EU at a Glance

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Part One:

The Composition and Operation of the EU







Terminology

- European Union (EU) 歐洲聯盟 -27 Countries
 Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech, Denmark, Estonia, France, Finland, Germany,
 Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal,
 Romania, Slovakia, Slovenia, Spain, Sweden.
- European Economic Area (EEA) 歐洲經濟區: consists of the Member States of the European Union (EU) and three countries of the European Free Trade Association (EFTA) (Iceland, Liechtenstein and Norway).
- Eurozone歐元區:
 The 20 eurozone members are Austria, Belgium, Croatia, Cyprus, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Portugal, Slovakia, Slovenia, and Spain.

The seven non-eurozone members of the EU are Bulgaria, Czech, Denmark, Hungary, Poland, Romania, and Sweden.





Schengen Area 申根區

Schengen Area signifies a zone where countries abolished their internal borders,

for the free and unrestricted movement of people and goods.

The 29 Schengen countries are –

All EU - Countries except Cyprus and Ireland.

But included 4 non-EU countries: Iceland, Liechtenstein, Norway, Switzerland.





Timeline of the EU Creations

- 1951 European Coal and Steel Community
 - Germany, France, Italy, the Netherlands, Belgium and Luxembourg
- 1957 The Treaties of Rome----European Economic Community (EEC)
- 1958 European Parliament established
- 1968 Customs Union (6 EEC member countries remove customs duties)
- 1973 First Expansion---Denmark, Ireland and the United Kingdom formally join the European Communities
- 1992 Maastricht Treaty----European Union created
- 1993 Single market--- 4 freedoms(free movement of people, goods, services and money)
- 1994 European Economic Area created
- 1995 Schengen Agreement---- Border-free travel





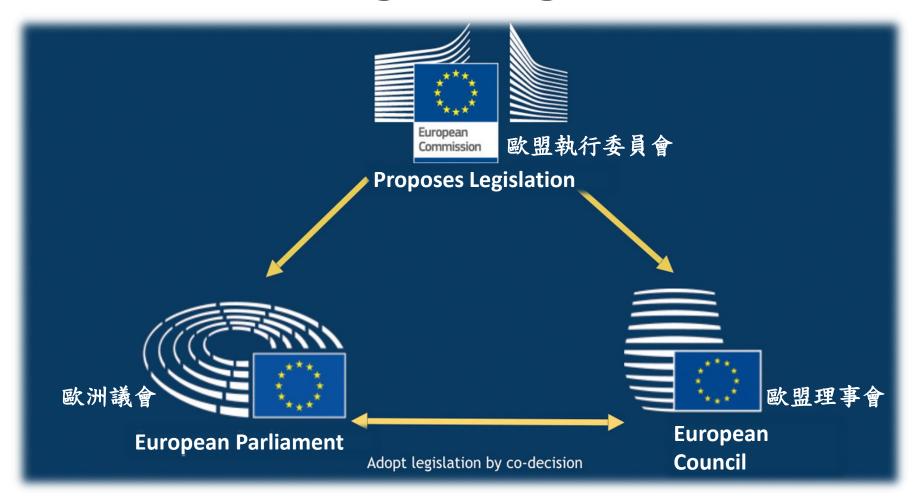
Timeline of the EU Creations ...cont.

- 1997 Treaty of Amsterdam ---- Reform the EU institutions
- 1999 The Euro (€) is born---- notes and coins launched
- 2004 8 Central and Eastern European countries joined EU
- **2007** Lisbon Treaty--- amends the previous treaties
- **2020 United Kingdom leaves the EU**





The Decision-Making Triangle 歐盟決策鐵三角







European Parliament:歐洲議會

Legislative body elected by EU citizens, which votes to pass EU laws, agreements and budgets, and oversees other EU institutions.

European Council:歐盟理事會

Brings together the leaders of all the member countries to set the overall EU agenda and political priorities.

(EU Summit 歐盟高峰會)

European Commission:歐盟執委會

Executive arm of the EU which drafts EU legislation and implements the decisions of the legislative bodies.

Council of the European Union (部長理事會)

Composed of national ministers , together with the Parliament, negotiated and adopts EU legislation.





Decision Process

European Council

Policy formation









Council of the **European**

Union

Amendation

and adoption

of the draft







Trilogue

Finalized

the draft





European

Council

Adopt



European Commission **Legislation draft**

European Parliament Negotiation and take position

European **Parliament Vote (Simple Majority**)

Trans-Position (Mercy

period)





How does the Council vote?

Depending on the issue under discussion, the Council of the EU takes its decisions by:

- Simple majority (14 member states vote in favor)單純多數決
- Qualified majority 合格多數決, 特定多數決
 (55% of member states, representing at least 65% of the EU population vote in favor)
- Unanimous vote (all votes are in favor) 共識決





Lessons from the coronavirus pandemic (Covid-19)

The pandemic showed the importance of coordination among European countries to protect people's health, both during a crisis and in normal times when we can tackle underlying health conditions, invest in strong health systems and train the healthcare workforce.





Creation of European Health Union 歐洲衛生聯盟

What is the European Health Union

The European Commission is building a **strong** European Health Union , in which all EU countries prepare and respond together to health crisis, medical supplies are available, affordable and innovative.





Building blocks of the European Health Union

- A. Establishment of the Health Emergency Preparedness and Response Authority (HERA) 歐洲衛生緊急整備暨應變局
- B. Extended mandate of the European Medicines Agency (EMA)
- C. Stronger mandate of the European Center for Disease Prevention and Control (ECDC)
- D. The pharmaceutical strategy for Europe
- E. European Health Data Space (EHDS)
- F. Europe's Beating Cancer Plan
- **G.** The Global Health Strategy





Part Two:

EU's Global Health Strategy







European Health Strategy – A new approach to global cooperation

• Support stronger World Health Organization (WHO) leading an effective global health system; European Union as full observer at WHO



- Health sovereignty(衛生主權): Expanded international partnerships, single and powerful voice of Team Europe
- Increased impact through innovative finance, pooled funding mechanisms and co-investment.





20 Guiding Principles



1. Prioritise tackling the root causes of ill health, paying particular attention to the rights of women and girls, and to vulnerable populations and disadvantaged groups.



2. Improve equitable access to a full range of essential health services from health promotion to disease prevention and affordable quality treatment, rehabilitation and palliative care to fight communicable and non-communicable diseases.



3. Improve primary healthcare with built-in surge capacity, and enhance core public health capacities to meet the requirements of the International Health Regulations.



4. Foster digitalisation as a fundamental enabler.



5. Boost global health research to develop the technologies and countermeasures which are necessary to improve health.



6. Address workforce imbalances and foster skills.



7. Strengthen capacities for prevention, preparedness and response and early detection of health threats globally.



8. Work towards a permanent global mechanism that fosters the development of and equitable access to vaccines and countermeasures for low- and middle-income countries.



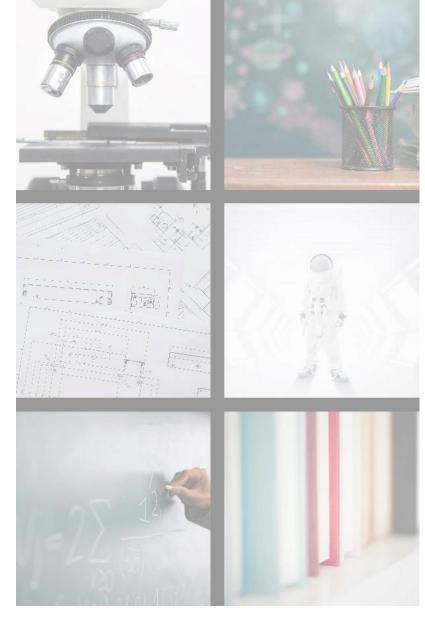
9. Negotiate an effective legally binding pandemic agreement with a One Health approach and strengthened International Health Regulations.



10. Build a robust global collaborative surveillance network to better detect and act on pathogens.







20 Guiding Principles...cont.



11. Apply a comprehensive One Health approach and intensify the fight against antimicrobial resistance.



12. Link effectively all policies and measures that have an impact on global health within the Commission, EU agencies and EU financing institutions.



13. Better link and coordinate policies and measures of the EU and its Member States to speak with one voice and deliver effective action worldwide.



14. Support a stronger, effective and accountable WHO.



15. Steer the new global health governance by filling gaps and ensuring coherence of action.



16. Ensure a stronger EU role in international organisations and bodies.



17. Expand partnerships based on equal footing, co-ownership, mutual interest and strategic priorities.



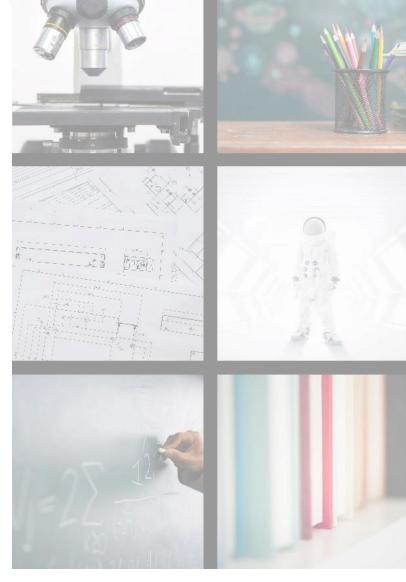
18. Strengthen engagement with key global health stakeholders.



19. Enhance EU finance for global health with maximum impact.



20. Assess progress and ensure the accountability of the EU's global health action through permanent monitoring and assessment.







Team Europe's key initiatives and support:

During the COVID-19 pandemic, EU and member states committed 53.7 billion € to support 140 partner countries

- Support Gavi in vaccine uptake and supply chains
- Expanded roll out of COVID19 vaccines in under-vaccinated countries
- Team Europe Initiative to boost manufacturing and access to vaccines, medicines and other health tools in Africa.
- Global Fund to Fight AIDS, Tuberculosis and Malaria to improve health systems
- EU-Latin America and Caribbean Partnership to improve health security and supply chains

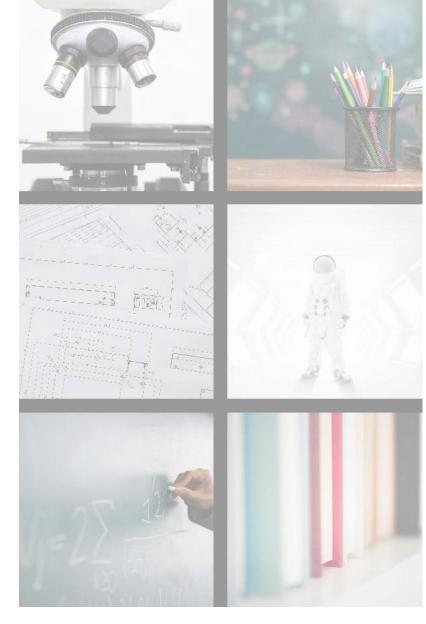






Team Europe and African partners

- During the high-level meeting of the European Union (EU) and the African Union (AU) Global Health Partnership held in Brussels, Belgium, on March 20, 2024, The Team Europe Initiatives (TEI) were launched.
- TEI will strengthen health security, support African public health institutions and promote the digitalization of health.







Team Europe's four initiatives

A. <Sustainable Health Security >

a) Initiative will strengthen prevention, preparedness and response to infectious threats and anti-microbial resistance(AMR, 微生物抗藥性) in African countries.



- b) It brings together the European Commission, Belgium, Denmark, France, Germany, Spain, ECDC and the Africa CDC.
- c) The initiative will benefit from €123 million from the EU budget from 2022-2027.
- d) June 20, 2024, in Paris, Africa Vaccines Manufacturing Accelerator (AVMA), EU and its Member States (MS) will contribute over €750 million.





four initiatives...cont.

B. The <Support to Public Health Institutes in Africa>

- a) To promote regional collaboration and networking among African and European institutes.
- b) To enhance health workforce training, research and knowledge exchange.
- c) To focus on reducing inequities in access to quality health care and disease prevention.
- d) To build integrated and holistic health systems and ultimately advancing universal health coverage.
- e) Bringing together the European Commission, Belgium, Czechia, Finland, France, Germany, Ireland, Italy, Netherlands, Portugal, Spain, Sweden, and Africa CDC,
- f) This initiative will benefit from €50 million from the EU budget from 2024-2027.



four initiatives...cont.

C. The <Digital Health initiative>

- a) To supports African partners in strengthening health systems and achieving universal health coverage through digital solutions.
- b) To help strengthen primary health care.
- c) The initiative will bring together the European Commission, Belgium, France, Germany, Luxembourg, Portugal, Spain and Sweden, and the Digital for Development (D4D) Hub.
- d) It will benefit from €87 million from the EU budget from 2024-2027.







Four initiatives...cont.

D. The <Social Protection initiative>

- a) To strengthen national social protection systems in Sub-Saharan Africa.
- b) This initiative brings together the European Commission, Belgium, France, Germany and Ireland.
- c) The EU contributes through ongoing bilateral cooperation worth approximately €250 million.







Part Three:

European Health Data Space (EHDS)







European Health DATA Space (EHDS)(歐洲衛生資料庫)

- A health-specific data sharing framework establishing clear rules, common standards and practices, digital infrastructures.
- A governance framework for the use of electronic health data by patients and for research, innovation, policy making, patient safety, statistics or regulatory purposes.
- Member States have budgeted €12 billion for investments in digital health under the Recovery and Resilience Facility.
- In addition, the Commission will provide over €810 million to support the EHDS.





Timeline of EHDS

- 2022.05.03 European Commission proposed a regulation
- 2023.12.06 European Council agreed the mandate for negotiation with European Parliament
- 2024.03.15 Agreement reached between EP and the Council
- 2024.04.24 MEPs voted with 445 in favor to 142 against (39 abstentions)



Why a Data-space needed?

- The EU has 0.45 billion population moving freely between member states.
- The EU has 27 member states and more than hundred digital information infrastructures.
- Data is key from innovation to integration.







Cross-border Healthcare in 2022

Cross-border healthcare refers to healthcare received by a person outside of their Member State of affiliation. <u>EU citizens have the right to receive healthcare in any EU country and to be partially or fully reimbursed by their home country.</u>





Objects of European Health Data Space

✓ Empower individuals through better digital access to their personal health data.

- ✓ Support free movement by ensuring that health data follow people.
- ✓ Set up strict rules for the use of anonymized (匿名), or pseudonymised (七名) health data for research, innovation and policy-making.





Growth potential of the health data economy



€5.5 billion

In savings in the EU over ten years from better access and exchange of health data in **healthcare**



20-30%

Additional growth of the digital health market



€5.4 billion

In savings in the EU over ten years from better use of health data for research, innovation and policy making





Benefits

As a citizen

- You will have control over your health data:
 - You will have access to your health data in electronic form immediately and without any cost.
 - You will be able to **share** your data with health professionals nationally or crossborder.
 - You will be able to add information, rectify errors, restrict access and obtain information on how your data are used.
 - You will have a right to health data, issued and accepted, in a common European format.
- Your security and privacy will be ensured
 - Researchers, industry or public institutions may only access health data
 - for specific purposes that benefit individuals and society.
 - that do not reveal the identity of the individual.
 - in closed, secure environments.
 - You will have a right to opt-out from such secondary use.







As a health professional

- You will have faster access to patient's health records, including across borders.
- You will have easier access to health records from different systems, greatly reducing the administrative burden.









As a researcher

- You will have **access** to large amounts of health data, in order to carry out research.
- You will be able to know what data is available, where, and of what quality.
- You will be able to access the data cheaper and more effectively.



As regulators and policy-makers

 You will have easier, more transparent and less costly access to health data for the benefit of public health and the overall functioning of healthcare systems and to ensure patient safety.







As industry

- Thanks to standardisation, you could more easily enter into new markets for electronic health records in other Member States.
- You will benefit from the greater availability of electronic health data, enabling the use of data for applied research and innovation.



Governance: European Health Data Space Board

- Co-chaired by a Member State and the Commission; composed of representatives of Member States, the Commission and Observers.
- It will contribute to the consistent application of rules across the EU.
- It is complemented by a stakeholder forum to gather insights from entities; such as patient organizations, researchers, and industry.





How will EHDS protect data privacy and security?

Access Restrictions

- For primary usage, you will have the ability to restrict access to your data. Member States will have the option to implement a complete opt-out.
- If you choose not to participate in secondary usage, you will have the right to opt out in a straightforward and reversible manner.
- However, for certain significant public interests and under strict safeguards, your data may still be utilized.



Data privacy and security? ...cont.

II. Health Data for Secondary Use

- a. Secondary use is only permitted for specific purposes outlined in the Regulation, based on a permit issued by a data access body.
- b. Clear guidelines govern the permissible and impermissible uses of the data. For instance, it is strictly prohibited to use the data to make decisions that may harm individuals or for marketing purposes.
- c. Data processing may only occur in secure processing environments that adhere to stringent privacy and cyber-security standards, with no personal data permitted to be downloaded from these environments.
- d. researchers, companies, or public institutions may access only pseudonymized data if the intended purpose cannot be fulfilled with anonymized data. Users are explicitly prohibited from re-identifying data subjects or attempting to do so.





Data privacy and security? ...cont.

III. Industry Access

- a. The industry will have the opportunity to request access to data for secondary use through the health data access bodies.
- b. Only the data necessary for the specific request will be made available, ensuring that individuals' identities remain confidential.
- c. However, the industry will not have access to data exchanged during primary use. In the context of healthcare, the EHDS only permits access to patient data by healthcare professionals and allows patients to access their own data.





Schedule of Implementation

EHDS schedule is structured over five years and has two main phases:

Secondary Legislation Phase (2025–2027)

The first two years will focus on drafting secondary legislation to define technical specifications for EHDS operations.

Member State Preparation Phase (2027–2029)

The second two years will involve member states preparing to meet their obligations, such as creating data hubs and integrating with the EU-wide data infrastructure





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