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12

Special report

The EU's response to the COVID-19 pandemic

The EU medical agencies generally managed well in unprecedented circumstances

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Executive summary

I The EU's two medical agencies – the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) – play a key role alongside the European Commission in the implementation of health policy in the European Economic Area. ECDC's mission is to identify, assess and communicate current and emerging threats to human health from communicable diseases. Its focus is on risk assessment. EMA is responsible for the scientific evaluation of applications for centralised marketing authorisations of medicines. ECDC and EMA had budgets of €61 and 358 million respectively at the start of the pandemic in 2020.

II For this report we assessed ECDC's and EMA's preparedness for and response to the COVID-19 pandemic, in the first comprehensive audit of the two agencies' performance in times of health crisis. It is part of a series of reviews and audits carried out by the ECA on the EU response to the COVID-19 pandemic. We also assessed the relevance of the Commission action to address the identified weaknesses. We expect our work to help both agencies be better prepared for any future health emergencies.

III We found that, within the limits of their respective powers and capacities, the two agencies generally responded well to the COVID-19 crisis. However, we also identified shortcomings in specific areas. Although not fully prepared for a protracted pandemic, both agencies responded as soon as its extent became clear. They also improved their transparency and scaled up the way they communicated with the public compared to the pre-pandemic period. The Commission and the agencies are in the process of implementing the lessons learned from the pandemic, but it is too early to tell whether this will be sufficient to prepare the agencies adequately for future public health emergencies.

IV Both agencies had drawn up detailed public health emergency plans that were activated promptly, but under the applicable legal and financial framework these did not address the expansion of capacity in the event of a severe and protracted pandemic. Both agencies had set up extensive international networks which proved useful in dealing with the pandemic. EMA had prepared a list of activities that could be deprioritised in emergency situations, but this was not the case of ECDC.

V For a few weeks after China reported the first cases of the new coronavirus, ECDC underestimated the seriousness of the situation. Based on additional evidence becoming available, it revised its opinion accordingly. Although its guidance and assistance for member states were not always timely, they were particularly

appreciated in countries with limited scientific capacity, even though national decision-makers did not always heed its cautious advice. The member state data collected by ECDC was often not comparable.

VI With Commission support, EMA leveraged regulatory flexibility to speed up the procedure for assessing COVID-19 vaccines and treatments, particularly through resource-intensive "rolling reviews". It became more active in monitoring medical shortages and managed to contain the impact on most of its other activities (including the assessment of non-COVID-19 products), although there were delays to inspections. EMA also scaled up its monitoring of COVID-19 medicines, and acted promptly when significant potential side effects were discovered. However, its efforts to proactively promote wider EU clinical trials were less successful.

VII In 2020, ECDC started issuing communications related to COVID-19 targeting the public. EMA publishes a lot of information on its website and increased the transparency of its reporting on COVID-19 products during the pandemic. However, neither agency's communications were always readily accessible for non-experts.

VIII Using the lessons learned from the early stages of the pandemic, the Commission adopted a series of decisions and proposals to amend the legal framework. These measures fill some of the gaps in the EU's capacity to respond to health emergencies, but they have also resulted in a more complex organisational set-up that relies on close cooperation among a wide range of stakeholders at all levels. The creation of a new Commission directorate-general (the Health Emergency Preparedness and Response Authority – HERA), whose responsibilities partially overlap with those of ECDC and EMA, also requires increased coordination.

IX We make the following recommendations:

- ECDC should further improve its internal organisation, procedures, systems and publications to be better prepared for future health emergencies;
- EMA should fine-tune its procedures and dissemination to be better prepared for future pandemics;
- the Commission, in cooperation with ECDC and EMA, should clarify the respective responsibilities of HERA, ECDC and EMA, and enhance coordination.

Introduction

01 COVID-19, the disease resulting from infection by the SARS-COV-2 virus, was initially detected in Europe in early 2020. It then spread rapidly across the continent. By mid-March 2020, cases had been reported in all EU member states, and the World Health Organization had declared Europe the epicentre of the global pandemic. These events called for coordinated intervention by the EU.

02 The Treaty on the Functioning of the European Union states that EU action in the area of health should support and complement action by the member states, which bear the main responsibility for health policy. The EU Health Security Committee, an informal advisory group consisting of representatives of EU member states, coordinates the member states' preparedness and response planning on public health and crisis communication. Together with the European Commission, two EU medical agencies – the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) – play a key role in the implementation of EU health policy.

ECDC

03 Under the legal framework in force at the beginning of the pandemic[1], ECDC's mission is to identify, assess and communicate current and emerging threats to human health from communicable diseases[2]. It is competent for the European Economic Area (EEA), which consists of the 27 EU member states plus Iceland, Liechtenstein and Norway. It had a budget of €61 million in 2020 and €90 million in 2023. It focuses on risk assessment, while the Commission and the Health Security Committee are responsible for risk management. ECDC's key tasks are shown in ***Figure 1***.

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1 Regulation (EC) No 851/2004 and Decision No 1082/2013, replaced in the later stages of the pandemic by, respectively, Regulations (EU) 2022/2370 and (EU) 2022/2371.

2 Article 3 of Regulation (EC) No 851/2004; Decision No 1082/2013/EU on serious cross-border threats to health assigned further responsibilities to ECDC.

Figure 1 – ECDC's mission in 2020

Source: ECA.

04 After the World Health Organization (WHO) declared COVID-19 a "public health emergency of international concern" and, later, a pandemic, ECDC's response mainly consisted of:

- collecting data and publishing statistics on COVID-19 infections, hospitalisations, deaths and vaccinations,
- publishing risk assessments, technical reports and other guidance for member states and EU experts and policymakers,
- public health communication.

EMA

05 EMA is responsible for the scientific evaluation of applications for centralised marketing authorisations of medicines in the EEA. EMA had a budget of €358 million in 2020 and €458 million in 2023.

06 The European medicines regulatory network links around 50 regulatory authorities (known as "national competent authorities", or NCAs) from the EEA countries, plus the European Commission and EMA. The NCAs are responsible for the authorisation of medicines that are marketed in the EU but do not pass through the centralised procedure. They also supply thousands of experts to serve as members of EMA's scientific committees, working parties and assessment teams. One such body, the Committee for Medicinal Products for Human Use (CHMP), plays a key role in the centralised authorisation procedure, while the Pharmacovigilance Risk Assessment Committee (PRAC) monitors the safety of medicines.

07 EMA intervenes at various stages in the development of a medicine, and issues **scientific guidelines** providing general advice on methodology and the design of studies.

(a) **Pre-authorisation phase**: EMA provides tailor-made **scientific advice** on, for instance, the best means of generating robust information on a medicine's safety and effectiveness.

(b) **Assessment and authorisation**: once a pharmaceutical company has submitted an application for marketing authorisation, EMA assesses whether there is robust evidence demonstrating quality, safety and efficacy so that the benefits of a medicinal product outweigh any risks.

(c) **Post-authorisation phase**: EMA assesses any subsequent applications for changes and extensions to the original marketing authorisation, and coordinates work to detect, assess, understand and prevent any adverse effects (**pharmacovigilance**).

European Commission

08 The Commission discharged its responsibilities in health matters solely through its Directorate-General for Health and Food Safety (DG SANTE). It is the Commission that takes the final decision to grant a marketing authorisation, based on a recommendation by EMA's responsible Committee. As partner DG of both agencies, DG SANTE is represented on the ECDC and EMA management boards. In reaction to the first lessons learned from the pandemic, in 2021 the Commission set up another directorate-general: the European Health Emergency Preparedness and Response Authority (HERA).

The pandemic cycle

09 For the purposes of this audit we distinguish three phases in the management of a pandemic:

- preparedness, or the capacity to respond promptly to public health emergencies – before the outbreak of the pandemic (paragraphs ***16***-***31***);
- response – action taken after the outbreak of the pandemic (paragraphs ***32***-***77***);
- lessons learned (through "in-action" and "after-action" reviews) and corrective action – both during and after the pandemic (paragraphs ***79***-***92***).

Audit scope and approach

10 This audit is part of a series of reviews and audits carried out by the ECA on the EU response to the COVID-19 pandemic[3]. We examined whether ECDC and EMA responded to the COVID-19 pandemic effectively, and whether the Commission supported their actions appropriately, focusing on the following sub-questions:

(1) Were ECDC and EMA well prepared for the outbreak of a pandemic?

(2) Did ECDC support the member states and the Commission in their management of the COVID-19 pandemic effectively?

(3) Did EMA manage its responsibilities during the COVID-19 pandemic effectively?

(4) Has the Commission since taken appropriate action to improve the response of ECDC and EMA to future pandemics?

11 We used as audit criteria the relevant parts of the "founding regulations" setting up ECDC and EMA, in the versions applicable at the start of the pandemic. We also used Decision 1082/2013/EU on serious cross-border health threats, European Parliament resolutions, Commission strategies, and ECDC and EMA planning documents and procedures. In some instances, we referred to WHO standards and compared the EU response to that of the US and the UK.

12 The audit focused on the action taken by the two agencies. We conducted interviews with staff from both agencies and from the Commission, and examined relevant public and internal documents. We interviewed representatives of eight national health agencies (Czechia, France, Germany, Greece, Italy, Lithuania, Spain and Sweden) selected to include the four most populated member states and four others to ensure geographical balance. We also interviewed representatives of the five national medicines agencies that had been most involved in the assessment of COVID-19 products (France, Germany, the Netherlands, Spain and Sweden) and a European patients' organisation. We sought feedback from medicines agencies in the EEA countries to obtain their views on the quality of cooperation with EMA during the pandemic, the way EMA carried out its tasks, and the usefulness of EMA's recommendations and guidance.

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[3] Special report 19/2022: "EU COVID-19 vaccine procurement" and Review 01/2021: "The EU's initial contribution to the public health response to COVID-19".

13 We approached EU member states only as sources of information. We did not assess or compare their actions during the pandemic. Where the Commission is concerned, we limited our examination to certain aspects of its cooperation with EMA and ECDC during the pandemic, as well as action it took which impacted on the two agencies (such as proposals to amend the legislation and set up new bodies with public health powers).

14 To assess preparedness we looked at action taken over the years before 1 January 2020, while the audited period for sub-questions 2, 3 and 4 was January 2020 – July 2023. We paid particular attention to EMA's procedure for assessing COVID-19 vaccines. We did not assess whether EMA's recommendations were justified, but only whether it made a thorough analysis in line with the agreed rules and guidelines.

15 This audit marks the first comprehensive assessment of EMA's and ECDC's performance in times of health crisis. We expect our work to help both agencies be better prepared for future health emergencies.

Observations

Although ECDC and EMA had emergency plans, they were not fully prepared for a protracted pandemic

16 The effectiveness of any response to a crisis is dependent on clear planning, sufficient capacity and agile structures, which make it possible to react quickly and adapt constantly to rapid changes. The response to a global pandemic is also dependent on a well-developed international network. We therefore assessed whether, when the pandemic broke out, ECDC and EMA each had suitable procedures, capacity and international cooperation arrangements in place to cope with a severe and protracted crisis.

ECDC had a detailed emergency plan but lacked agility

17 At the start of the pandemic, ECDC used a public health emergency (PHE) plan with standard operating procedures and job action sheets that set out in detail the procedure for managing a public health emergency. The emergency plan was not designed for a protracted pandemic. It focused on organising the response but did not pronounce on how departments were to address the reallocation of human resources. In particular, it did not rank activities by priority or set out how to deal with multiple public health emergencies simultaneously.

18 ECDC's human resources were stable in the run-up to the pandemic. The agency had little leeway to recruit additional staff in times of crisis, and little capacity to help the member states most in need of assistance (see also paragraph ***36***). Originally it also had very limited capacity in areas such as mathematical modelling (see paragraph ***41***), making it difficult to react quickly to stakeholders' demands.

19 ECDC was restructured at the beginning of 2020, after an external evaluation in 2019 drew attention to "an excessively hierarchical structure, which is unconducive to the desired flexibility"[4]. However, the note explaining the reorganisation emphasised that "changing the structure will not be sufficient to increase the efficiency of the ECDC's organisational performance to the desired level". (see also paragraphs ***35***-***36***).

[4] Third external evaluation of ECDC (2013-2017), page 114.

20 ECDC performed both event-based surveillance to detect new diseases or outbreaks and indicator-based surveillance to collect, monitor, analyse and interpret structured data (indicators) produced by member states. The agency had several IT tools in place for surveillance, notification and epidemic intelligence (see ***Box 1***).

Box 1

IT tools used by ECDC for surveillance, notification and epidemic intelligence

- The Early Warning and Response System[5] is a notification tool to enable the Commission, ECDC, and the competent authorities at national level to be in permanent communication for the purposes of preparedness, and early warning and response.
- The European Surveillance System (TESSy) is the main tool for indicator-based surveillance. It is used to collect, analyse and disseminate official surveillance data on infectious diseases.
- EpiPulse, launched in 2021, is the online surveillance portal for European public health authorities to collect, analyse, share and discuss infectious disease data.

21 ECDC was already supporting capacity-building through training programmes and workshops, the planning of simulation exercises, guidance on after-action reviews, and the facilitation of coordination and information exchange among member states. In October 2018, it initiated collaboration among EU/EEA national immunisation technical advisory groups to share information and discuss priorities.

22 In 2018, ECDC launched a health emergency preparedness self-assessment tool as an additional resource for member states to assess their level of preparedness for public health emergencies. The agency did not follow up the number of member states using this tool or the results of any self-assessments.

Recent EMA action enhanced the flexibility of its response to the pandemic

23 EMA was significantly affected by Brexit. In 2017, in preparation for its relocation from London to Amsterdam, it had activated a "Brexit-preparedness business

[5] Article 18 of Regulation (EU) 2022/2371.

continuity plan" in which it prioritised its activities and included arrangements for the organisation of virtual meetings to make it more crisis-proof. EMA's IT infrastructure was compatible with remote working and remote scientific meetings. Consequently, the COVID-19 lockdown had little impact on the continuity of operations.

24 In 2019, due to Brexit, EMA faced an increase in resignations (6 % of total staff) and requests for long-term leave (about 3 % of total staff), reducing the number of active staff to just above what the agency felt it required for its minimum core activities. As part of the Brexit plan, it had already deprioritised several activities.

25 In December 2018, EMA adopted a plan with guidance on its activities in the event of emerging health threats. The plan was drafted with an influenza-type pandemic in mind but was also applicable to other types of health threat. It included the possibility of rapid scientific advice, and of fast-tracking the authorisation of new treatments and vaccines during a pandemic.

26 In October 2019, the Executive Director reorganised EMA, regrouping three divisions into a single Human Medicines Division and creating four task forces. This new structure was conducive to the organisational flexibility and coordination needed in times of crisis.

27 With Commission support, EMA had already started monitoring shortages of medicines before the pandemic (even though this was not yet formally required). To this end, in 2016, together with the Heads of Medicines Agencies network of NCA heads, EMA had set up a task force, which in 2019 issued guidance on the detection, notification and reporting of shortages.

ECDC and EMA had been gradually strengthening their international networks

28 One critical function of ECDC's public health emergency strategic team is international collaboration. This involves strengthening cooperation and coordination between ECDC and its partners in non-EU countries.

29 ECDC's main international partner is the WHO Regional Office for Europe. The two bodies signed their first agreement in 2005, soon after ECDC came into existence. Collaboration was strengthened in 2011 by establishing a framework for technical cooperation, joint activities and a joint coordination group. As the tasks and

responsibilities of WHO's regional office overlap with those of ECDC, close cooperation is key to avoid duplication of effort.

30 ECDC had signed agreements fostering the exchange of information and collaboration with key non-EU partners, including the US and China in 2007. In June 2019, the agency set up a network of global disease prevention and control centres, including seven from outside the EU (Africa, Canada, the Caribbean, China, Israel, Thailand and the US), which further facilitated the exchange of information and expertise during the pandemic.

31 For its part, EMA is a founding member of the International Coalition of Medicines Regulatory Authorities (ICMRA), whose chair and secretariat it has provided since 2019. Its emerging health threats plan also requires it to engage in regular interaction with international partners as part of its routine preparedness activities. In 2019, the agency had standing confidentiality arrangements and mutual recognition agreements with key partners such as Australia, Canada, Japan, Switzerland, the US and the WHO. Despite the scaling-back of its international cooperation activities in preparation for Brexit, EMA was able to make use of existing structures and networking to share information and align approaches for COVID-19 medicine approval.

ECDC's useful contributions were impeded by low data quality

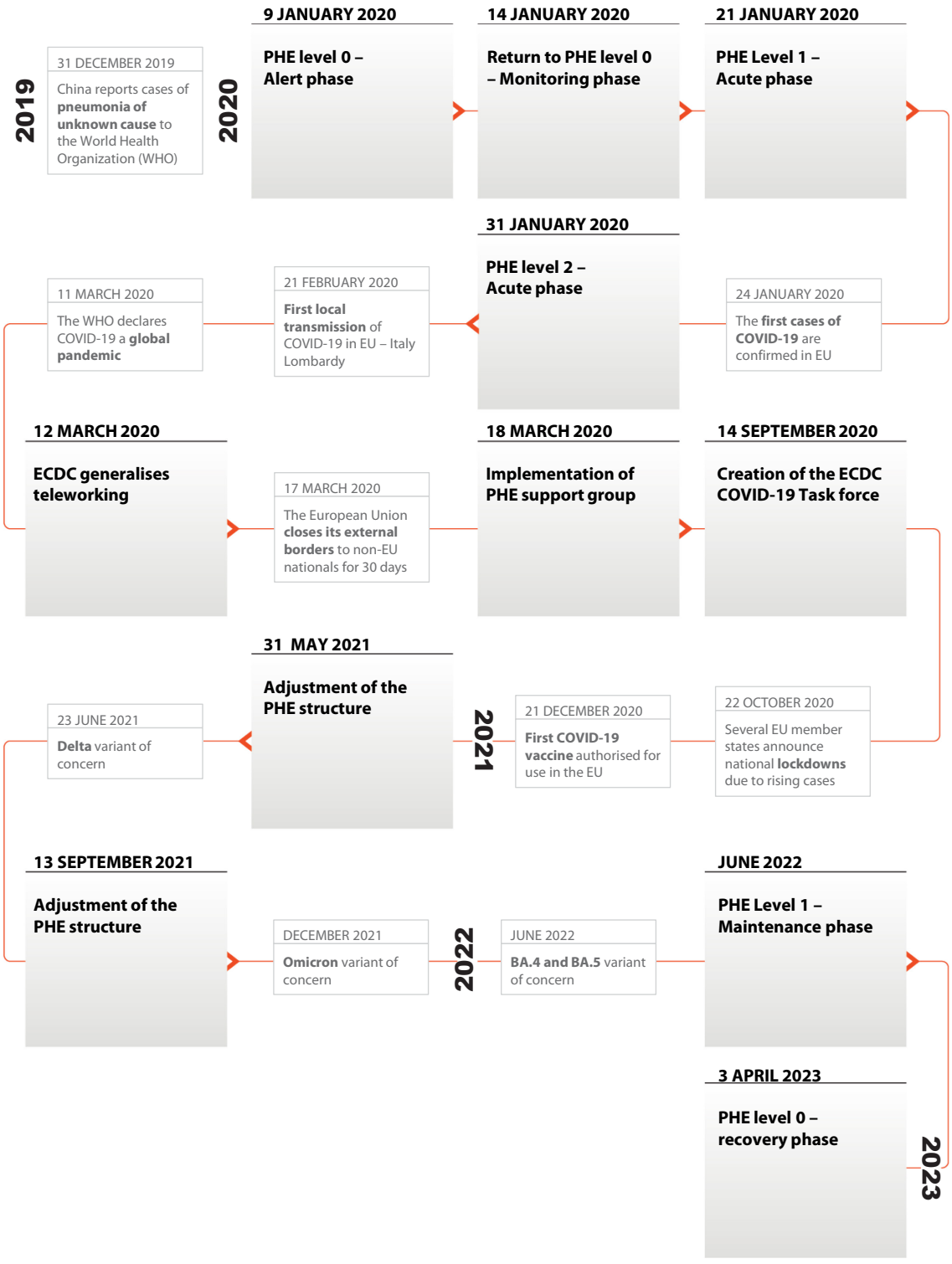
32 Public health decision-making in emergency situations must be based on accurate real-time data and analysis. The decision on serious cross-border health threats, which was applicable in 2020-2022, made ECDC responsible for operating and coordinating a network for the epidemiological surveillance of communicable diseases. The exponential spread of the COVID-19 virus obliged ECDC to act promptly and adapt quickly to a rapidly changing situation. We assessed whether the agency managed to do this, and whether it fulfilled its mission and tasks, in particular by putting in place efficient decision-making processes and organisational arrangements, promptly and accurately assessing risks, collecting good-quality data from member states, coordinating the network, and providing clear, timely and relevant risk assessment and guidance for both health authorities and the public.

ECDC initially underestimated the risks and needed to adjust its organisational structure

33 One week after China alerted the WHO to a cluster of pneumonia cases of unknown origin in Wuhan on 31 December 2019, ECDC published its first threat assessment brief, asserting that, "considering there is no indication of human-to-human transmission and no cases detected outside of China, the likelihood of introduction to the EU is considered to be low, but cannot be excluded". It activated phase 2 (alert) of the emergency plan, before briefly returning to the lowest phase (monitoring) on 14 January, after a second risk assessment found that there was "no clear indication of sustained human-to-human transmission". But just one week after that ECDC activated level 1 of the acute phase, moving on 31 January to the highest level and staying there until June 2022. ***Figure 2*** shows the chronology of changes in emergency levels.

34 On 14 February 2020, less than a month before the first lockdowns in the EU, ECDC still considered that "the risk associated with SARS-CoV-2 infection for the EU/EEA and UK population is currently low". As late as the start of March 2020, ECDC assessed the risk for the EU population to be low to moderate. Most national disease prevention and control centres, including that of the US, also initially underestimated the seriousness of COVID-19. In its 12 March 2020 rapid risk assessment, three days after Italy declared a national lockdown, ECDC recognised the need for "immediate targeted action".

Figure 2 – Timeline of ECDC's PHE response to COVID-19



Source: ECA based on ECDC.

35 Between January 2020 and June 2022, eleven different ECDC officials occupied the post of PHE manager. According to a report commissioned by ECDC, the PHE structure was generally seen as "somewhat ineffective" and overly subject to change. The PHE plan gave the manager decision-making power. In practice, however, the

manager did not have that power, but often needed to go through the full PHE management team even for operational decisions, adding to bureaucracy and slowing down decision-making (see also paragraph ***45***).

36 From March 2020 the pandemic started to have a significant impact on ECDC's other tasks. During the 2020-2022 period, up to one third of the ECDC staff worked almost exclusively on COVID-19 issues. At the peak of the pandemic in 2020, most of the agency's scientific staff were involved in the COVID-19 response. As a result, around 35 % of all tasks planned for 2020 had to be postponed or cancelled[6]. These included completing the optimisation of surveillance platforms and processes, enhanced cooperation with the WHO, several training activities, and strengthening the surveillance of healthcare-associated infections.

Member state data collected by ECDC was often not comparable

37 In the early stages of the pandemic, the Commission asked the member states to report COVID-19 cases through the Early Warning and Response System (see ***Box 1***). In parallel, ECDC asked the member states to report structured case-based data on new COVID-19 infections in TESSy (also ***Box 1***). Data collection became a challenging task once the number of cases ran into the hundreds of thousands at the peak of the pandemic. Member states' systems were often not compatible with the automatic transfer of data to TESSy, making the process labour-intensive.

38 ECDC's monitoring of the pandemic was initially predominantly based on the number of infections, hospitalisations and deaths reported by member states. As the pandemic evolved, reporting instructions and data fields had to be often modified, putting a further burden on member states. The key changes included the introduction of reporting on tests, variants of concern and vaccinations.

39 Owing to national methodological differences in classifying "causes of death" and counting COVID-19 cases (leading to both under and over-reporting), data was often not comparable. Some countries recorded all deaths where COVID-19 might have been a factor as being actually due to COVID-19, without requiring laboratory tests, while others required a positive test result for deaths to be attributed to COVID-19. Quality issues relating to COVID-19 statistics were also mentioned in Annex V of our special report 26/2022.

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[6] ECDC Consolidated Annual Activity Report 2020, page 3.

40 The quality, in terms of completeness[7], accuracy and comparability, of the data submitted through TESSy varied considerably, both between member states and between different variables. ECDC found that some countries had significantly under-reported numbers of infections and deaths, while others did not report at the proper time on any of the additional variables requested by ECDC. One reason for these discrepancies was the lack of any integration between national and EU systems, while another was the sheer workload faced by national and regional departments at peaks of the pandemic. ECDC supplemented its data by extracting information from official national data sources.

41 On 13 October 2020 the Council tasked ECDC with providing data on population size, hospitalisation rates, rates of admission to intensive care and mortality rates, if possible on a weekly basis. From 16 October 2020 until 1 February 2022, ECDC published weekly colour-coded maps to comply with this recommendation. As member states had very different testing strategies and did not always strictly follow ECDC's definition of COVID-19 deaths and cases, their infection rates were not comparable, which undermined the validity of the colour-coding and forced ECDC to add several disclaimers. This limited the usefulness of the ECDC maps, which most EU member states did not use for their decision-making. In addition, ECDC developed mathematical modelling to forecast the evolution of the pandemic.

42 Although past experience indicates that the daily counting of cases or deaths may have a counterproductive effect on the monitoring of an emerging epidemic, COVID-19 reporting was based on reporting of confirmed cases, which depended heavily on the testing strategies used. These strategies varied significantly both between member states and over time. Limited use was made of targeted representative surveillance strategies that can provide more reliable information on trends, such as "sentinel surveillance" (monitoring of disease occurrence rates through regular reports from a smaller number of healthcare professionals) and the analysis of virus concentrations in wastewater.

[7] See point 5 of ECDC's weekly surveillance reports.

ECDC issued useful risk assessments, guidance and public information, but this did not lead to a coordinated EU response

43 ECDC updated its risk assessments (see paragraph ***33***) almost every ten days during the first quarter of 2020, and every month thereafter. Between July 2020 and November 2021, the agency published weekly surveillance reports and overviews of the evolving epidemiological situation by country.

44 In February 2020 ECDC started issuing non-binding guidance to healthcare professionals on how to deal with COVID-19 patients. During the pandemic, it issued and regularly updated guidance on measures to prevent the spread of COVID-19 (contact-tracing, isolation, protection of vulnerable persons, travel precautions, etc.). Travel and work guidance was issued jointly with other EU agencies (the European Union Aviation Safety Agency, the European Maritime Safety Agency, the European Union Railway Agency, and the European Agency for Safety and Health at Work), or with the WHO. ECDC also helped member states conduct evaluations and in-action/after-action reviews, and developed online training courses on COVID-19.

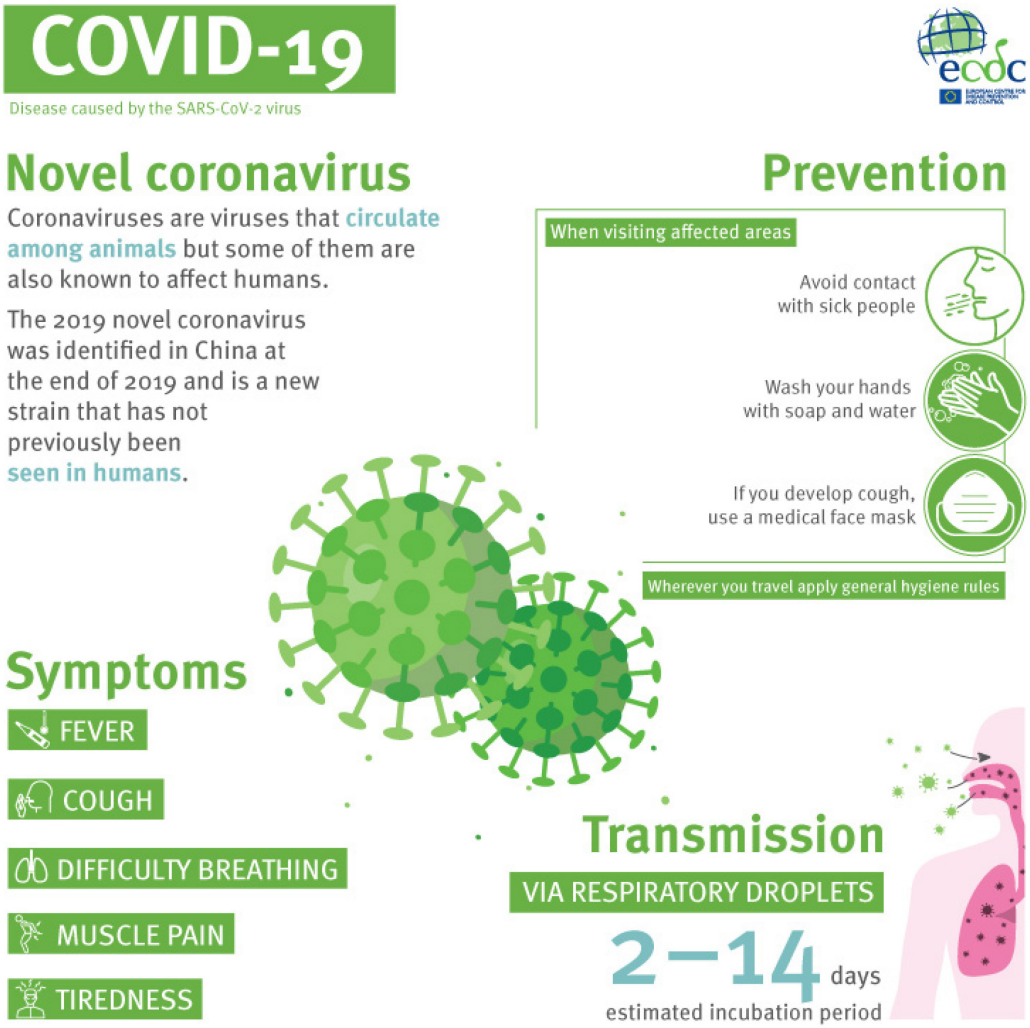
45 In its risk assessment and guidance documents, ECDC presented "options for response" from which member states could choose. Most of the experts we interviewed found the ECDC guidance very useful, particularly for countries with less scientific capacity. However, some considered that it was not always timely, especially during the early stages of the pandemic, or not sufficiently precise for concrete action. Guidance on key issues such as face masks and contact-tracing only came towards the end of the first wave (April-May 2020), after several member states had already issued their own guidance, leading to the risk of a potential duplication of effort and diverging advice.

46 In its July 2020 rapid risk assessment and further travel guidance issued in March 2021, ECDC stated that it did not consider travel restrictions within and to the Schengen area as an efficient way of reducing transmission. Nevertheless, most EU member states continued to impose restrictions of different kinds on the free movement of citizens, under the conditions agreed in the Council.

47 In addition to issuing guidance documents, the ECDC experts provided on-the-spot assistance in Italy and Greece, where they reviewed the epidemiological situation and supported the development of surveillance, infection prevention and control, and risk communication. The agency did not have the capacity to offer this expertise to all countries. Some of the member states we interviewed mentioned that they had similar needs and would have liked more help from ECDC.

48 Although ECDC made the most of its key outputs in the public space, it did not directly target the public at large but considered health professionals and policymakers to be its main stakeholders. Its communication policy for 2022-2027 explicitly includes EU citizens as a target group. In 2020 ECDC published already a series of COVID-19 infographics (see as an example ***Figure 3***) and other media content accessible to a broader audience.

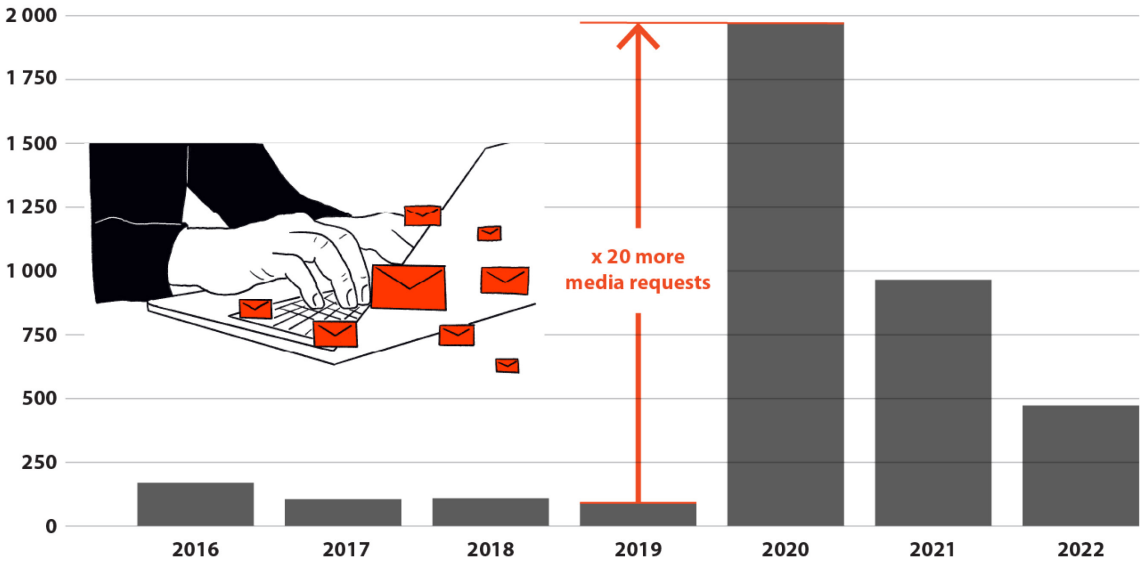
Figure 3 – ECDC infographic published on 26 February 2020



Source: ECDC.

49 ECDC received 20 times as many media requests in 2020 as in 2019 (see ***Figure 4***). However, most of its publications during the pandemic targeted public health authorities, using technical English that was difficult for non-experts to understand.

Figure 4 – Number of media requests received by ECDC



Source: ECA based on ECDC, Consolidated Annual Activity Report 2022.

EMA successfully fast-tracked COVID 19 products, but its communications were not always readily accessible

50 We assessed whether EMA adopted effective crisis procedures, in particular to accelerate the authorisation of COVID-19 products. It needed to mitigate the impact of the pandemic on the authorisation and availability of medicines, while also scaling up its pharmacovigilance of COVID-19 products. We also assessed whether EMA provided transparent and readily accessible information to the general public and further developed its international cooperation. See ***Annex I*** for the timeline of EMA's response to the pandemic.

EMA put appropriate crisis procedures in place

While they accelerated the authorisation process, rolling reviews were very resource-intensive

51 We used both published and confidential documents to examine whether EMA streamlined the authorisation of COVID-19 vaccines (including boosters) and treatments, correctly applying the ICMRA principles and its own internal procedures and guidelines. We did not assess the soundness of EMA's scientific evaluations.

52 All COVID-19 vaccines and most COVID-19 treatments in the EU were approved under the centralised procedure. Many were granted conditional marketing authorisation, which is valid throughout the EEA for one year and can be renewed

annually[8]. They can be converted into standard authorisations once the holder fulfils certain specific obligations. The UK and the US have another option, called authorisations for emergency use. Authorisations of this type allow quicker approval of certain treatments for which there were indications of possible COVID-19 efficacy, even without sufficient data for a conditional authorisation.

53 As soon as the full extent of the pandemic became clear, EMA gave priority to all activities relating to COVID-19. It also set up a COVID-19 pandemic task force in March 2020. During the early stages of the pandemic, it proactively reached out to potential developers of COVID-19 vaccines and treatments and took several other measures to speed up their authorisation (see ***Box 2***). In addition, the Commission amended the rules for variations to the terms of marketing authorisations to facilitate the adaptation of COVID-19 vaccines to new viral variants.

Box 2

Measures taken by EMA to speed up the development and authorisation of COVID-19 vaccines and treatments

- Together with the Commission and the Heads of Medicines Agencies, issued a COVID-19 business continuity plan for the European medicines regulatory network[9] on 28 May 2020. The plan provided guidance for dealing with both COVID-19 and non-COVID-19 procedures, stating clearly that COVID-19 procedures should always get priority.
- Agreed with other international medicines regulators on the key principles of a trial design for COVID-19 vaccines under the umbrella of the ICMRA (July 2020).
- Issued guidelines ("considerations") on COVID-19 vaccine approval in November 2020.
- Organised virtual pre-submission meetings and provided accelerated formal (non-binding) scientific advice to potential applicants – with no charge in respect of COVID-19 products. Developers also often asked EMA for informal advice.

[8] Article 14(7) of Regulation (EC) No 726/2004 and Article 6(1) of Regulation (EC) No 507/2006.

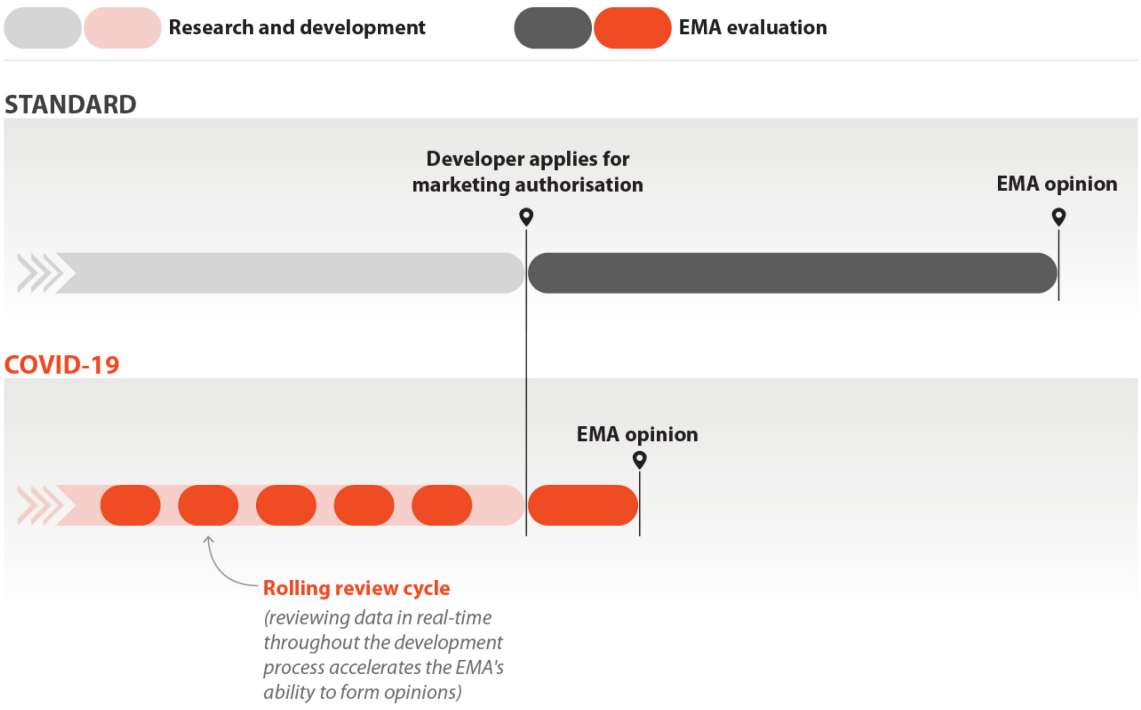
[9] EMA/199630/2020.

- Used “rolling reviews” to accelerate the procedure as provided for in its emerging health threats plan.
- Accepted the use of clinical trial results for a period of less than two months after vaccination as a basis for initial marketing authorisation, on the understanding that follow-up data must be provided promptly after authorisation.
- Shortened the evaluation time for paediatric investigation plans.
- Made increased use of multinational assessment teams.

54 All authorised COVID-19 vaccines and most COVID-19 treatments were assessed under a rolling review procedure, which allowed EMA to assess data from ongoing studies as they become available rather than await their validation by peer review (see ***Figure 5***). The main criteria for the use of rolling review were:

- the product reviewed must be of strategic importance in the context of the pandemic,
- the product dossier and manufacturing plan must be sufficiently mature for an application for (conditional) marketing authorisation to be expected within no more than four months.

Figure 5 – Standard assessment compared with rolling review



Source: ECA based on EMA.

55 The EMA Committee for Medicinal Products for Human Use (CHMP) would normally appoint three of its members to act as rapporteur, co-rapporteur and peer reviewer for each application for authorisation. In 2021, to free up resources, EMA decided no longer to appoint a peer reviewer. During the pandemic EMA increasingly struggled to find (co-)rapporteurs because of the workload associated with rolling reviews and the limited number of NCAs with the necessary expertise. The feedback from stakeholders indicated that the workload required by rolling reviews was difficult to plan and unsustainable.

56 Moreover, during the pandemic, EMA reached temporary bilateral confidentiality arrangements relating to COVID-19 vaccines and treatments with 14 non-EU national regulatory authorities. In December 2020, EMA launched the "OPEN" initiative, a pilot project under which regulators from Australia, Canada, Japan, Switzerland and the WHO conduct near-concurrent reviews of certain new medicines and exchange product assessment findings and reports, thus accelerating both regulatory decision-making and the availability of medicines in low and middle-income countries.

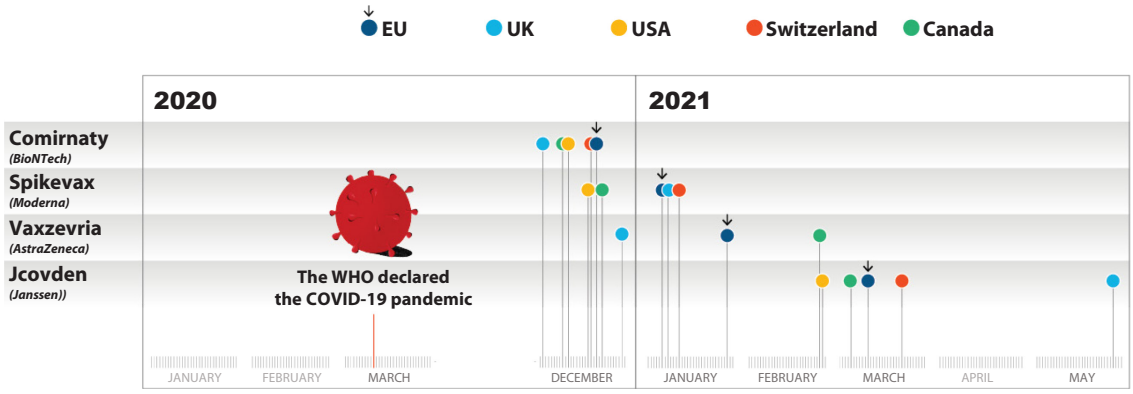
57 Some health agency representatives we interviewed stated that rolling reviews continued to be used for COVID-19 products even after the need for new vaccines and treatments receded. They mentioned that EMA's pandemic task force had agreed to use rolling review even for COVID-19 products that did not warrant such a resource-intensive procedure.

58 EMA's advice with regard to COVID-19 vaccine development was aligned with WHO and ICMRA guidance, taking "COVID-19 of any severity" as the primary efficacy endpoint (outcome of interest) for clinical trials. In vaccine testing, efficacy is assessed by comparing the number of people who develop the outcome of interest in the vaccinated group with those in the placebo group during the observation period. This is the standard method for assessing vaccine efficacy and the observation period was approximately two months. Later data showed that effectiveness against infection was significantly lower over a longer period, in particular against new variants, but the protection against severe disease was longer lasting.

59 Nearly all developers of COVID-19 vaccines first applied for authorisation from a non-EU regulator, but most also applied in the EU some days or weeks later. The duration of the EU authorisation procedure was largely in line with that of the US and the UK. As a result, most COVID-19 vaccines were authorised for sale in the EU either before or within a few days or weeks after they were first authorised in a non-EU

jurisdiction (see ***Figure 6***). The time lapse between the submission of a formal application and EMA's opinion was much shorter than for other new vaccines.

Figure 6 – Date of first authorisation of COVID-19 vaccines



Source: ECA based on EMA, UK government, US Food and Drug Administration, Swissmedic and Health Canada websites.

60 EMA recommends medicinal products whose benefits outweigh their risks for the overall target population. It considered that the risk-benefit balance of all COVID-19 vaccines it assessed during 2020-2023 was positive. In its assessments it included the limited availability of treatments, the seriousness of the disease and the 70-95 % efficacy of vaccines as reasons for issuing a positive opinion, even though the duration of protection and efficacy against transmission remained unclear. All COVID-19 vaccines were recommended unanimously. The Commission decision authorising a given vaccine or treatment was always taken within days of EMA's recommendation – sometimes the same day.

61 We found that, in accordance with its emerging health threats plan, EMA used rolling reviews to accelerate the assessment of COVID-19 products. However, it could have applied this approach more selectively. We also checked and did not find any material ways in which EMA's assessments departed from the guidelines that EMA and the ICMRA had developed for COVID-19 vaccines, or from the generally agreed procedures for medicine assessment.

EMA tried to promote EU clinical trials but largely had to rely on those held outside the EU

62 Clinical trials are authorised not by EMA but by national regulators. EMA's assessment of the efficacy and safety of new products is based on the reports submitted by developers on both non-clinical and clinical trials. To check that clinical trials have been conducted and reported correctly, EMA relies on good clinical practice

inspections carried out by NCAs and any supporting information from its international partners. NCAs from EU countries can carry out good clinical practice inspections anywhere in the world, and other forms of oversight can mainly be exercised by local authorities. As the most important clinical trials for COVID-19 vaccines were mainly held outside the EU, they were authorised only by non-EU authorities.

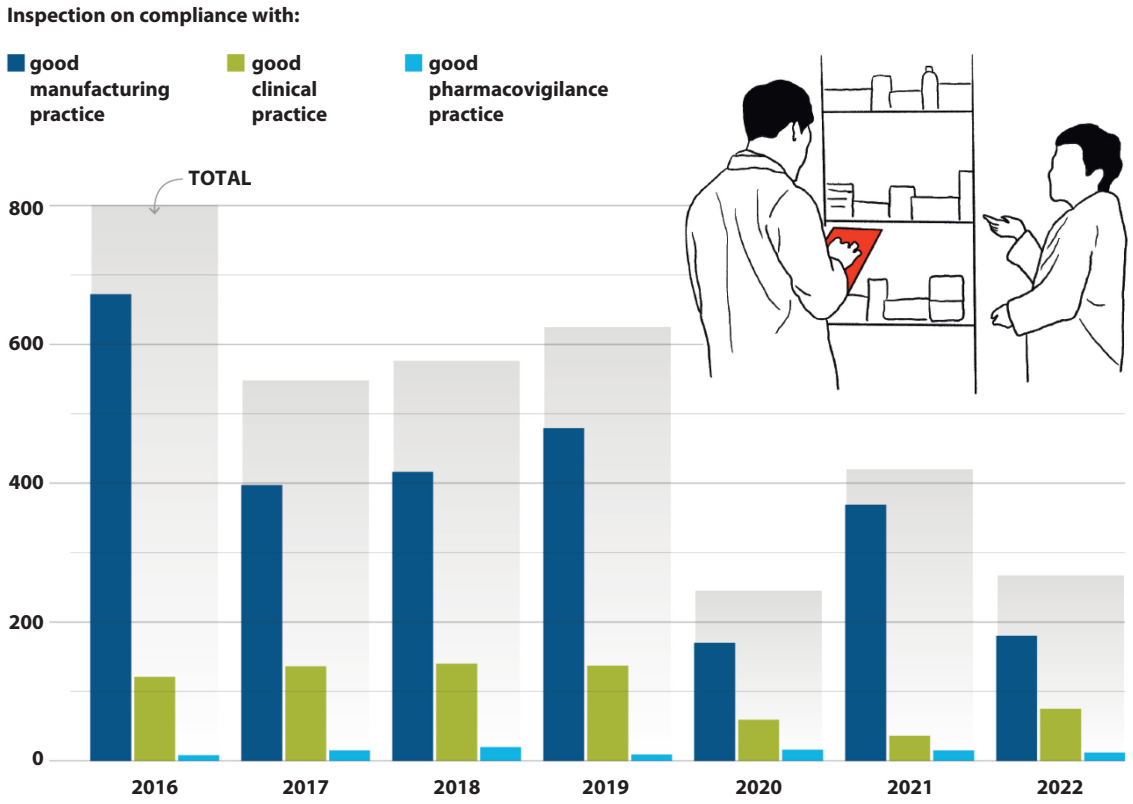
63 To generate sufficient evidence for clear-cut recommendations, clinical trials need to involve many participants. In March 2020 EMA proactively promoted pooling EU research resources in large-scale, multi-centre clinical trials of COVID-19 treatments. This met with little success. Nearly all large-scale clinical trials of COVID-19 vaccines were held outside the EU.

EMA limited the impact of the pandemic on the authorisation and availability of medicines

64 The European medicines regulatory network's COVID-19 business continuity plan contained a set of principles for the handling of regulatory procedures during the pandemic, the purpose of which was to avoid or limit delays in the authorisation of new medicines and/or avoid disruption in the supply of both COVID and non-COVID medicines. The Commission, EMA and the Heads of Medicines Agencies also agreed that some regulatory flexibility would apply from April 2020 to clinical trials, remote inspections and the extension of good practice certificates.

65 The responsibility for carrying out inspections lies with NCAs. EMA committees can request inspections, and EMA coordinates inspections that relate to centralised procedures. During the pandemic, compliance verification was often done remotely. The number of inspections of good clinical and manufacturing practice declined owing to travel and safety restrictions (see ***Figure 7***), while inspections of good pharmacovigilance practice remained at pre-pandemic levels. This increased the inspection backlog for all products.

Figure 7 – Number of inspections requested in connection with centralised authorisation procedures, 2016-2022



Source: ECA, based on data from EMA's annual reports 2020-2022.

EMA scaled up its pharmacovigilance of COVID-19 products

66 As less common side effects may only emerge once a medicine has been used for a long time and by many people, EMA continues to monitor the safety of authorised products. In May 2020, anticipating the future need to assess whether there is a causal link between COVID-19 vaccines and certain side effects, EMA commissioned independent research to prepare for the real-world monitoring of vaccines, and the European medicines regulatory network issued a pharmacovigilance plan.

67 For initial authorisation EMA required post-vaccination safety follow-up in the form of clinical trials involving several thousands of vaccinees for at least six weeks after vaccination. Population-level data provides additional evidence post authorisation. New side effects, some of them "common" or "very common", were discovered after the granting of a conditional marketing authorisation. All COVID-19 products, as any new product, were on the list of medicines under additional monitoring. EMA supports member states by operating and maintaining IT systems for

pharmacovigilance, such as the EudraVigilance system for managing and analysing information on suspected adverse reactions to medicines.

68 Healthcare professionals and consumers can report suspected side effects to NCAs via a web-based application. These records are then converted into individual case safety reports. In 2021 the EMA handled 1.68 million such reports on COVID-19 vaccines (48 % of the total of 3.5 million). In 2022 there were 1.14 million reports (39 % of 2.9 million), and 0.22 million (11 % of 1.9 million) in 2023[10]. The case safety reports are aggregated and combined with information from other sources to serve as a basis for "safety signals" requiring further investigation by EMA.

69 EMA brought forward the timetable for assessing safety signals in relation to COVID-19 vaccines. In all cases it concluded that the benefits continued to outweigh the risks. In most cases, the Pharmacovigilance Risk Assessment Committee (PRAC) recommended updating the product information and/or risk management plan.

70 In 2021-2022, 34 (25 %) of the 135 safety signal procedures assessed by PRAC related to COVID-19 vaccines. These procedures were accelerated. 15 signal procedures resulted in update of the product information. A vast majority (12 out of 15 cases) of the new side effects in signal procedures were detected and assessed already in the first year post-authorisation. In other cases (three out of 15)it took more than a year from the date of authorisation of the vaccine to gather the necessary evidence to conclude in a signal procedure that a specific adverse event should be included in the product information as a side effect.

71 As the protection offered by vaccines appeared to be waning over time, and given the appearance of worrying new variants such as Delta and Omicron, it was essential to monitor vaccine effectiveness very closely. ***Annex II*** shows how both agencies have continued monitoring vaccines and vaccination rates. Their respective website provides links to many efficacy, safety and "real-world effectiveness" studies, which is helpful for scientific experts. However, these studies are not summarised in overview, which would be more helpful for patients and policymakers.

EMA helped to counter medical shortages during the pandemic

72 During the pandemic the EU was confronted with shortages of medicines, especially those used in intensive care. The causes were increased demand, the

[10] 2021, 2022 and 2023 annual reports on Eudravigilance.

lockdowns, and export restrictions imposed by India and China, two major suppliers of medicines and their ingredients.

73 In 2020, EMA and the Commission set up an EU Executive Steering Group on Shortages of Medicines Caused by Major Events, as well as a system of industry single points of contact to facilitate communication between EMA and marketing authorisation holders. In early 2022, EMA's role in managing shortages was formalised and strengthened in its extended mandate (see paragraph ***84***). We sought feedback from members of EMA's committees and management board about EMA's performance during the pandemic. Many rated it highly, but opinions were slightly less positive on the agency's handling of shortages, a field where it has restricted power.

EMA made additional efforts to improve transparency, but its communications were not always readily accessible to the general public

74 EMA held regular press briefings on COVID-19 and other public health emergencies between 2021 and the first half of 2023. It also organised four stakeholder meetings between November 2020 and November 2021 to explain the approval procedure, its recommendations and the safety monitoring of COVID-19 vaccines.

75 Early in the pandemic EMA started providing public health advice and published statements, guidance and recommendations on the use of COVID19 products. EMA and ECDC also issued several joint statements on booster doses in response to requests from stakeholders. Some of the member state representatives we interviewed considered, however, that EMA should have restricted itself to its role of regulator and refrained from giving guidance on the use of products, which was not explicitly part of its mandate.

76 EMA strives to publish a "European public assessment report" within seven days of each decision to authorise a COVID-19 product, as well as a risk management plan, protocols and public abstracts of the results of compulsory post-authorisation safety studies, conclusions of assessments, recommendations, opinions and approvals, and decisions taken by its scientific committees. We compared the public and internal versions of public assessment reports and found no material omissions of public-interest information about the safety and efficacy of the vaccines concerned.

77 EMA assesses any information submitted after its initial authorisation of a product, and will publish a new public assessment report if it considers that

information to be in the public interest. Any additional unpublished information can be requested through access-to-document procedures.

78 Although EMA makes a lot of information available to the public and introduced a separate section on COVID-19 on its website, it remains difficult for interested non-experts or non-English speakers to find relevant information on the agency's website – for example regarding any analysis by population sub-group.

The Commission's efforts to address some of the weaknesses it identified have met with limited success

79 We assessed whether the Commission, ECDC and EMA have drawn appropriately on the lessons learned from the pandemic to improve preparedness for future pandemics.

80 Based on some early lessons learned from the first phase of the pandemic, the Commission took several initiatives impacting the mandates of ECDC and EMA:

- In November 2020, with a view to building a European Health Union, the Commission put forward proposals for a regulation on serious cross-border threats to health, which would also amend the EMA and ECDC regulations (see paragraph ***84*** and ***88-90*** respectively). Legislative urgency meant that none of these proposals was based on a formal impact assessment, and ECDC was consulted only briefly.

- In September 2021 the Commission set up the Health Emergency Preparedness and Response Authority (HERA) as a new directorate-general. HERA's mission is to improve the EU's preparedness for and response to serious cross-border health threats.

- In April 2023 the Commission adopted a proposal to reform the EU's pharmaceutical legislation, including further substantial amendments to the EMA Regulation. At the time of the audit the proposal had not yet been adopted by the co-legislators.

HERA was created to fill gaps in the EU's operational set-up, with a mandate that partially overlaps with that of ECDC and EMA

81 The Commission decided to set up HERA because the EU lacked a mechanism to ensure the development, production and distribution of medicines, vaccines and other

medical counter-measures – such as gloves and masks – when an emergency hits. For reasons of urgency, the decision was not based on an impact assessment. It has therefore not been demonstrated that the creation of a new Commission directorate-general was a better solution than, for example, setting up a new agency or assigning additional responsibilities to existing structures such as ECDC, EMA or DG SANTE. HERA's establishing decision requires an in-depth review of HERA by 2025. The European Parliament welcomed the creation of HERA, but also emphasised that it should become an independent EU agency with sufficient funding and a higher level of transparency and democratic scrutiny. It also recalled that the Commission "must carry out (…) an assessment of the need to establish HERA as a distinct entity" before the end of December 2024[11].

82 Most stakeholders voiced concern that HERA's mandate might overlap with that of ECDC and generate double requests to member states. Our analysis showed that both ECDC and HERA are involved in the surveillance of infectious diseases. HERA's mandate includes preparing the EU for cross-border health threats in the area of medical counter-measures, which often requires close collaboration with ECDC and EMA. These three bodies have distinct roles, but some aspects of their responsibilities and activities overlap, which makes it essential that they should share information to avoid the duplication of information-gathering activities. HERA signed a non-binding working agreement with both ECDC and EMA on 14 March 2023. The text of the agreement is vague, however, and many issues still require further clarification.

EMA's mandate was extended from March 2022, and further amendments are foreseen

83 In October 2021 EMA presented some early lessons learned from the COVID-19 pandemic to its management board. A comprehensive report was published in December 2023. In early 2022, EMA issued an interim update of the emerging health threats plan, aligning it with the amended EMA Regulation and the Commission's proposal to amend the cross-border health threats regulation.

84 Regulation (EU) 2022/123, extending EMA's mandate, was adopted in January 2022 and entered into force in March 2022. It sets out specific tasks for EMA in relation to public health emergencies and granted EMA 61 additional staff posts in 2021, and a further 43 for 2023-2025, for a total of 980 posts. The main changes were:

[11] European Parliament resolution of 12 July 2023, paragraph 76.

- The creation of a permanent emergency task force to take over the activities of the COVID-19 pandemic task force. The new task force became operational on 22 April 2022 and should play a key role in addressing future emergencies.
- EMA became officially responsible for monitoring and mitigating shortages of critical medicines, and has similar responsibilities in respect of medical devices during a crisis.

85 The proposal to amend the EU's pharmaceutical legislation was published, after some delays, in April 2023. Several of the amendments drew on the lessons learned from the COVID-19 pandemic:

- a shorter period between applications and the granting of marketing authorisations for all new medicines;
- rolling reviews for innovative medicines to speed up the authorisation process (see paragraphs ***54***-***57***);
- the option of granting temporary emergency marketing authorisations in a public health emergency, as a more flexible instrument in addition to conditional marketing authorisations (see paragraph ***52***);
- measures to improve medicines security of supply at all times (not just during crises).

86 In January 2022, the Commission, the Heads of Medicines Agencies and EMA launched the ACT EU initiative for accelerating clinical trials in the EU. The initiative, a response to EMA's recommendation from March 2020 (see paragraph ***63***), outlines ten "priority actions" to transform clinical trials in the EU[12]. The COVID-19 pandemic made it clear that, to avoid fragmentation, there was a need for a faster and more robust procedure for the coordinated approval of multinational clinical trials by member states[13].

[12] Accelerating Clinical Trials in the EU (ACT EU), p. 3.

[13] Communication from the Commission, COVID-19 - Sustaining EU Preparedness And Response: Looking Ahead, COM (2022) 190 Final, p. 11.

ECDC's mandate has been clarified and strengthened

87 McKinsey's 2020 strategic and performance review of the ECDC response to the COVID-19 pandemic called for a bolder interpretation of ECDC's mandate, more effective prioritisation and resource allocation, and more timely and actionable guidance. These conclusions are consistent with our observations (see paragraphs ***17***, ***18***, ***35***, ***36***, ***45***, ***47*** and ***48***).

88 The two amended regulations that entered into force in December 2022 (on cross-border health threats and the ECDC founding regulation) assigned new rights and responsibilities to ECDC, including:

- establishing and coordinating an EU health task force as a deployable public health workforce providing operational response and crisis preparedness support to EU/EEA countries and international organisations;
- operating and coordinating a network of EU reference laboratories designated by the Commission[14];
- the right to issue non-binding recommendations;
- assessing member states' prevention, preparedness and response plans every three years;
- digitalising surveillance systems.

89 In April 2023 ECDC published its long-term surveillance framework for 2021-2027. In May 2023 it published a technical report on the lessons learned from the pandemic, with guidance for member states on how to improve their preparedness and details of the support they could expect from the agency.

90 In its July 2023 resolution on the lessons learned from the COVID-19 pandemic and recommendations for the future, the European Parliament welcomed ECDC's extended mandate but also called for greater European cooperation, more independence for the agency and the introduction of a systematic obligation for member states to send it comprehensible and comparative data.

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[14] Article 15 of Regulation (EU) 2022/2371.

91 The review of ECDC's mandate resulted in an additional 73 posts for the 2020-2024 period, bringing the total to 353. The new EU health task force is composed of a pool of experts drawn from ECDC and member states, and is being prepared for field deployments in response to specific outbreaks, as well as training, simulation exercises and after-action reviews. In September 2023 ECDC approved an updated public health emergency plan that takes into account the lessons learned from the COVID-19 pandemic and considers the possibility of a protracted pandemic.

92 One of the first lessons which the Commission learned from the pandemic was that "faster detection and response depends on stronger global surveillance and more comparable and complete data" and "a new European pandemic information gathering system, building on the existing Early Warning and Response System and an upgrade of TESSy, should be set up to manage and exchange data in real time and integrated into the new global system". As a first step, the Commission has recently assessed what is needed to ensure alignment of the Early Warning and Response System with the new cross-border health threats regulation.

Conclusions and recommendations

93 Our overall conclusion is that, within the limits of their powers and capacities, the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) have generally managed their response well to the COVID-19 crisis. However, there is room for improvement in specific areas. Although the two agencies were not fully prepared for a severe and protracted pandemic, they responded as soon as its extent became clear. They also improved their transparency and scaled up the way they communicated with the public. The Commission and the agencies are now implementing the lessons learned from the pandemic, but it is too early to tell whether this will be sufficient to prepare the agencies adequately for future public health emergencies.

94 We found that both ECDC and EMA had drawn up detailed public health emergency plans, but under the applicable legal and financial framework these did not address the expansion of capacity in the event of a severe and protracted pandemic (see paragraphs ***17***-***21***). Unlike EMA, ECDC had not prepared a list of activities that could be deprioritised in emergency situations (see paragraphs ***17*** and ***23***). EMA was still in business continuity mode in the wake of Brexit, and continued in that mode until the end of the pandemic (see paragraphs ***23*** and ***24***). Both agencies had set up extensive international networks which subsequently proved useful in dealing with the pandemic (see paragraphs ***28***-***31***).

95 For a few weeks after China reported the first cases of COVID-19, ECDC underestimated the seriousness of the situation. It then quickly stepped up its response (see paragraphs ***32***-***36***), developing several new initiatives such as pandemic modelling (see paragraph ***41***). The data reported to ECDC was of limited quality, and there were significant differences in what countries were able to report (see paragraphs ***37***-***41***). ECDC's guidance and assistance for member states was particularly appreciated in countries with limited scientific capacity, even though national decision-makers did not always heed its cautious and, at times, belated advice (see paragraphs ***43***-***45***). In 2020, ECDC started issuing communications targeting the public, but most publications continued to target public health experts (see paragraphs ***48*** and ***49***).

Recommendation 1 – Further improve ECDC's organisation, procedures, systems and publications to be better prepared for future health emergencies

ECDC should:

(a) cooperate with the member states to work further on a robust European surveillance system for infectious diseases, based on EU-wide harmonised case definitions, allowing ECDC to collect comparable data by country and by region;

(b) streamline its internal procedures so it can issue more timely and practical guidance;

(c) publish information in plain language that is more accessible for the general public.

Target implementation date: 2026.

96 The EMA put appropriate crisis procedures in place. The rolling review of COVID-19 vaccines and therapeutics was resource-intensive but did allow the agency to accelerate the authorisation process (see paragraphs ***51***-***61***). EMA limited the impact of the pandemic on the authorisation and availability of medicines. However, EMA's efforts to promote EU clinical trials met with little success (see paragraphs ***62***-***65***). It scaled up its pharmacovigilance of COVID-19 (see paragraphs ***66***-***70***) and became more active in monitoring medical shortages (see paragraphs ***72*** and ***73***). It publishes a wide range of information on its website; during the pandemic it intensified the transparency of its communication about COVID-19 products in particular, but the information it publishes is not always readily accessible for non-experts (see paragraphs ***74***-***78***).

Recommendation 2 – Fine-tune EMA's procedures and dissemination to improve its pandemic preparedness

EMA should:

(a) review the criteria and processes for the implementation of rolling reviews during public health emergencies to use its resources more efficiently;

(b) work with the Commission and the member states to promote the practice of pan-European clinical trials;

(c) assess which elements of the systems and guidance that it developed to deal with the pandemic should be retained for future pandemics or other crises, updating these elements to reflect scientific and technical developments;

(d) improve accessibility of plain language information for non-experts on the EMA website, in particular for medicines attracting high interest in case of future public health emergencies.

Target implementation date: 2026.

97 The Commission used the lessons learned in the early stages of the pandemic to adopt a number of decisions and proposals to amend the legal framework (see paragraph ***80***). These measures fill some of the gaps in the EU's capacity to respond to health emergencies, but they have resulted in a more complex organisational set-up that relies on close cooperation involving many international, European, national and sub-national stakeholders. In 2021 the Commission created a new directorate-general whose competences partially overlap with those of ECDC (see paragraph ***81***).

Recommendation 3 – Clarify the responsibilities of the Health Emergency Preparedness and Response Authority, ECDC and EMA, and enhance coordination

The Commission should, in cooperation with ECDC and EMA:

(a) clarify the respective responsibilities of HERA, ECDC and EMA, including through revision of working agreements;

(b) ensure that clear coordination mechanisms are in place to help the EU respond quickly to future health emergencies.

Target implementation date: 2026.

This report was adopted by Chamber I, headed by Mrs Joëlle Elvinger, Member of the Court of Auditors, in Luxembourg at its meeting of 19 June 2024.

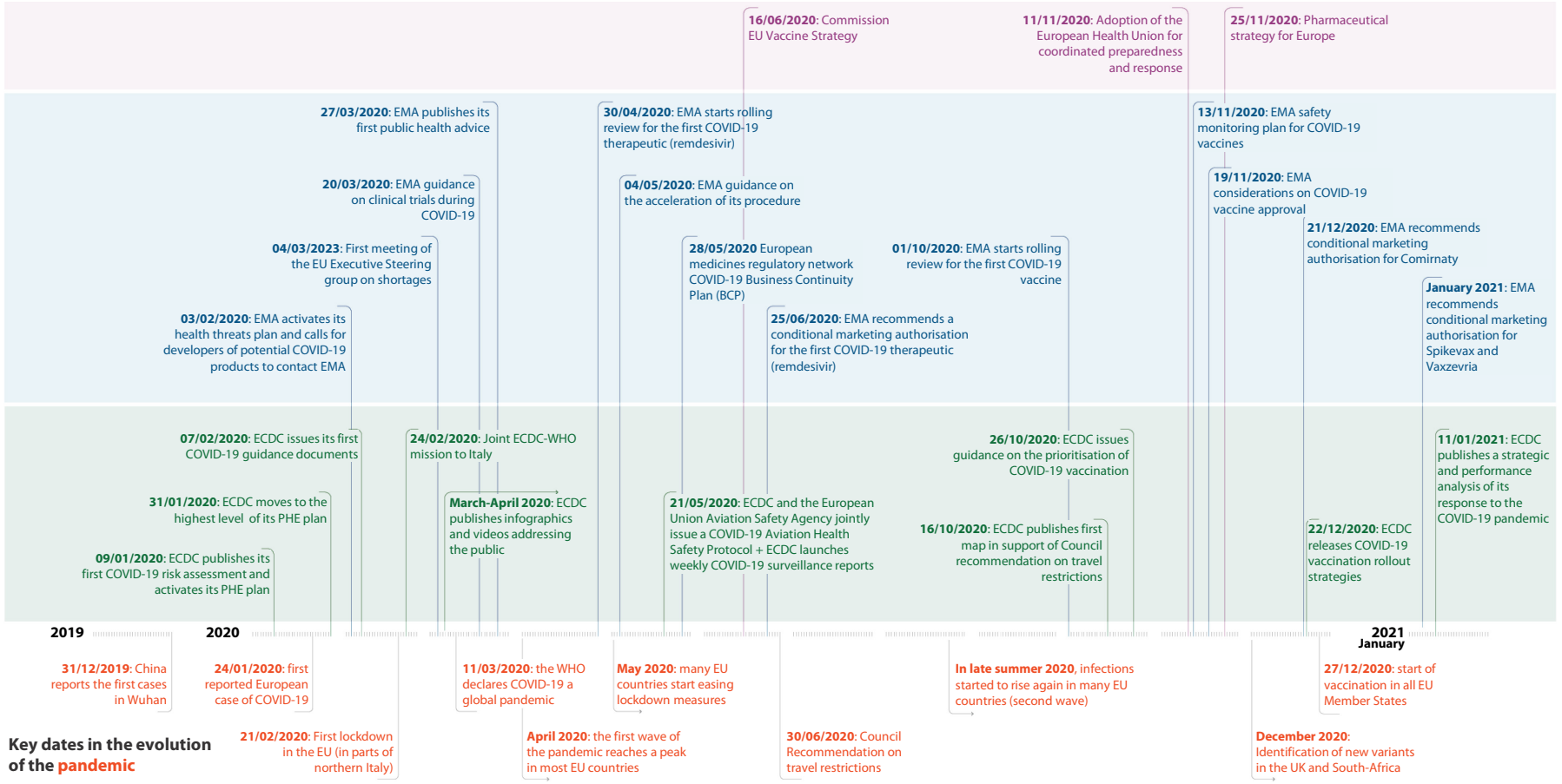
For the Court of Auditors

Tony Murphy
President

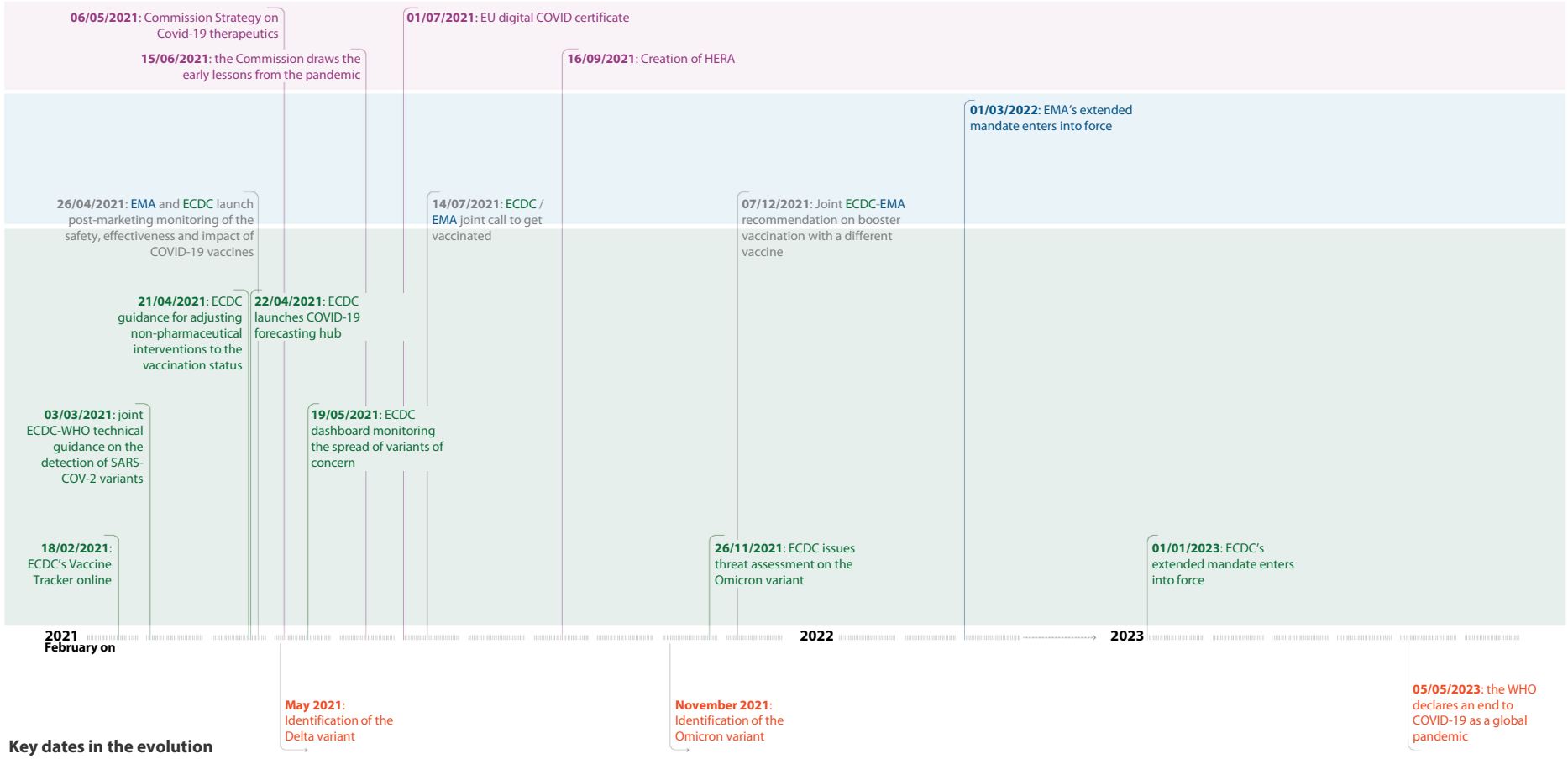
Annexes

Annex I – Milestones in the pandemic and the EU's response

Key milestones in EU's response (actions taken by **European Commission**, **EMA** and **ECDC**)



Key milestones in EU's response (actions taken by **European Commission**, **EMA** and **ECDC**)



Key dates in the evolution of the pandemic

Annex II – Monitoring of vaccination rates and vaccines

Instrument	Operational	Agency	Output
European Vaccination Information Portal (EVIP)	Since **April 2020**	**ECDC, in cooperation with EMA and the Commission**	**Evidence-based information** on COVID-19 and non-COVID-19 vaccines and vaccination
Systematic review	**January 2021 – February 2022**	**ECDC**, in cooperation with the Robert Koch Institute and the National Immunization Technical Advisory Groups	**Systematic review** on the efficacy, effectiveness and safety of COVID-19 vaccines that were authorised in the EU/EEA
Vaccine tracker	Since **February 2021**	**ECDC**	**Monitoring** of COVID-19 vaccine uptake
Joint Advisory Board	Since **April 2021**	**ECDC**, **EMA**	**Coordination and oversight** of EU-funded observational studies on the effectiveness, safety and impact of COVID-19 vaccines
Technical reports on COVID-19 vaccine effectiveness	Since **October 2021**	**ECDC**	**Interim analyses** of COVID-19 vaccine effectiveness
Vaccines Monitoring Platform	**May 2022**	**ECDC**, **EMA**	**Real-world evidence** through EU-funded post-authorisation studies on both COVID-19 and non-COVID-19 vaccine use, safety and effectiveness

Source: ECA based on ECDC and EMA.

Abbreviations

CHMP: Committee for Medicinal Products for Human Use

ECDC: European Centre for Disease Control

EEA: European Economic Area

EMA: European Medicines Agency

HERA: Health Emergency Preparedness and Response Authority

ICMRA: International Coalition of Medicines Regulatory Authorities

NCA: National Competent Authority

PHE: Public health emergency

PRAC: Pharmacovigilance Risk Assessment Committee

SARS-CoV-2: Severe acute respiratory syndrome coronavirus 2

TESSy: The European Surveillance System

TFEU: Treaty on the Functioning of the European Union

WHO: World Health Organization

Glossary

Conditional marketing authorisation: Authorisation to make a medicine available to address unmet needs on the basis of data that is less comprehensive than normally required, provided the existing data indicates that the medicine's benefit outweigh its risks and the applicant is in a position to provide comprehensive data in the future.

Impact assessment: Analysis of the likely (*ex ante*) or actual (*ex post*) effects of a policy initiative or other course of action.

Pharmacovigilance: Constant monitoring of the safety of medicines during clinical trials and after authorisation.

Risk assessment: Systematic identification and appraisal of risks linked to an operation or process, that can serve as the basis for managing those risks.

Risk management: Systematically identifying risks and taking action to mitigate or eliminate them, or to reduce their impact.

Rolling review: Accelerated review procedure that can be used by the European Medicines Agency to assess medicines more quickly.

Standard marketing authorisation: Authorisation to make a medicine available after the European Medicines Agency has examined comprehensive data and concluded that the medicine's benefits outweigh its risks.

Surveillance: In a public health context, the systematic and ongoing collection, organisation, and analysis of data for public health purposes, and the dissemination of public health information.

Replies of the Commission

https://www.eca.europa.eu/en/publications/sr-2024-12

Replies of ECDC

https://www.eca.europa.eu/en/publications/sr-2024-12

Replies of EMA

https://www.eca.europa.eu/en/publications/sr-2024-12

Timeline

https://www.eca.europa.eu/en/publications/sr-2024-12

Audit team

The ECA's special reports set out the results of its audits of EU policies and programmes, or of management-related topics from specific budgetary areas. The ECA selects and designs these audit tasks to be of maximum impact by considering the risks to performance or compliance, the level of income or spending involved, forthcoming developments and political and public interest.

This performance audit was carried out by Audit Chamber I Sustainable use of natural resources, headed by ECA Member Joëlle Elvinger. The audit was led by ECA Member João Leão, supported by Paula Betencourt, Head of Private Office; Emmanuel Rauch, Principal Manager; Eddy Struyvelt, Head of Task; Vasileia Kalafati, Deputy Head of Task; Malgorzata Frydel, Auditor. Thomas Everett provided linguistic support, Alexandra Mazilu provided graphical support and Cécile Fantasia provided secretarial support.

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The two medical agencies of the EU, the European Centre for Disease Prevention and Control and the European Medicines Agency alongside the European Commission played an important role in the response of the EU to the COVID-19 pandemic. We found that, although not fully prepared for a protracted pandemic, both agencies generally managed well. The European Commission and the agencies are in the process of implementing the lessons learned from the pandemic. However, we identified some remaining shortcomings. We make recommendations to help the agencies to be better prepared for future health emergencies.

ECA special report pursuant to Article 287(4), second subparagraph, TFEU.

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