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ARBEITSDOKUMENT

zum Sonderbericht Nr. 28/2016 des Europäischen Rechnungshofs (Entlastung 2015): Der Umgang mit schwerwiegenden grenzüberschreitenden Gesundheitsgefahren in der EU: Wichtige Schritte wurden unternommen, doch weitere müssen folgen

Haushaltskontrollausschuss

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Introduction

In the previous decades, various events posing threats to health and life¹ have led to increased attention for health security at international and EU levels. Those events have also showed that serious health threats are often cross-border problems, and may require a multi-sectorial and multilateral response.

The Treaty on the functioning of the European Union (TFEU) states that a high level of human health protection shall be ensured and that Union action shall cover the monitoring, early warning and combating of serious cross-border threats to health. Thus the Commission's role in health policy consists mainly of providing support and taking complementary action.

At international level, the Commission collaborates with the Global Health Security Initiative (GHSI) and the World Health Organisation (WHO) in the context of the growth in international travel and trade, and the emergence and re-emergence of international disease threats and other public health risks.

Within the EU framework, the Commission defined an EU health strategy for 2008-2013, which had as one of its three objectives to protect people from health threats². An evaluation by the European Commission (2011) found that the strategy acts as a reference for actions taken at national and EU levels and confirmed that the principles and objectives identified in 2007 would remain valid for the next decade in the context of Europe 2020.

A key milestone in building a stronger EU health security framework was the adoption in 2013 of a decision on serious cross-border threats to health, introducing important innovations as regards, for example, the coordination of preparedness planning and the strengthening of the role of the Health Security Committee (HSC). Another innovation of the decision is the joint procurement of medical counter-measures.

The EU health and research framework programmes also support activities in the field of health security. The EU health second programme ran from 2008-2013 and the third is being implemented in the period 2014-2020. The Consumer, Health, Agriculture and Food Executive Agency (Chafea) is largely responsible for the management of the health programme. Other EU funds for health security are the research framework programmes (FP7 in 2007-2013 and Horizon 2020 for 2014-2020). DG Research and Innovation and DG Migration and Home Affairs are in charge of this thematic areas.

In defining the audit scope and objectives the Court considered the EU framework for protecting citizens from serious cross-border threats to health to consist mainly of Decision No 1082/2013/EU on serious cross-border threats to health and the EU resources made available to support its implementation. Overall, this framework fits into the wider context of the EU health strategy.

The audit work addressed the following main audit question:

¹ In 2003 the severe acute respiratory syndrome (SARS) epidemic; the worldwide H1N1 pandemic of 2009; the 2011 E.coli outbreak in Germany; the 2014 Ebola outbreak in west Africa, and the 2016 Zika virus outbreak in South and Central America.

² The other two are fostering good health in an ageing Europe, and supporting dynamic systems and new technologies.

Is the EU framework for protecting citizens from serious cross-border threats to health adequately implemented?

The Court examined: i) whether the innovations introduced by the decision are effectively implemented; ii) whether the existing systems for early warning and response and epidemiological surveillance are adequately managed and implemented; iii) whether the EU health programmes are making effective contributions to protecting citizens from threats to health; and iv) whether the Commission's internal coordination in terms of health security funding and public health crisis management is adequate.

The audit involved the Commission (DG Health and Food Safety, DG Migration and Home Affairs, DG Research and Innovation, the Research Executive Agency and the European Research Council Executive Agency) and the European Centre for Disease Prevention and Control (ECDC), information visits to four MS (Estonia, Italy, the Netherlands and the United Kingdom) and to World Health Organisation (WHO) Europe.

European Court of Auditors' (ECA) observations

The decision on serious cross-border threats to health introduced certain innovations for EU health security, but their implementation and development were hampered by delays, and strategic and operational challenges remain

MS and the Commission should consult each other within the HSC with a view to coordinating their efforts to develop, strengthen and maintain their capacities for the monitoring, early warning and assessment of, and response to, serious cross-border threats to health. That consultation should be aimed at sharing best practices and experience in preparedness and response planning, promoting the interoperability of national preparedness planning and addressing the need for different sectors to work together in preparedness and response planning at Union level. It should also support the implementation of core capacity requirements for surveillance and response.

The Commission adopted a template for providing the preparedness information 4 months before the deadline for completion of the questionnaire by the MS, during the Ebola crisis. The replies were mostly delayed, but this exercise initiated the required exchange of information on preparedness and response planning. However, most of that information is anonymised and aggregated which limits the usefulness of the data provided, and there is no verification of its accuracy. In addition, the Court observed that the ECDC was not involved sufficiently early in the IT preparations for using the online survey tool, which made some MS have reservations about the findings included in the progress report. Despite the existence of extensive guidance on generic preparedness planning for all types of health threats, the guide was not up to date and MS did not use it.

The Court therefore observed insufficient clear-cut results from the preparedness planning consultation and coordination.

The Commission should measure the effectiveness of Union policies and programmes. SMART (specific, measurable, achievable, relevant and time-bound) objectives and indicators need to be defined, in close contact with the MS, and a methodology to enable clear progress measurement and evaluation. MS in turn need to demonstrate their progress.

DG Health and Food Safety's objectives for health in the current programming period include a specific objective related to the protection of citizens from serious cross-border health threats. For this objective, the Commission set the targets for MS integrating the developed common approaches in the design of their preparedness plans. However, the Court observed that the concept was not developed neither the progress measuring was agreed despite the refinement of methodology done by the Commission in 2016.

The Court thus observed weak measurement of performance in preparedness coordination.

With regard to ECDC's role, the Court found that, in relation to generic preparedness, ECDC is insufficiently formalised because it was given new tasks without update of its status. In addition, the Commission raised doubts about the ECDC's mandate and concluded that the HSC was the appropriate and mandated body to discuss matter of preparedness.

Insufficient MS responsiveness to speed up the joint procurement of pandemic influenza vaccine and absence of an EU mechanism to address urgent needs for medical countermeasures within the framework of the decision on serious cross-border threats to health. Overall, the Court found that progress in organising the joint procurement of pandemic influenza vaccine, initiated after the 2009 H1N1 pandemic, had been slow and that there is no mechanism at EU level to address urgent needs for medical countermeasures, potentially reducing the EU's preparedness for pandemic influenza.

The decision on serious cross-border threats to health establishes the HSC, composed of representatives from the MS, and chaired by the Commission. The terms of reference were drafted for four working groups under the HSC and the participation is voluntary. Overall, the work of the HSC has been very important and has initiated the development of collaborative mechanisms. The HSC became a main platform where representatives from relevant Commission services and MS joined forces and started exchanging information, including with WHO. However, from the moment when Ebola was declared a public health emergency of international concern by WHO, most HSC work and its audio conferences focused on the response to the Ebola crisis, which was a low-risk health threat for the EU. The HSC needs to enhance its strategic work.

MS, when intending to adopt public health measures to combat a serious cross-border threat to health, should first inform and consult the other MS and the Commission on those measures to ensure consistency of action. However, this can be challenging as seen during the Ebola outbreak where some MS diverged from ECDC and WHO guidelines and did not coordinate national responses.

The important role of existing systems and procedures for early warning and response and epidemiological surveillance is widely recognised but there are certain upgrades to be made

Despite extensive use and wide appreciation of the Early Warning and Response System (EWRS), further enhancements are needed, including for the interfaces with other alter systems. The Court observed that EWRS has inherent limitations due to the outdated system design, which does not allow for the integration of the latest IT tools, social media connections or full mobile device compatibility. The system could provide better support to health emergency situations, and could be upgraded to a situational awareness platform at EU level for maintaining a real-time overview of national public health measures taken for dealing with serious cross-border health threats. In addition, the procedural or technical

interfacing with other rapid alert systems at Union level was not yet completed.

The updated EU level approach to early warning and response for serious chemical and environmental threats is not yet tested.

The EU system for epidemiological surveillance generally works well, but some further work is required to optimise data comparability and quality. ECDC's efforts to address issues in epidemiological surveillance data reporting have not yet been fully effective to ensure optimal data comparability and quality. MS could also still improve in this area by consistently using EU-level case definitions and optimising their data delivery to ECDC.

The performance of the health programme as regards protecting citizens from health threats showed weaknesses

The Court examined whether the EU health programmes are making effective contributions to protecting citizens from threats to health. It examined the management by Chafea and performance of 20 actions, and audited the progress of the health threats objective under the current third health programme in terms of relevant actions formulated in the annual work plans and the related performance measuring by the Commission.

Overall, the Court found that the performance of the health programmes, as regards protecting citizens from serious cross-border health threats, showed weaknesses. It identified a lack of sustainable results for health threat actions under the second health programme (2008-2013) and weaknesses in measuring the indicator for the health threat objective under the third health programme. For the 2014-2016 period, the Court also found a relatively low level of spending on health threat actions, considering the importance and ambition of the relevant objective and available resources.

Most of the 14 projects in the 20 actions sample performed well in terms of producing the agreed deliverables. However, many of those were not being used after the projects had finished, so there was a significant lack of sustainability of results. In addition, the Court found that Chafea and/or the Commission give very limited technical feedback on the content of project deliverables and policy relevance when projects are finished. Raising awareness of the results of co-funded actions in order to maximise their uptake and impact can be improved. The same conclusion was reached in the audit of five procurement items in DG Health and Food Safety and Chafea.

However, there is evident benefit in the audited projects in terms of EU-wide networking and capacity building. All project grants are implemented by consortia of partners, and although there is a certain concentration of activities with a limited number of national agencies, much experience has been gained. Nevertheless, the Commission does not take sufficient structured action, in collaboration with its partners, agencies and committees to optimise the policy feedback loop. It could be more effective in helping beneficiaries to overcome barriers for targeted dissemination and assessing, and promoting the policy relevance of completed actions.

The third health programme for Union in the field of health (2014-2020) covers four specific objectives and indicators, one of which addresses serious cross-border threats to health (objective 2). The objective should be measured through the increase in the number of MS integrating coherent approaches in the design of their preparedness plan.

The financial envelope for the implementation of the programme is 449 million euro, and there should be a balanced distribution of budgetary resources between the different objectives of the programme. The expected overall amount for that period for objective 2 is 12 069 000 or 3% of the total programme amount across the four objectives. Even if some adjustments might be done in the 2016 review, the evidence shows that fewer actions had been included in the annual work programme for 2014 and 2015 than initially planned. Consequently, the programme was not on track to spend the forecast 3% of the total available resources on objective 2 by 2020.

The Court also examined the methodology for measuring the indicator for the health threats objective and found that there is no clear method to measure the progress under the relevant specific indicator from the funded actions. This raises concerns over whether a sufficient number of policy-relevant actions to achieve some balance between the objectives, and make a real impact for serious cross-border threats to health, can be funded by 2020.

There are gaps in the Commission's internal coordination in terms of health security activities and public health crisis management

The coordination between Commission services for health security funding different EU programmes does not fully ensure synergies.

The Commission experience of research programmes shows that there is a need to better involve end-users to ensure a better take-up of results. DG Migration and Home Affairs took the initiative to develop a 'Community of Users for Disaster Risk and Crisis Management', which provides a forum for information exchanges between users and other stakeholders.

Projects operating in the same thematic area might be funded from different EU programmes and involve a range of Commission services. The risk of overlaps persists, and opportunities for achieving more synergies remain.

A memorandum of understanding signed in May 2013 by DG Health and Food Safety, DG Migration and Home Affairs and DG European Civil Protection and Humanitarian Aid Operations covers the coordination of their respective crisis management structure. The memorandum was put in place to increase the EU's capacity to respond to major multi-sector emergencies. However, the Court found that at the time of the audit, standard operating procedures to implement the agreement were still being developed, mainly due to the evolving of Ebola crisis, that shift the focus from the organisation of work.

The Court also found weaknesses in the Commission's management of its Health Emergencies Operations Facility. The content of the manual setting the operations facility was outdated at the time of the audit. In addition, the Commission had not performed an internal evaluation of the functioning of the Health Emergencies Operations Facility during the Ebola crisis in 2014. The Court further found that there had not been any continuous training of relevant staff to ensure the taking up of duties if the highest alert level is raised, and working time arrangements were not adequate to address the challenges of a public health emergency.

Conclusions

The Court overall conclusion is that Decision No 1082/2013/EU on serious cross-border

threats to health represents an important step for dealing better with such threats in the EU. However, significant weaknesses at the level of the MS and the Commission affect the implementation of the decision and the related EU framework.

The Court found that the implementation and development of the innovations introduced by the decision on serious cross-border threats to health since its entry into force in December 2013 were hampered by delays, potentially reducing their effective functioning. The procedures for obtaining and exchanging relevant information with a view to better coordinating efforts in relation to preparedness are not sufficiently robust and have not yet delivered clear-cut results. As regards the Commission's measurement of performance for the implementation of the cross-border health threats policy area, the Court found that key elements of the Commission's specific objective and indicator are not clearly defined and agreed with the MS.

The Court further found that: ECDC's role in relation to generic preparedness is insufficiently formalised, which may limit its capacity to properly plan its related tasks in the long term or respond effectively to assistance requests; MS have shown insufficient responsiveness to speed up the joint procurement of pandemic influenza vaccine; and the EU does not have a mechanism to address urgent needs for medical countermeasures within the framework of the decision on serious cross-border threats to health. Finally, the work and role of the HSC have proven to be very important, but it is facing some strategic and operational challenges, which need to be tackled to enable it to make full use of its strong mandate and thereby ensure the highest possible level of protection against health threats in the EU.

It is necessary to speed up the development and implementation of the innovations introduced by the decision, and tackle the remaining operational and strategic challenges for the HSC. This requires a better common understanding between MS and the Commission of the objectives and joint priorities for the enhanced coordination and information exchange efforts under the decision, in particular in the areas of preparedness planning, joint procurement and organising the work of the HSC in the long term. For preparedness and response planning, an additional challenge is to consider the development occurring in the wider international context.

ECA's recommendations

1. In order to speed up the development and implementation of the innovations and tackle the remaining operational and strategic challenges for the HSC:
 - a) The Commission should propose to the HSC that it develop a strategic roadmap for the implementation and development of the decision. This roadmap should reflect joint priorities to facilitate a common understanding of how to achieve clear-cut results towards 2020. Work in this area should take account of the international initiatives in this domain and of preparedness guidance already developed at EU level;
 - b) The Commission should ensure that lessons learned from the first reporting cycle on preparedness planning are applied for the next round of reporting in 2017 and improve its performance reporting for the implementation of the decision towards 2020. It should ensure that reported progress is accurate and based on methodologies agreed with the MS where relevant;

- c) The Commission, in cooperation with the MS, should identify how best make use of the HSC working groups and ensure that their work is well structured around technical issues and serves as an input to the HSC;
 - d) The Commission and the MS need to ensure that the work on the joint procurement of pandemic influenza vaccine accelerates and delivers results as soon as possible.
2. In order to further upgrade the EWRS and develop more integrated solutions for related risk management procedures, the Commission, in cooperation with the MS and ECDC, should:
- a) examine and propose in 2017 options for modernising and enhancing the EWRS. This should include integrated or complementary options for EU-level situational awareness and incident management for serious cross-border threats to health;
 - b) obtain regular feedback from users on integrated solutions for risk management and the operation and development of the EWRS.
3. In order to address the main weaknesses identified in the performance of the health programme for actions addressing health threats, the Commission should:
- a) examine and propose options in 2017 for ensuring a greater sustainability of results for health threat-related actions funded under the health programme towards 2020. This should include need and policy relevance, and more collaborative analyses of ongoing and completed actions;
 - b) define and agree, in consultation with the MS, a clear methodology for collecting performance information needed to report progress towards 2020 under the specific indicator for health threats in the third health programme;
 - c) clearly identify in 2017 which priorities under the objective to protect citizens from serious cross-border threats to health provide opportunities for funding policy-relevant actions towards 2020.
4. In order to bridge the gaps in the Commission's internal coordination in terms of activities relevant to health security and public health crisis management, and to improve the design of its Health Emergencies Operations Facility:
- a) the Commission should define from 2017 a more structured, detailed approach for coordination between DG Health and Food Safety and other Commission services which perform activities relevant to health security. This should allow for the identification of potential synergies and enhance cooperation on common issues such as the limited uptake of outputs for EU co-funded actions and enabling stakeholders to better target policymakers;
 - b) the Commission should take immediate action to operationalise the memorandum of understanding for crisis management structures between DG Health and Food Safety, DG Migration and Home Affairs and DG European Civil Protection and Humanitarian Aid Operations; this includes organising joint lessons learned activities and mutual training on policy areas and systems, as well as putting in place standard operating

procedures;

- c) the Commission should without delay review its Health Emergencies Operational Facility and ensure that it is updated in line with lessons learned from the Ebola crisis and major EU-Level exercises; a continuous monitored training plan is in place for all relevant staff potentially involved in its operations; and, if possible, exchange views with ECDC and DG European Civil Protection and Humanitarian Aid Operations, in particular on the design of their respective crisis management manuals or structures.

European Commission's replies

The Commission and MS are working to put in place the infrastructure required to implement effectively the decision on serious cross-border threats to health. This is a complex matter, which faced delays in certain areas, but those have not significantly weaken the effectiveness of the EU response to cross-border health threats.

The Commission accepts recommendations 1 and 2, which are already being dealt with. With regard to recommendation 3, a) and c) are accepted but only partially. The Commission recognises that sustainability is a pending issue, although much has been done in recent years.

The recommendation 4 b) and c) is also accepted by the Commission, although 4a) only partially. Good cooperation between the respective Commission services is in place and discussions between services are under way to further develop coordination.

Empfehlungen des Berichterstatters

Das Europäische Parlament

1. begrüßt den Bericht des Europäischen Rechnungshofs, schließt sich dessen Empfehlungen an und fordert die Kommission auf, diese Empfehlungen bei der Umsetzung weiterer Schritte im Zusammenhang mit dem Umgang mit schwerwiegenden grenzüberschreitenden Gesundheitsgefahren in der EU zu berücksichtigen;
2. bekräftigt die Empfehlung des Europäischen Rechnungshofs, dass die aus dem ersten Berichterstattungszyklus gewonnenen Erkenntnisse im Vorfeld des nächsten Berichts angemessen anzuwenden sind; um sicherzustellen, dass die künftige Berichterstattung in angemessener Weise erfolgt, muss der Prozess in allen Mitgliedstaaten einheitlich sein;
3. erkennt die seit der gesundheitspolitischen Strategie 2008–2013 erzielten Fortschritte an, betont jedoch, dass eine bessere und strategischere Überwachung erforderlich ist;
4. unterstützt die Empfehlung des Europäischen Rechnungshofs, wonach der Gesundheitssicherheitsausschuss (HSC) einen strategischen Plan zur Bewältigung der operativen und strategischen Herausforderungen, vor denen dieser steht, entwickeln sollte;
5. nimmt zur Kenntnis, dass das Europäische Zentrum für die Prävention und die Kontrolle von Krankheiten (ECDC) über keinen förmlichen Prozess zur wirksamen Reaktion auf Unterstützungersuchen verfügt;
6. betont, dass die verschiedenen Dienststellen der Kommission, deren Aufgabenbereich mit Gesundheitsthemen im Zusammenhang steht, sowie die GD Gesundheit und

Lebensmittelsicherheit im Hinblick auf eine verbesserte Zusammenarbeit einen strukturierten Ansatz entwickeln;

7. bedauert, dass sich die Mitgliedstaaten nicht geschlossen um eine Beschleunigung der gemeinsamen Beschaffung des pandemischen Grippeimpfstoffs bemüht haben, und erkennt an, dass Influenza jedes Jahr ein Problem für die Gesundheitsdienste in den einzelnen Mitgliedstaaten darstellt; ein koordiniertes Vorgehen aller Mitgliedstaaten wird sich positiv auf die Gesundheit der EU-Bürger auswirken und die Kosten verringern;
8. fordert die Kommission, die Mitgliedstaaten und das ECDC auf, bei der Weiterentwicklung des Frühwarn- und Reaktionssystems (EWRS) zusammenzuarbeiten; ist der Auffassung, dass es wichtig ist, ein solches System, das in großem Umfang genutzt wird, auf den neuesten Stand zu bringen, sodass eine optimal Nutzung sichergestellt werden kann.