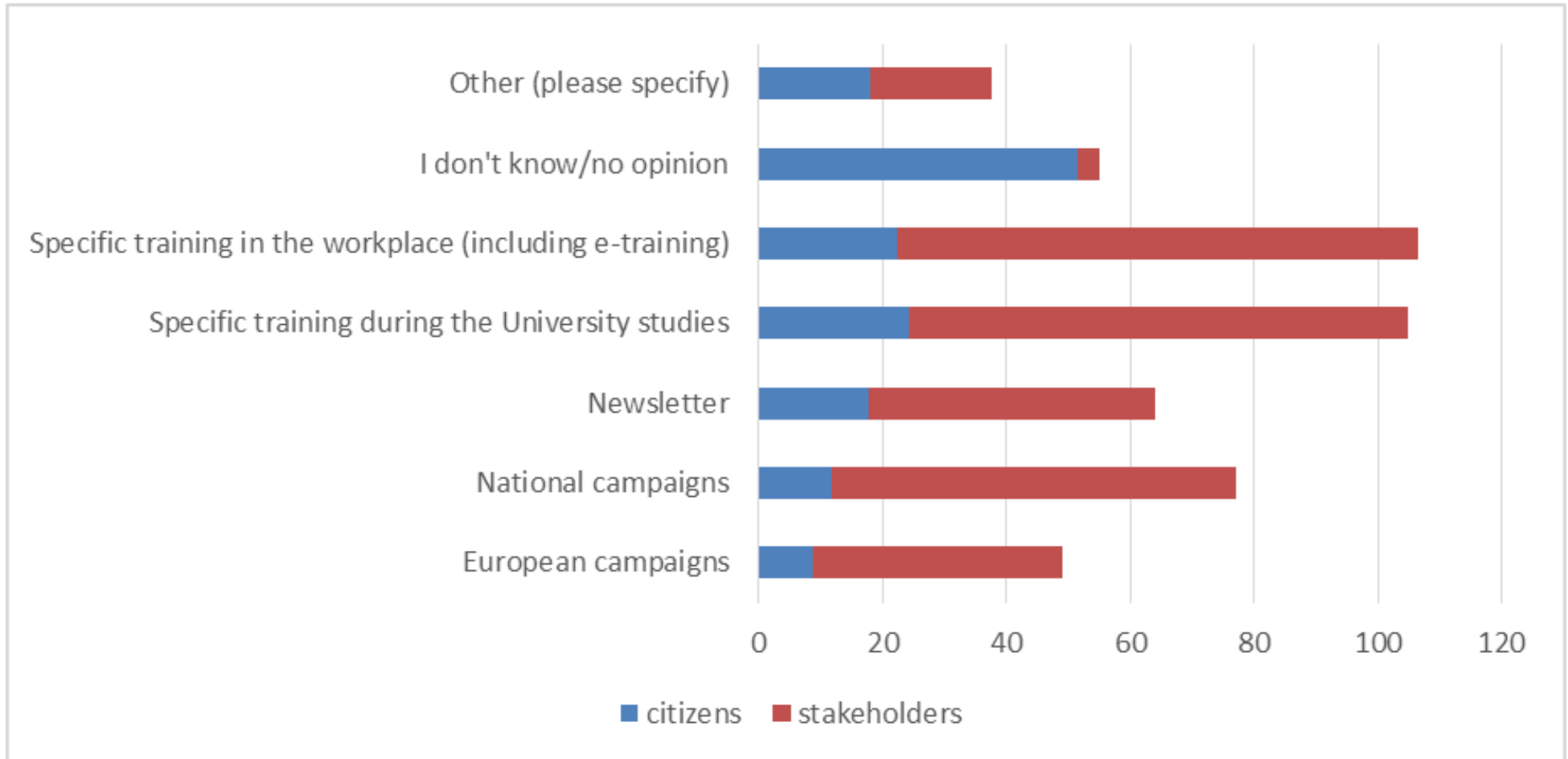
Graph 3 – Opinion of respondents (N=8927) about the impact of specific factors on vaccine hesitancy. Multiple answers possible.



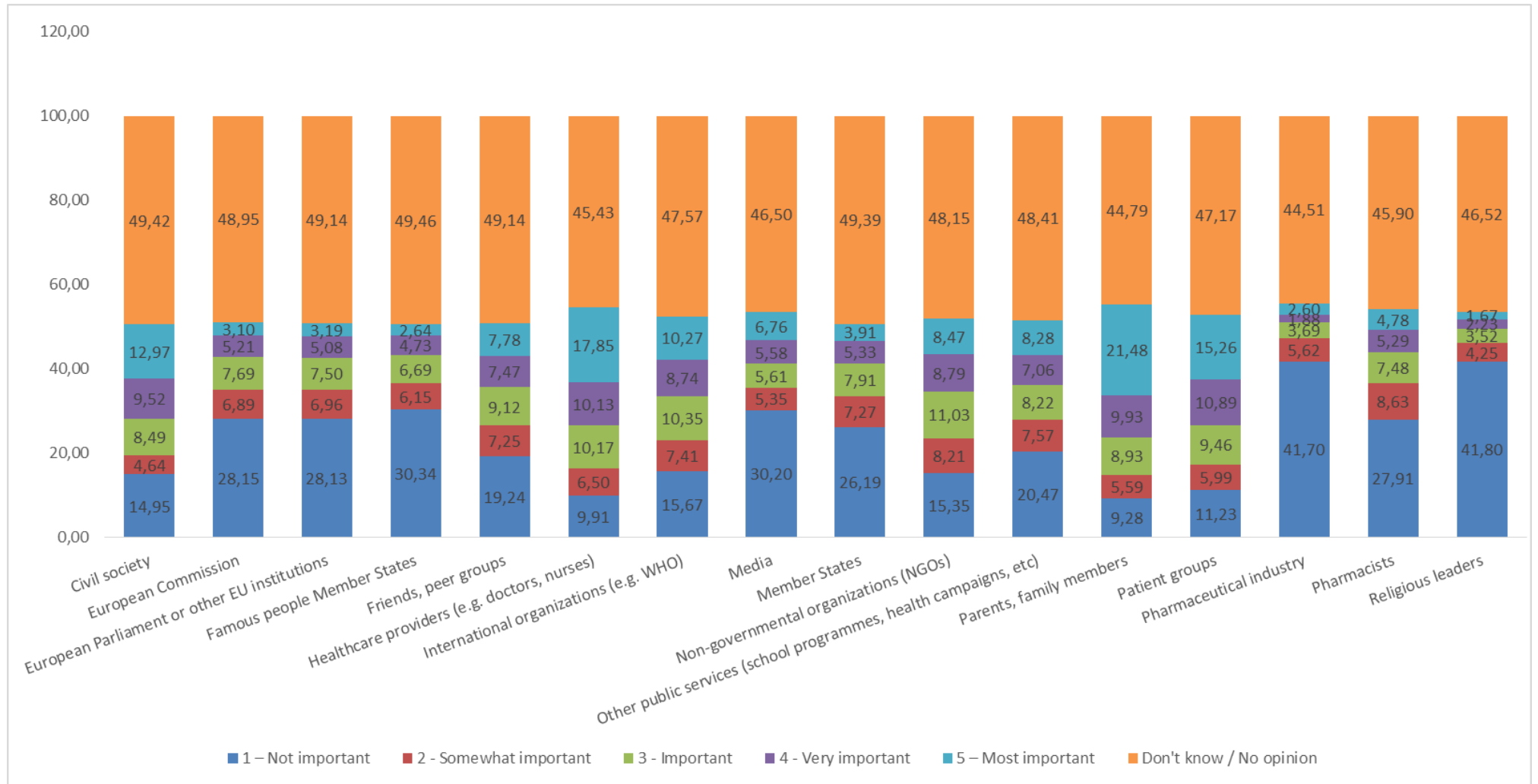
Graph 4 – Opinion of stakeholders (N=239) and citizens (N=8688) on how health authorities can better communicate about the safety and effectiveness of vaccines to the general public. Statistics in percentage. Multiple answers possible.



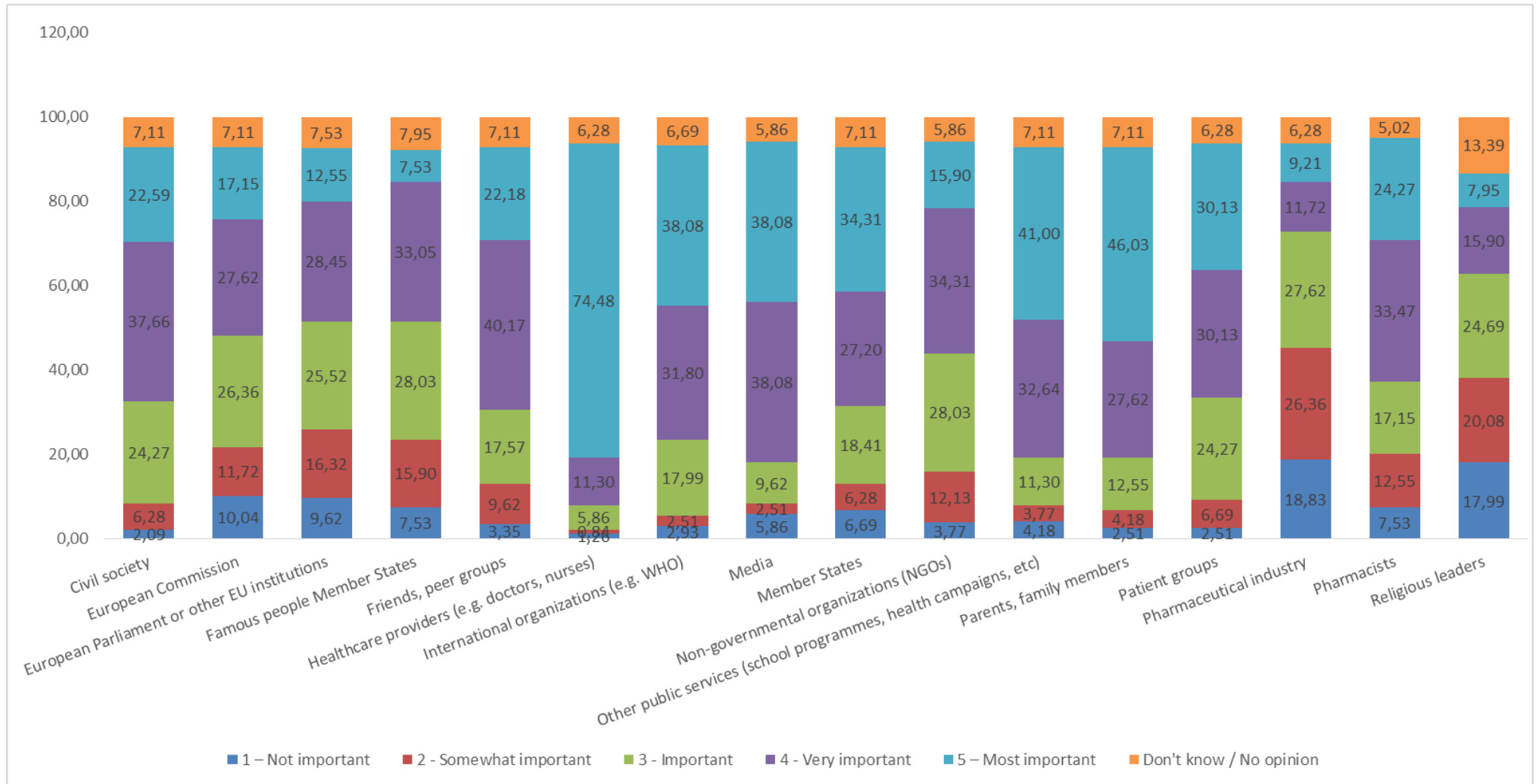
Graph 5 – Opinion of stakeholders (N=239) and citizens (N=8688) on how health authorities can better communicate about the safety and effectiveness of vaccines to the healthcare workers. Statistics in percentage. Multiple answers possible.



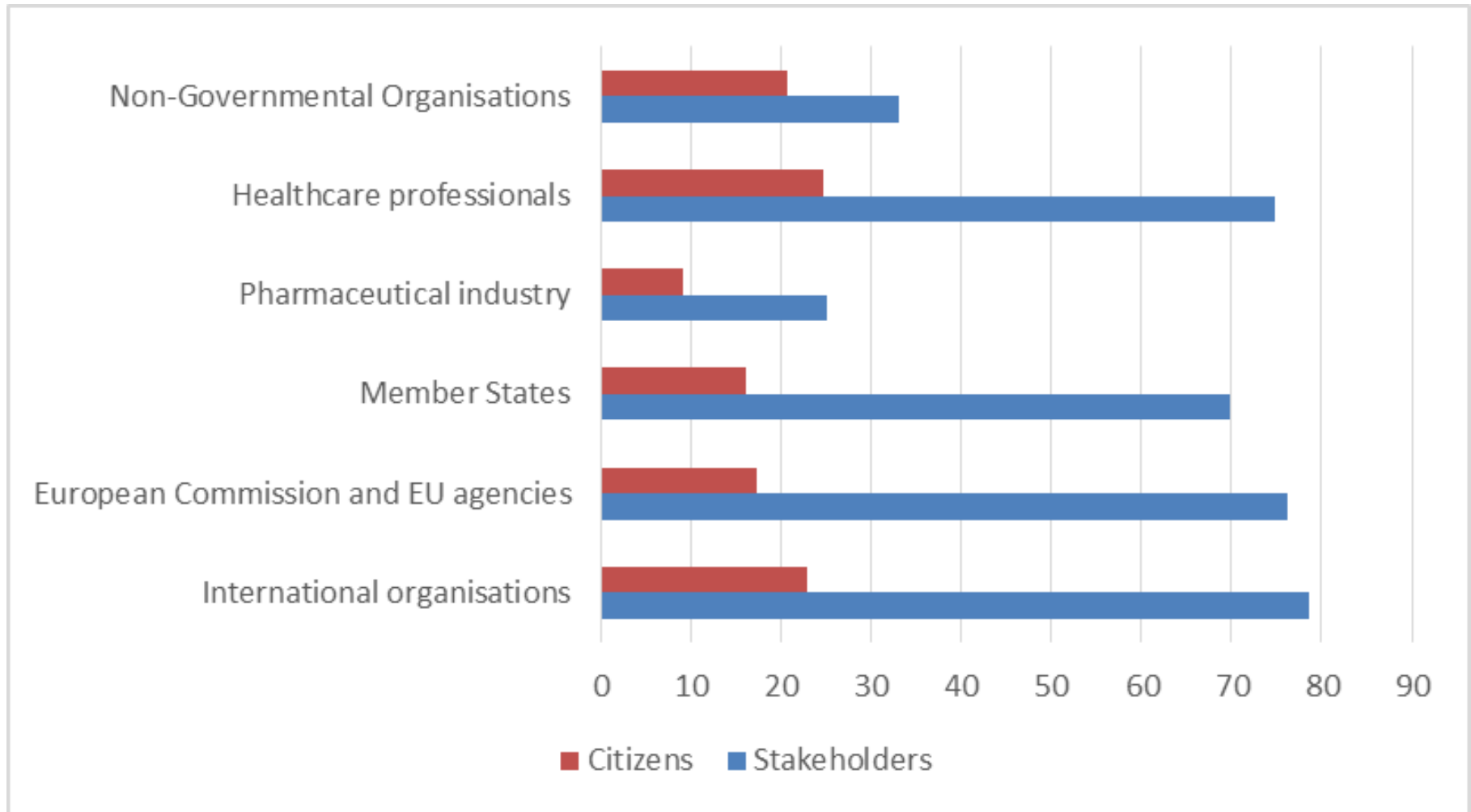
Graph 6 – Opinion of citizens (N=8688) on the most important actors in promoting the use of recommended vaccination. Statistics in percentage.



Graph 7 - Opinion of stakeholders (N=239) on the most important actors in promoting the use of recommended vaccination. Statistics in percentage.



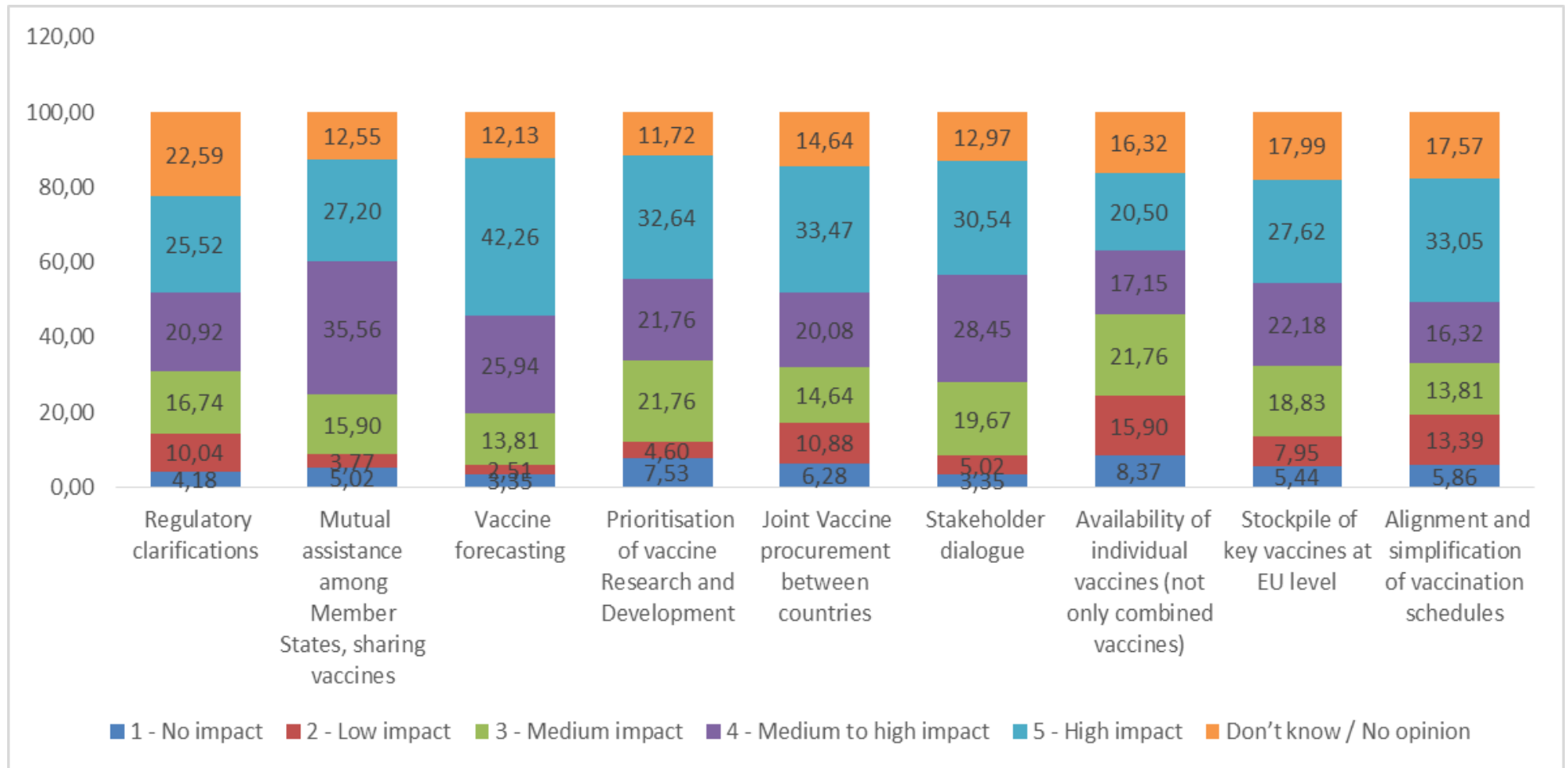
Graph 8 – Opinion of stakeholders (N=239) and citizens (N=8688) on who should make efforts in providing scientific arguments in favour of vaccination. Selection of the highest efforts. Statistics in percentage.



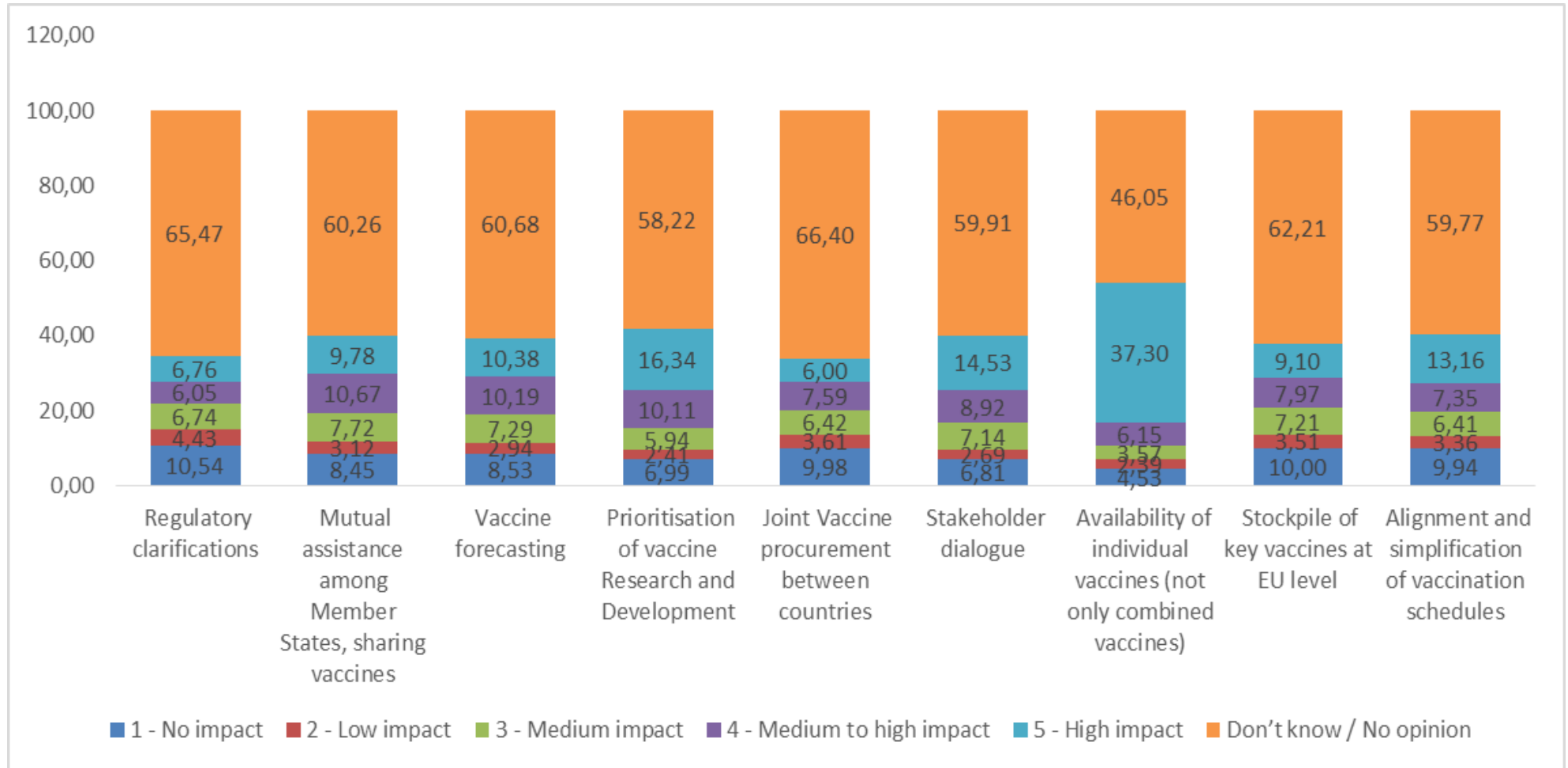
Graph 9 – Opinion of stakeholders (N=239) and citizens (N=8688) on which organisations are responsible for ensuring that vaccination programmes function well. Statistics in percentage.



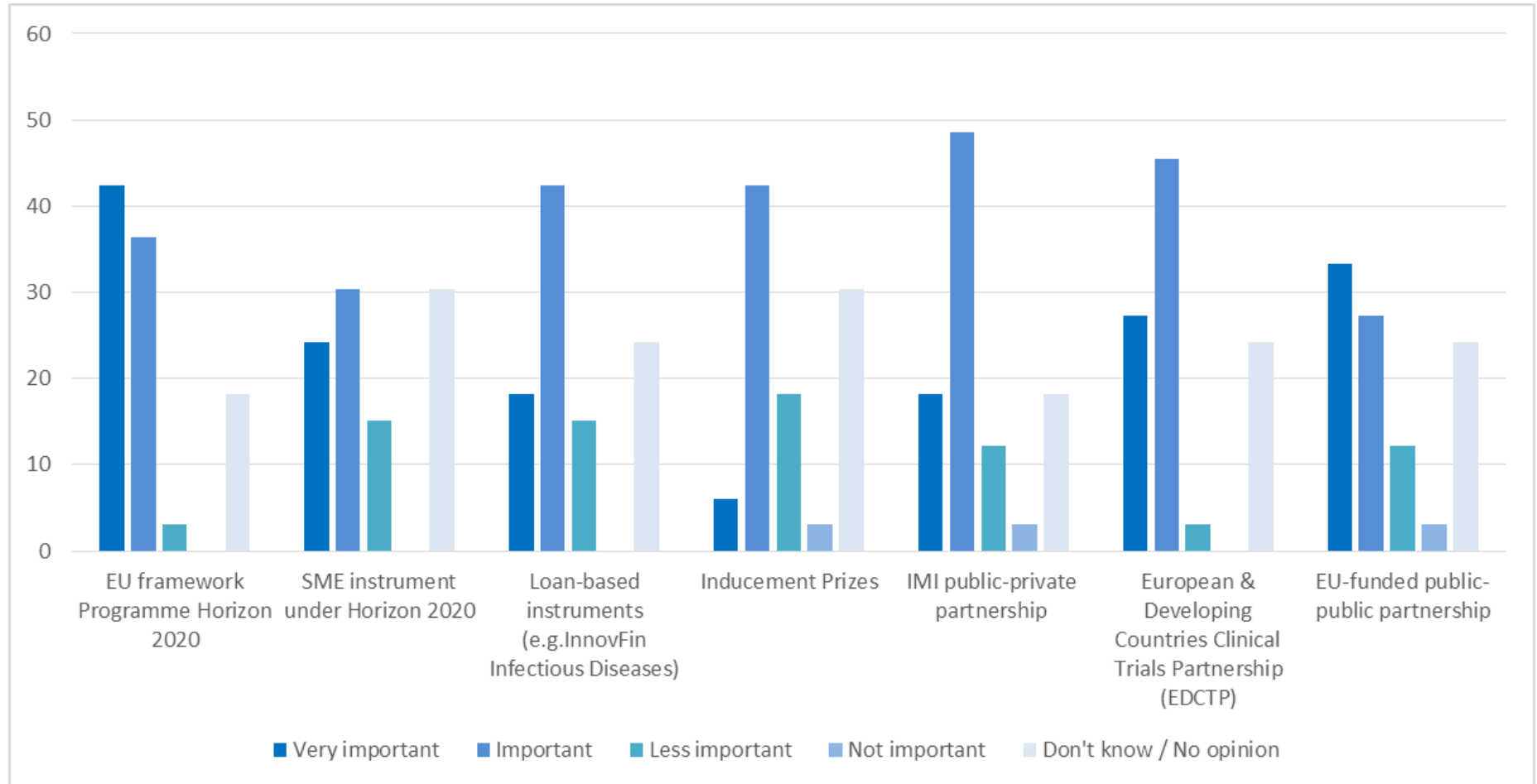
Graph 10 – Opinion of stakeholders (N=239) on which policy interventions would have the biggest impact on mitigating vaccine shortages at EU level.



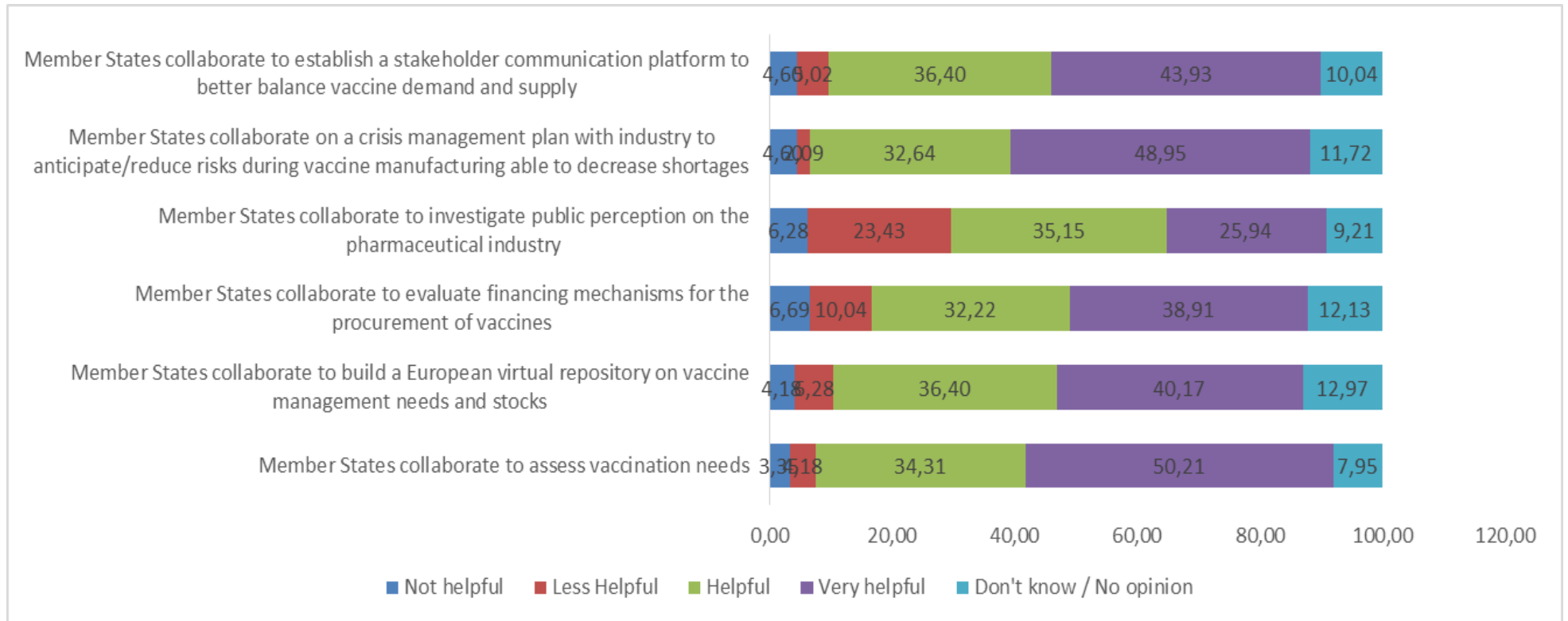
Graph 11 – Opinion of citizens (N=8688) on which policy interventions would have the biggest impact on mitigating vaccine shortages at EU level.



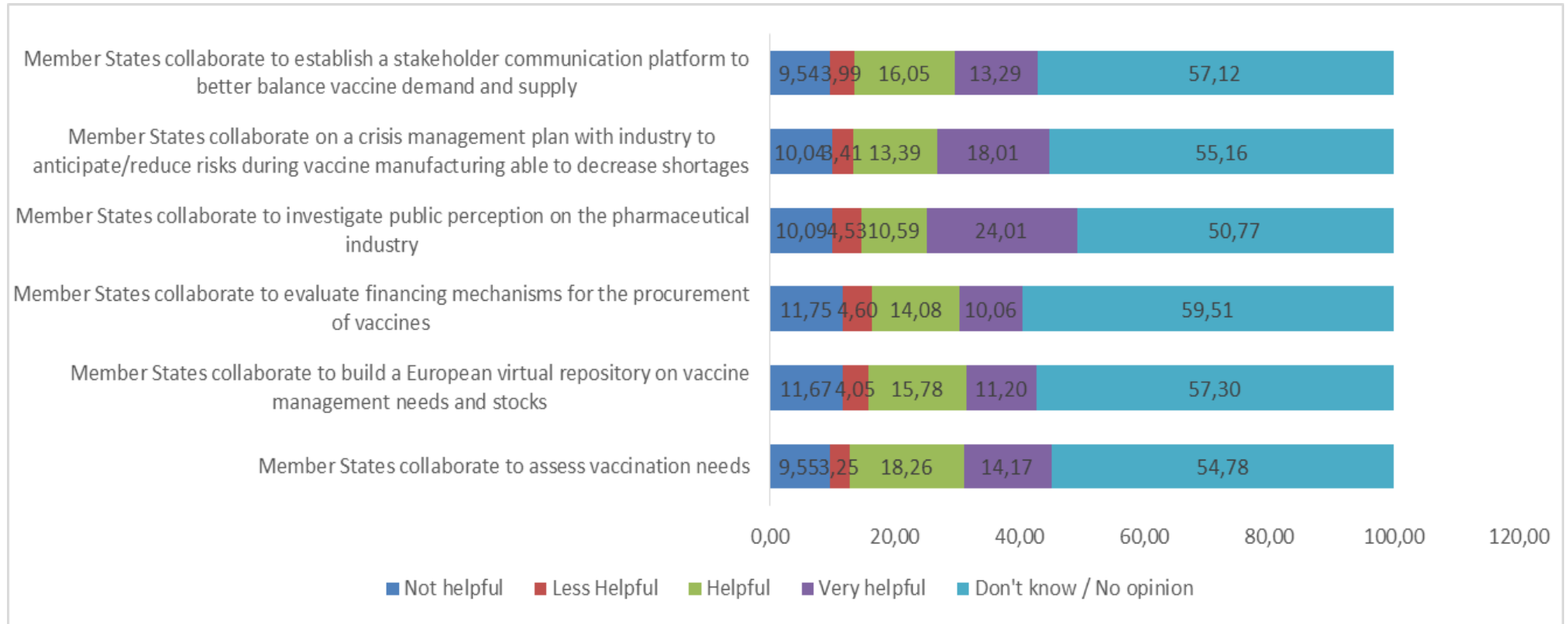
Graph 12 - Opinion of stakeholders (N=33) on importance of different funding instruments to stimulate vaccines R&D. Statistics in percentage.



Graph 13 – Opinion of stakeholders (N=239) on which EU facilitated activities are helpful in order to increase the contribution of vaccination to public health preparedness and help EU Member States’ efforts to ensure vaccine supply. Statistics in percentage.



Graph 14 – Opinion of citizens (N=8688) on which EU facilitated activities are helpful in order to increase the contribution of vaccination to public health preparedness and help EU Member States’ efforts to ensure vaccine supply. Statistics in percentage.



Graph 15 – Opinion of stakeholders (N=33) on helpfulness of EU-facilitated activities to increase the efficiency and effectiveness of EU funding of vaccine R&D. Statistics in percentage.

