4.7.2023

Amendment 1
José Ramón Bauzá Díaz
on behalf of the Renew Group

Report
Dolors Montserrat
COVID-19 pandemic: lessons learned and recommendations for the future
(2022/2076(INI))

Motion for a resolution
Paragraph 40

40. Underlines the importance of decision-making based on scientific evidence and of consistent, adapted and coordinated communication taking account of the different levels of health literacy that citizens and businesses have from all the stakeholders involved, including the EU institutions, the Member States’ public authorities, the scientific community, the private sector and civil society organisations, such as representatives of health professional and patients organisations; underlines the need for different communication tools that take account of the different levels of health literacy that citizens and businesses have;

40. Underlines the importance of decision-making based on scientific evidence and of consistent, adapted and coordinated communication taking account of the different levels of health literacy that citizens and businesses have from all the stakeholders involved, including the EU institutions, the Member States’ public authorities, the scientific community, the private sector and civil society organisations, such as representatives of health professional and patients organisations; **stresses the need for the EU governance to ensure that all relevant stakeholders are consulted and supports the establishment of advisory committees at EU and national levels to help the decision-making process for each policy**; underlines the need for different communication tools that take account of the different levels of health literacy that citizens and businesses have;

Or. en
4.7.2023

Amendment 2
José Ramón Bauzá Díaz
on behalf of the Renew Group

Report
Dolors Montserrat
COVID-19 pandemic: lessons learned and recommendations for the future
(2022/2076(INI))

Motion for a resolution
Paragraph 75

Motion for a resolution
Amendment

75. Stresses that Parliament should have scrutiny powers over and the ability to monitor HERA, thus contributing to accountability and transparency; suggests that Parliament be invited as an observer to the health crisis board to be established under Council Regulation (EU) 2022/2372;

75. Stresses that Parliament should have scrutiny powers over and the ability to monitor HERA, thus contributing to accountability and transparency; reiterates the need to invite Parliament as an observer to the health crisis board to be established under Council Regulation (EU) 2022/2372;

Or. en
Amendment 3
José Ramón Bauzá Díaz
on behalf of the Renew Group

Report
Dolors Montserrat
COVID-19 pandemic: lessons learned and recommendations for the future
(2022/2076(INI))

Motion for a resolution
Paragraph 77

Motion for a resolution

77. Looks forward to the establishment of a memorandum of understanding among the Directorate-General for Health and Food Safety, HERA and other Union agencies and bodies, as soon as HERA becomes a full-fledged agency;

Amendment

77. Looks forward to the establishment of a memorandum of understanding among the Directorate-General for Health and Food Safety, HERA and other Union agencies and bodies, and to their review or assessment, as soon as HERA becomes a full-fledged agency;

Or. en
Amendment 4
José Ramón Bauzá Díaz
on behalf of the Renew Group

Report
Dolors Montserrat
COVID-19 pandemic: lessons learned and recommendations for the future
(2022/2076(INI))

Motion for a resolution
Paragraph 84

84. Calls on the Commission to assess the possibility of making the EMA’s decisions on the approval of vaccines and medical products directly applicable in the Member States, in the event of a crisis;

84. Recommends that the EMA’s decisions on the approval of vaccines and medical products be made directly applicable in the Member States, in the event of a crisis;

Or. en
Motion for a resolution

Motion for a resolution

91. Calls on the Commission, the EMA and the competent authorities to capitalise on all the pragmatic efforts made during the COVID-19 crisis, in particular as regards regulatory flexibility, with a view to effectively tackling medicine shortages, including in emergency situations; supports the use of this procedure for medicinal products of major therapeutic interest in crisis times and beyond, where appropriate; considers that greater harmonisation of regulatory procedures at EU level, including accelerated approval times and reduced costs, will be beneficial to all; appreciates the efforts made by major regulators worldwide (such as the EMA, the US Food and Drug Administration and the UK Medicines and Healthcare products Regulatory Agency) to harmonise their approaches and extend mutual recognition to each other’s procedures;
Amendment 6  
José Ramón Bauzá Díaz  
on behalf of the Renew Group

Report  
Dolors Montserrat  
COVID-19 pandemic: lessons learned and recommendations for the future  
(2022/2076(INI))

Motion for a resolution  
Paragraph 97

97. Recalls the importance of health literacy and health education in preventing, preparing for and responding to health threats and that it contributes to the population’s better understanding of the countermeasures for and risk assessment of different threats; underlines that health education campaigns based on the latest scientific evidence could help improve population behaviour in this regard, and should take into account people who are experiencing exclusion and the needs of people with learning disabilities; stresses that all efforts to increase health literacy, including digital literacy, should take into account people who are experiencing exclusion and the needs of people with learning disabilities; underlines that inequalities in knowledge of, access to and use of IT technologies, as well as regional, national, social and economic discrepancies, should be taken into account;

Or. en
126. **Calls on the Commission**, in the context of the revision of the pharmaceutical legislation, to further develop the electronic product information (ePI) and promote digitalised and efficient regulatory processes where appropriate, as one of the tools to mitigate medicine shortages in case they occur, while always ensuring availability of a paper information leaflet for all products; urges the Commission to work with the EMA and the EU regulatory network, including the industry and all relevant stakeholders, to develop and implement the use of ePI for all medicines in the EU, in all the languages of the Member States where the medicines are marketed;

126. **Supports the Commission’s intention**, in the context of the revision of the pharmaceutical legislation, to further develop the electronic product information (ePI) and promote digitalised and efficient regulatory processes where appropriate, as one of the tools to mitigate medicine shortages in case they occur, while always ensuring availability of a paper information leaflet for all products; urges the Commission to work with the EMA and the EU regulatory network, including the industry and all relevant stakeholders, to develop and implement the use of ePI for all medicines in the EU, in all the languages of the Member States where the medicines are marketed;
4.7.2023

Amendment 8
José Ramón Bauzá Díaz
on behalf of the Renew Group

Report
Dolors Montserrat
COVID-19 pandemic: lessons learned and recommendations for the future (2022/2076(INI))

Motion for a resolution
Paragraph 176

Motion for a resolution
Amendment

176. Reiterates the key role of the ECDC in aggregating surveillance and monitoring data at EU level and in facilitating forecasting of future demand for vaccines and therapeutics against infectious diseases; highlights the usefulness of the COVID-19 vaccine tracker developed by the ECDC and calls for this concept to be extended to other vaccination campaigns, such as the HPV vaccine campaign;
Amendment 9
José Ramón Bauzá Díaz
on behalf of the Renew Group

Report
Dolors Montserrat
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(2022/2076(INI))

Motion for a resolution
Paragraph 177

77. Calls for vulnerabilities in the global value chain to be assessed and requests the development of shortage prevention and management plans across all Member States; calls for the continual improvement of early warning systems and information sharing between countries on medicines shortages, at both European and international levels, and for the Commission to introduce temporary measures in times of crisis to mitigate shortages and facilitate the circulation of medicines among Member States;

177. Calls for vulnerabilities in the global value chain to be assessed and requests the development of shortage prevention and management plans across all Member States; calls for the continual improvement of early warning systems and information sharing between countries on medicines shortages, at both European and international levels, and for the Commission to introduce temporary measures in times of crisis to mitigate shortages and facilitate the circulation of medicines among Member States, including the acceptance of different packaging formats, a reuse procedure to enable marketing authorisation holders to obtain approval in another Member State, the extension of the validity of good manufacturing practices certificates, longer expiry periods, and the use of veterinary medicinal products; recalls that the Commission should strictly monitor the use of such measures to ensure that patient safety is not compromised and to keep medicines available in the event of difficulties or shortages;

Or. en
Amendment 10
José Ramón Bauzá Díaz
on behalf of the Renew Group

Report
Dolors Montserrat
COVID-19 pandemic: lessons learned and recommendations for the future
(2022/2076(INI))

Motion for a resolution
Paragraph 196

196. Regrets the lack of transparency in the joint procurement agreements negotiated by the Commission with pharmaceutical companies, which was partly justified by respect for the right to confidentiality; stresses that transparency in the work of the EU institutions is of the utmost importance, especially under the conditions of the unprecedented pandemic crisis; recalls that joint procurement agreements should be carried out in a transparent, timely and effective way, with clear and transparent stages for the process, scope, tender, specifications, timelines and formalities defined and calls for the adoption of a transparent policy for advance purchase agreements and joint procurement;

Amendment

196. Regrets the lack of transparency in the joint procurement agreements negotiated by the Commission and the Member States with pharmaceutical companies, which was partly justified by respect for the right to confidentiality; stresses that transparency in the work of the EU institutions is of the utmost importance, especially under the conditions of the unprecedented pandemic crisis; recalls that joint procurement agreements should be carried out in a transparent, timely and effective way, with clear and transparent stages for the process, scope, tender, specifications, timelines and formalities defined and calls for the adoption of a transparent policy for advance purchase agreements and joint procurement;

Or. en