

23<sup>rd</sup> January 2024

Claire Haughey MSP  
Convener, Health Social Care and Sport Committee

By email only - [HSCS.committee@Parliament.Scot](mailto:HSCS.committee@Parliament.Scot)

Dear Ms Haughey

Thank you for your letter of 21<sup>st</sup> November 2023.

Decision No 1082/2013/EU of the European Parliament and of the Council was introduced to strengthen and provide a more coordinated and wider approach to health security at Union level. The UK was bound to this decision but following the UK's withdrawal from the EU there is no longer a requirement for the UK to apply EU law or policy.

Scottish Ministers have indicated that, where appropriate, they would like to see Scots Law remaining aligned with EU law. This could be introduced in primary legislation or secondary legislation in Scotland where powers exist to do so. In addition, specific provision was made in the UK Withdrawal from the European Union (Continuity) (Scotland) Act 2021 for Scottish Ministers to give effect to the Government's preference to stay aligned with EU law.

The key issues for Decision No 1082/2013/EU related to coordinated EU action on monitoring health threats and early warning and response to those threats, in order to add value to the protection and improvement of human health. Prior to the UK's withdrawal from the EU, we had access to the expertise, surveillance outputs and resources provided by the European Centre for Disease Prevention and Control (ECDC) and the Early Warning and Response System (EWRS) of the European Union, a system with restricted access for monitoring public health threats in the EU. Access and postings are confidential and accessed by ECDC, the Member States and the Directorate General Health and Food Safety.

Public Health England, now the UK Health Security Agency (UKHSA), acted as the National Focal point with the EU on various health security related issues and coordinated surveillance activities and scientific expertise and was the UK portal for the EWRS.

In light of the lessons learnt during the COVID-19 pandemic and in order to facilitate adequate EU-wide preparedness for and response to all cross-border threats to health, it was agreed that measures in Decision No 1082/2013/EU needed to be broadened to include:

1. additional reporting requirements and analysis regarding health systems indicators
2. strengthening of cooperation between Member States and Union agencies and bodies, particularly ECDC, the European Medicines Agency, and international organisations, in particular the World Health Organization (WHO).
3. a legal framework to make it possible to immediately adopt case definitions for the surveillance of novel threats and to provide for the establishment of a network of EU reference laboratories and a network to support monitoring of disease outbreaks that are relevant to substances of human origin.
4. strengthening the capacity for contact tracing via the creation of an automated system, using modern technologies, while respecting data protection legislation.
5. ensuring public investments in research, development, manufacturing, production, procurement, stockpiling, supply and distribution of medical countermeasures for the purpose of preparing for and responding to cross-border threats to health are transparent in accordance with applicable legislation.
6. improving pandemic preparedness.

To address serious cross-border threats to health and their consequences, and following the outcome of various considerations and consultations, Regulation (EU) 2022/2371 was developed.

This Regulation lays down rules on:

- a) the Health Security Committee (HSC)
- b) prevention, preparedness and response planning, including
  - I. preparedness plans at EU and national levels; and
  - II. reporting and assessing preparedness at national level
- c) joint procurement of medical countermeasures
- d) emergency research and innovation
- e) epidemiological surveillance and monitoring.

This Regulation also establishes:

- a) a network of EU reference laboratories for public health
- b) a network for substances of human origin; and
- c) an advisory committee for the occurrence and recognition of a public health emergency at Union level

The proposals described above are welcome developments at a pan-European level, with a focus on strengthening and improving the timely, coordinated response to future threats. The directive only applies to Member States and the changes are not of a nature that we can opt into or legislate for. We have contacted colleagues in UKHSA and we are of the view that there is nothing in the directive that would impact on our own internal UK coordination, or the commitments made in the Trade and Cooperation Agreement under the Health Security Chapter.

UKHSA is the point of contact with the EU and ECDC on matters of health security and efforts are being made to see where the UK, as a third country, may be able to access systems such as EWRS and contribute to and receive the benefits of being part of The European Surveillance System (TESSy). During the COVID-19 pandemic, limited access to these was granted and there is some qualified optimism that this can be built on.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Paul Johnston', written in a cursive style.

Paul Johnston  
Chief Executive  
Public Health Scotland