The Structure and Function of the European Union

歐洲聯盟的組成及運作

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7. June. 2023

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; excluding Switzerland).

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

The 27 Schengen countries are –

Austria, Belgium, Czech , Croatia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, and Switzerland.

Schengen Area signifies a zone where 27 European countries abolished their internal borders, **for the free and unrestricted movement of people, in harmony with common rules for controlling external borders and fighting criminality by strengthening the common judicial system and police cooperation**.

EU MAP

27 Countri

THE MEMBER STATES OF THE EUROPEAN UNION

Council of the European Union

Rue de la Loi/Wetstraat 175
1048 Bruxelles/Brussel
BELGIQUE/BELGIË
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www.consilium.europa.eu

Timeline of the EU Creation

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

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

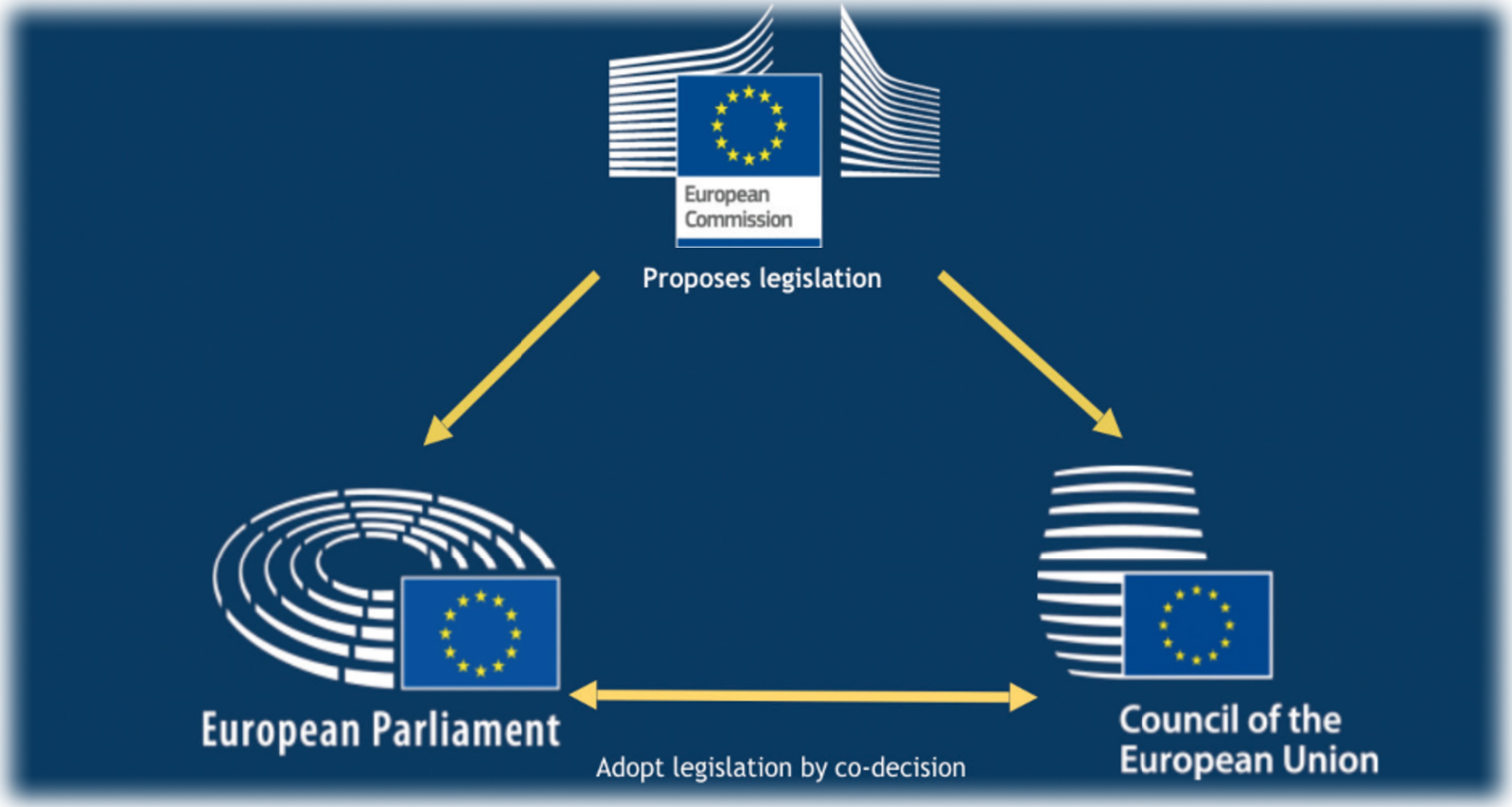
2007 Lisbon Treaty- amends the previous treaties

(The Treaty on the Functioning of the EU)

2020 ??????? leaves the EU

The Decision Making Triangle 歐盟決策鐵三角

歐盟執行委員會



歐洲議會　　歐盟理事會

European Council

Presidency

Rotated every Half a year

European Parliament

How many Official Languages ?

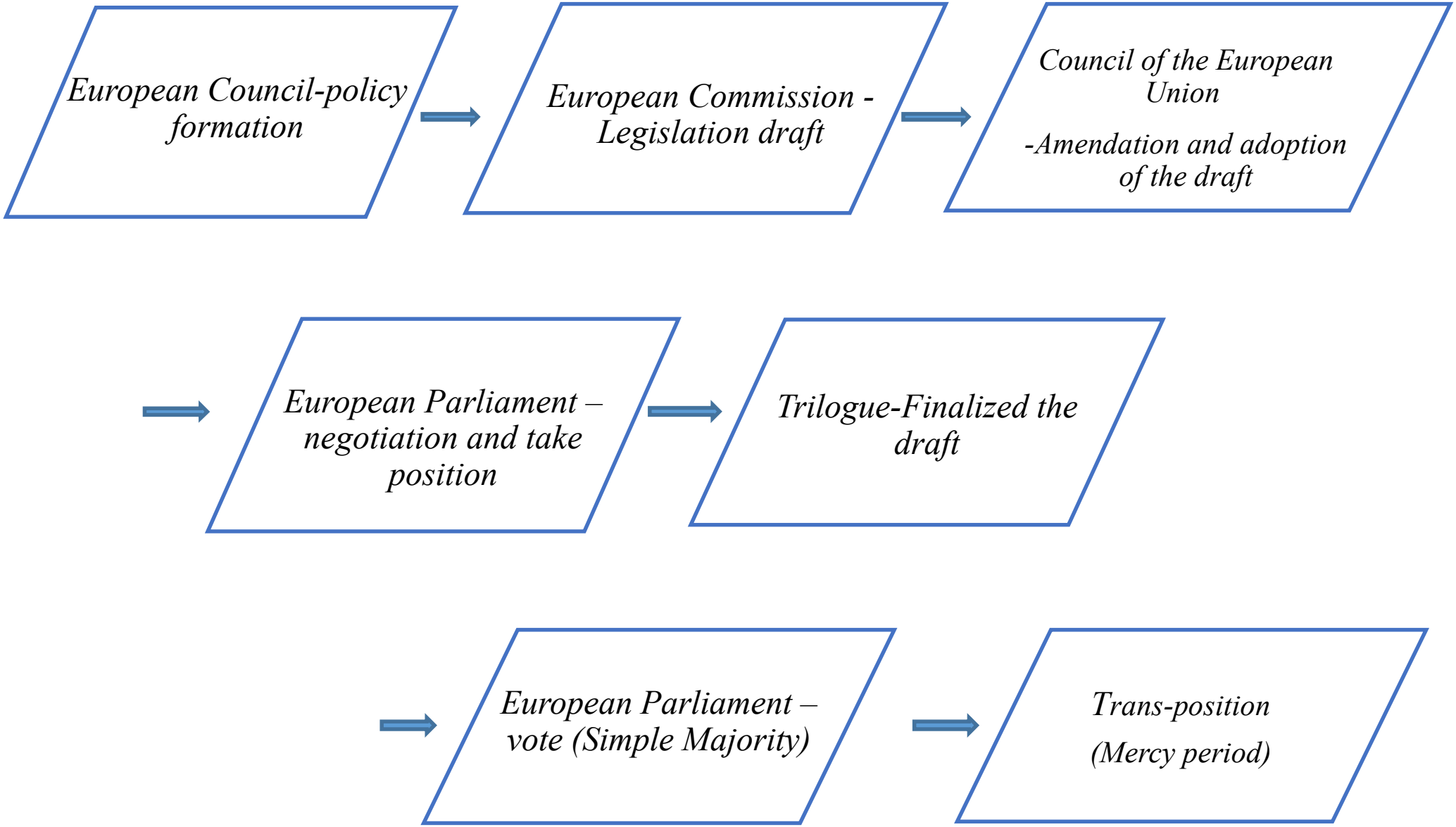
European Commission

- **European Parliament: legislative body elected by EU citizens, which votes to pass EU laws, agreements and budgets, and oversees other EU institutions.**

- **European Council: brings together the 「 leaders 」 of all the member countries to set the overall EU agenda and political priorities （EU Summit 歐盟峰會）**

- **Council of the European Union: composed of national 「 ministers 」 , together with the Parliament, negotiates and adopts EU legislation. （部長理事會）**

- **European Commission: executive arm of the EU which drafts EU legislation and implements the decisions of the legislative bodies**


European Council-policy formation
European Commission - Legislation draft
Council of the European Union
-Amendation and adoption of the draft
European Parliament – negotiation and take position
Trilogue-Finalized the draft
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 favour)

- **qualified majority** 合格多數

  (55% of member states, representing at least 65% of the EU population, vote in favour)

- **unanimous vote** (all votes are in favour)

The EU can set 2 kinds of rules for the member states

1. Legally binding acts

- Regulations
- Directives
- Decisions

2. Non-binding acts

- Recommendations
- options

Commission

Public Health

Reform of the EU pharmaceutical legislation

26 April 2023

Commission adopted a proposal for a new Directive and a new Regulation, which revise and replace th existing general pharmaceutical legislation.

- MAIN DOCUMENTS
  - Commission proposal for the Pharmaceutical Regulation *(/publications/proposal-regulation-down-union-procedures-authorisation-and-supervision-medicinal-products_en)* EN | •••
  - Commission proposal for the Pharmaceutical Directive *(/publications/proposal-directive-uni code-relating-medicinal-products-human-use_en)* EN | •••
  - Communication on Pharmaceutical Reform and Antimicrobial Resistance (AMR) *(https://eur lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023DC0190&qid=1682665765572)*
  - Commission proposal for a Council Recommendation on stepping up EU actions to combat antimicrobial resistance in a One Health approach (AMR) *(/antimicrobial-resistance/eu-acti antimicrobial-resistance_en)* EN | •••
- MEDIA
  - EC corporate page on the Pharmaceutical Sector Reform *(https://commission.europa.eu/st and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union/ eu-pharmaceutical-legislation_en)* EN | •••
  - Press release *(https://ec.europa.eu/commission/presscorner/detail/en/IP_23_1843)* EN | •••
  - Q&As
    - Pharmaceutical Legislation *(https://ec.europa.eu/commission/presscorner/detail/en/qanda_23_1844)*
    - Recommendation on AMR *(https://ec.europa.eu/commission/presscorner/detail/en/qanda_23_1845)* EN | ••
  - Factsheets

Could the EU make decisions on behalf the members states ?

The competences of the EU are divided into three categories:

- the EU has **exclusive competence** (Article 3 TFEU) (only the EU can act)
- **competences are shared** between the EU and the Member States (Article 4 TFEU) (The Member States can act only if the EU has chosen not to)
- the EU has **competence to support, coordinate or supplement** the actions of the Member States (article 6 TFEU) – in these areas, the EU may not adopt legally binding acts that require the Member States to harmonise their laws and regulations.

The Treaty on the Functioning of the EU

-Based on the Lisbon treaty (Signed in Dec. 2007, Effective in Dec, 2009)

Article . 3

歐盟專屬權責 (Union Exclusive Competence) :

1. The Union shall have exclusive competence in the following areas

除了另行規定外，歐盟有專屬權力就下列議題立法，交由會員國執行。

- (a)customs union; 關稅同盟
- (b)the establishing of the competition rules necessary for the functioning of the internal market;
  為使內部市場運作順暢之競爭法規定
- (c)monetary policy for the Member States whose currency is the euro; 歐元區之貨幣政策
- (d)the conservation of marine biological resources under the common fisheries policy;
  共同漁業政策中有關海洋生物資源保育
- (e)common commercial policy. 共同貿易政策

2. The Union shall also have exclusive competence for the conclusion of an international agreement when its conclusion is provided for in a legislative act of the Union or is necessary to enable the Union to exercise its internal competence, or in so far as its conclusion may affect common rules or alter their scope. 歐盟亦可代表會員國締結國際契約。

TFEU - Article . 4

歐盟及會員國共享權責 (Shared Competence) :

歐盟及會員國均可就下列議題立法，惟歐盟必須先與會員國協調並獲得授權。

1. The Union shall share competence with the Member States where the Treaties confer on it a competence which does not relate to the areas referred to in Articles 3 and 6.

2. Shared competence between the Union and the Member States applies in the following principal areas:

- (a)internal market; 內部市場
- (b)social policy, for the aspects defined in this Treaty; 里斯本條約所規定之社會政策
- (c)economic, social and territorial cohesion; 經濟。社會及區域凝聚政策
- (d)agriculture and fisheries, excluding the conservation of marine biological resources; 農業及漁業政策（除海洋生物資源保育外）
- (e)environment; 環境政策
- (f)consumer protection; 消費者保護

- (g)transport; 運輸政策
- (h)trans-European networks; 泛歐網絡
- (i)energy; 能源政策
- (j)area of freedom, security and justice; 自由、安全、司法政策
- (k)common safety concerns in public health matters, for the aspects defined in this Treaty. 「里斯本條約」規定有關公共安全事項

3. In the areas of research, technological development and space, the Union shall have competence to carry out activities, in particular to define and implement programmes; however, the exercise of that competence shall not result in Member States being prevented from exercising theirs.

4. In the areas of development cooperation and humanitarian aid, the Union shall have competence to carry out activities and conduct a common policy; however, the exercise of that competence shall not result in Member States being prevented from exercising theirs.

Article . 6

會員國主導權則 (Competence to support, coordinate or supplement actions of the Member States):

The Union shall have competence to carry out actions to support, coordinate or supplement the actions of the Member States. The areas of such action shall, at European level, be:

歐盟就以下議題僅能採取行動來支持、協調或補充

- (a)protection and improvement of human health; 衛生保健
- (b)industry; 工業政策
- (c)culture; 文化政策
- (d)tourism; 觀光政策
- (e)education, vocational training, youth and sport; 教育、青年、體育及職訓政策
- (f)civil protection; 保護平民（災難預防）
- (g)administrative cooperation. 行政合作

TFEU - TITLE XIV

PUBLIC HEALTH

Article 168

(ex Article 152 TEC)

- **A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.**
- **The European Parliament and the Council shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:**

(a) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives (人體器官、組織、血液); these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;

(b) measures in the veterinary and phytosanitary fields (動植物檢疫標準)which have as their direct objective the protection of public health;

(c) measures setting high standards of quality and safety for medicinal products and devices for medical use. (藥品與醫療器材之品質及安全標準)

EU action on health (1)

- **A. Pharmaceuticals and Substances of human origin**

1) Medicinal products
2) European Medicines Agency (EMA)
3) Blood, tissues, cells and organs

- **B. Diseases and health threats**

1) Crisis preparedness and response
2) Communicable diseases
3) European Centre for Disease Prevention and Control (ECDC)
4) Vaccination
5) Antimicrobial resistance
6) Non-communicable diseases (NCD)

- **C. Risk assessment**

1) Scientific committees

EU action on health (2)

- **D. Improving health systems**

1) Cross-border healthcare (for care disease)
2) European Reference Networks (European Health Data Space)
3) eHealth : Digital health and care (passed in 2022, will effective in 2025)
4) Health technology assessment (basic standeard for free movement)
5) Health workforce (State of Health Report)
6) Health systems performance assessment (Expert, Advisor)
7) Expert Panel on Effective ways of Investing in Health

- **E. Promoting good health**

1) Tobacco
2) Nutrition and physical activity
3) Alcohol
4) Social determinants

The excutive body of public health

in the European Commission

A. Directorate-General for Health and Food Safety (DG SANTE)

B. European Medicine Agency (EMA)

C. European Centre of Disease Prevention and Control (ECDC)

D. European Food Safety Authority (EFSA)

A . Directorate-General for Health and Food Safety (DG SANTE) 歐盟衛生暨食品安全總署

The European Commission's Directorate for Health and Food Safety (DG SANTE) supports the efforts of EU countries to protect and improve the health of their citizens and to ensure the accessibility, effectiveness and resilience of their health systems.

This is done through various means, including by

- **Proposing legislation**
- **Providing financial support**
- **Coordinating and facilitating the exchange of best practices between EU countries and health experts**
- **Health promotion activities**

EU action on health (2)

- **D. Improving health systems**

1) Cross-border healthcare (for care disease)
2) European Reference Networks (European Health Data Space)
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- **E. Promoting good health**

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B. European Medicines Agency (EMA) 歐洲藥品局

The mission of the European Medicines Agency (EMA) is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the European Union (EU).

What EMA do :

- **Evaluate applications for marketing authorization**
- **Monitor the safety of medicines across their life cycle**
- **Facilitate development and access to medicines**
- **Provide information to healthcare professionals and patients**

Evaluate applications for marketing authorisation

EMA's scientific committees provide independent recommendations on medicines for human and veterinary use, based on a comprehensive **scientific evaluation of data.**

The Agency's evaluations of marketing-authorisation applications submitted through the **centralised procedure** provide the basis for the authorisation of medicines in Europe.

Authorisation of medicines (藥品上市審核)

All medicines must be authorised before they can be marketed and made available to patients. In the European Union (EU), there are two main routes for authorising medicines: a centralised route and a national route.

1. Centralised authorisation procedure (集中審核程序)

Under the centralized authorisation procedure, pharmaceutical companies submit a single marketing-authorisation application to EMA.

This allows the marketing-authorisation holder to market the medicine and make it available to patients and healthcare professionals throughout the EU on the basis of a single marketing authorisation.

EMA's Committee for Medicinal products for Human Use (CHMP) or Committee for Medicinal products for Veterinary Use (CVMP) carry out a scientific assessment of the application and give a recommendation on whether the medicine should be marketed or not.

Once granted by the European Commission, the centralised marketing authorisation is valid in all EU Member States as well as in the European Economic Area (EEA) countries Iceland, Liechtenstein and Norway.

Scope of the centralised procedure

The centralised procedure is compulsory for :

- **Human medicines containing a new active substance to treat:**
  - -Human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS);
  - -Cancer;
  - -Diabetes;
  - -Neurodegenerative diseases;
  - -Auto-immune and other immune dysfunctions;
  - -Viral diseases.
- **medicines derived from biotechnology processes, such as genetic engineering;**
- **advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines;**
- **orphan medicines (medicines for rare diseases);**
- **veterinary medicines for use as growth or yield enhancers.**

It is optional for other medicines:

- **containing new active substances for indications other than those stated above;**
- **that are a significant therapeutic, scientific or technical innovation;**
- **whose authorisation would be in the interest of public or animal health at EU level.**

2. Scope of the National procedure

While the majority of new, innovative medicines are evaluated by EMA and authorised by the European Commission in order to be marketed in the EU, most generic medicines and medicines available without a prescription (OTC) are assessed and authorised at national level in the EU.

C. European Centre for Disease Prevention and Control (ECDC)
歐洲疾病預防暨控制中心

Within the field of its mission, the Centre shall:

- **search for, collect, collate, evaluate and disseminate relevant scientific and technical data;**
- **provide scientific opinions and technical assistance including training;**
- **provide timely information to the Commission, the Member States, Community agencies and international organisations active within the field of public health;**
- **coordinate the European networking of bodies operating in the fields within the Centre's mission, including networks that emerge from public health activities supported by the Commission and operating the dedicated surveillance networks;**
- **exchange information, expertise and best practices, and facilitate the development and implementation of joint actions.**

D. European Food Safety Authority (EFSA) 歐洲食品安全局

Mission

Safety in the food chain from farm to fork is at EFSA's core. EFSA contribute to protecting human life and health, taking account of animal health and welfare, plant health and the environment.

EFSA deliver independent and transparent scientific advice to policy makers, through cooperation with our partners, and in an open dialogue with society.

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.

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.

The legal basis of European Health Union

The 「 **Regulation on Serious cross-border threats to health** 」 now gives the EU :

- a robust preparedness planning and a more integrated surveillance system
- a better capacity for accurate risk assessment and targeted response
- solid mechanisms for to address future cross-border health threats

SUMMARY OF:

Regulation (EU) 2022/2371 on serious cross-border threats to health

(enter into force on 26, Dec, 2022)

• WHAT IS THE AIM OF THE REGULATION?

The regulation is designed to create a more robust mandate for coordination and cooperation for a more effective response to serious cross-border health threats, such as the COVID-19 pandemic. It aims to:

- **strengthen prevention, preparedness and response planning;**
- **reinforce epidemiological surveillance and monitoring;**
- **improve data reporting; and**
- **strengthen EU intervention. Such as** joint procurement of medical countermeasures and the possibility to adopt common measures at EU level.

Building blocks of the European Health Union

1. **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)

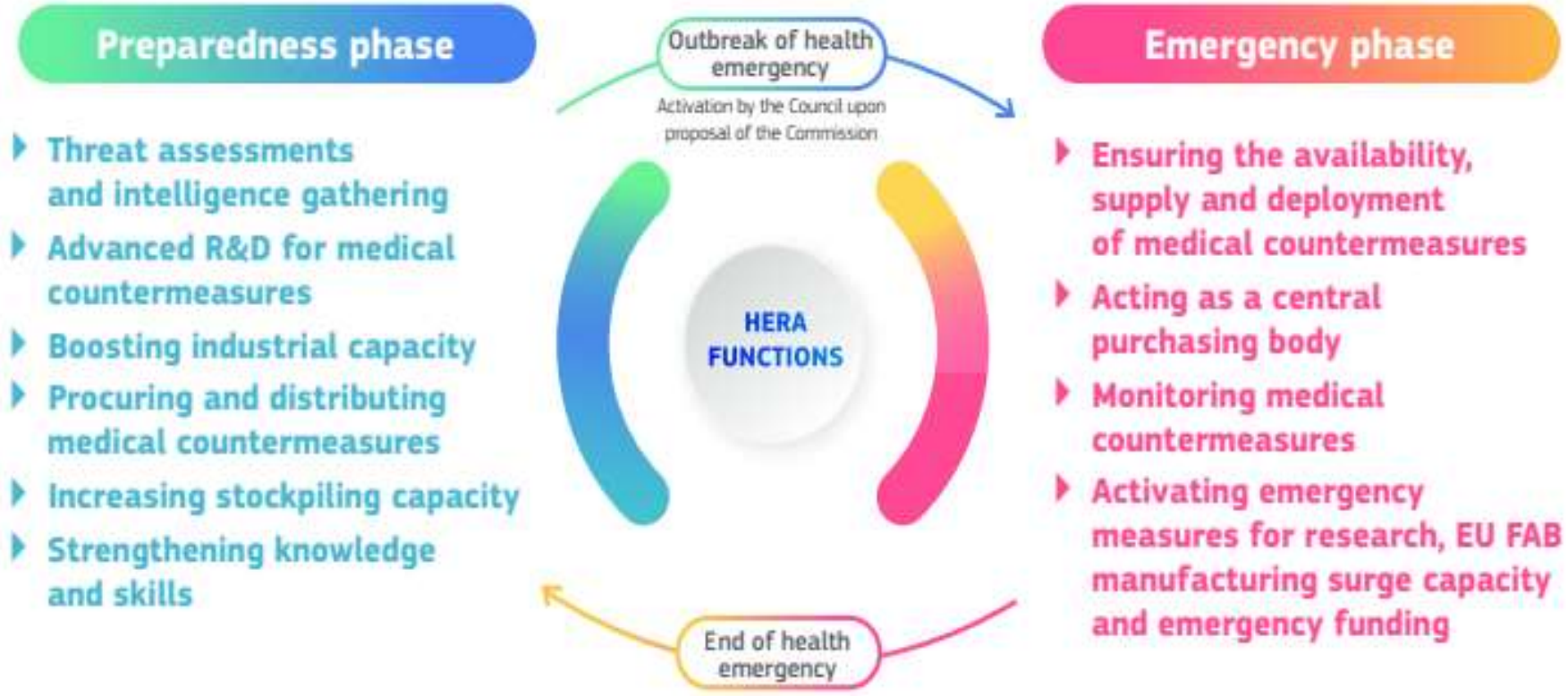
   D. The pharmaceutical strategy for Europe

   E. European Health Data Space

   F. Europe's Beating Cancer Plan

   G. The Global Health Strategy

A. HERA


Preparedness phase
Threat assessments and intelligence gathering
Advanced R&D for medical countermeasures
Boosting industrial capacity
Procuring and distributing medical countermeasures
Increasing stockpiling capacity
Strengthening knowledge and skills
Outbreak of health emergency
Activation by the Council upon proposal of the Commission
HERA FUNCTIONS
End of health emergency
Emergency phase
Ensuring the availability, supply and deployment of medical countermeasures
Acting as a central purchasing body
Monitoring medical countermeasures
Activating emergency measures for research, EU FAB manufacturing surge capacity and emergency funding

Joint procurement of medical countermeasures

A reinforced system of joint procurement of medical countermeasures, also open to partner countries such as members of the European Free Trade Association, is open to Andorra, Monaco, San Marino, Vatican City State and EU candidate countries.

B. Extended mandate of the European Medicines Agency (EMA)

1. Supporting the development and authorization of medicines

- - **Data Analysis and Real-world Interrogation Network (DARWIN EU)**

2. Improve the Availability of medicines and medical devices

- - Medicine Shortages and Safety Steering Group (MSSG)
- Industry Single Point of Contact Network (iSPOC)
- European shortages monitoring platform (ESMP)

3. Clinical Trial Regulation (Effective on 1/2/2023)

- All initial clinical trial applications in EU must be submitted via the clinical trial information system (CTIS)
- 3 years transition period from 2023-2025. In the next 2 years, by 31/1/ 2023 , all ongoing trials will have to be transitioned to CTIS.
- To strengthen EU as an attractive location for clinical research.
- Authorization of clinical trial remain the competence of the member states.

C. Stronger Mandate of ECDC

- **To provide "non-binding"science-based recommendations for the management and control of "Communicable diseases".**
- **To provide science-based recommendations to strengthen the health systems; by filling in any identified gaps.**
- **To develop "secure and interoperable"digital platform reporting** on relevant health system data **and applications in support of epidemiological surveillance** which **linked** to other available information sources and data.
- **To provide future-oriented epidemiological modelling and scenario development to EU members' decision-makers.**
- **To coordinate two new networks : Network of EU reference laboratories for public health and Network of supporting the use of substances of human origin.**

D. The pharmaceutical strategy

- **To give** all European equal access to affordable, safe and effective medicines and treatments.
- **To dive** innovation in unmet medical needs.
- **To boost** EU resilience by promoting global and diversified supply chains.

E. European Health Data Space

- **A trustworthy and efficient** framework for the use of health data

- **To allow** individuals to have digital access and control of their personal health data.

- **To support** free movement with health data follows them.

- **For** research, innovation, policy-making, patient safety, statistics and regulatory purposes.

F. Europe's beating cancer plan

- **To improve** cancer detection and treatment.
- **To ensure** better integrated and comprehensive cancer care.
- **To address** unequal access to qualify cancer care and medicines.

G. The European Global Health Strategy

- **To support** strong multilateral system around the World Health organization (WHO).

- **To actively participates** in the negotiation of the pandemic agreement (CA+).

- **To engage** in revision of International Health Regulation(IHR).

- **To engage** in the pandemic fund host by the World Bank.

Supervising Body at EU level --Health Security Committee

The regulation establishes a strengthened Health Security Committee to combat serious cross-border threats to health, composed of representatives of Member States .

The Health Security Committee works on:

- **coordinating** and liaising with the European Commission on its prevention, preparedness and response planning;
- **coordinating** the risk and crisis communication and responses of Member States;
- **adopting** opinions and guidance, including on specific response measures based on expert opinions from EU technical agencies; and
- **setting** annual priorities and objectives in a working programme.

Financing (經費來源)

EU4Health programme 2021-2027 – a vision for a healthier European Union

The EU4Health programme was adopted as a response to the COVID-19 pandemic and to reinforce crisis preparedness in the EU. The pandemic highlighted the fragility of national health systems. The EU4Health programme will bring a contribution to the long-term health challenges by building stronger, more resilient and more accessible health systems.

Health is an investment and, with a €5.3 billion budget during the 2021-27 period, **the EU4Health programme is an unparalleled EU financial support in the health area.** EU4Health is a clear message that public health is a priority for the EU and it **is one of the main instruments to pave the way to a European Health Union.**

The European Health Technology Assessment (HTA)

- **Enter into force on 12, Jan, 2022, with 3 years preparation period (will apply on 12, Jan, 2025)**

- **"EUnetHTA 21" was set up as a joint consortium of national HTA agencies from 13 EU states.**

- **Only access the clinical domains, no economic assessment on any conclusion on pricing and reimbursement.**

Timeline of EU HTA

- **12 Jan, 2025** : New oncology medicines and advanced therapy medicinal products will be assessed at EU level.

- **13 Jan, 2028** : orphan medicinal products

- **13 Jan, 2030** : All new medicines

In the Future……

* What will be the cause of next health crisis ?

  Zoonotic disease(人畜共通病)? Climate change?

  Anti-Microbial Resistance?

* Could Non-Pharmaceutical Intervention still dominate?

  Or can we rely on vaccine or medicine ?

* How about Silent Pandemic ?

Homework:

1. Who is Robert Schuman?

2. Who is the President of the European Council ?

3. Who is the President of the European Commission ?

4. Where is European Parliament Located?

5. In which year, which country left EU ?

Reference

1. Everything you wanted to know about European Union health policies but were afraid to ask.

   (3rd edition, European Observatory on Health Systems and Policies)
Https://apps.who.int/iris/bitstream/handle/10665/354182/9789289059022-eng.pdf?sequence=1&isAllowed=y

2. European Health Union web-site:

https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/promoting-our-european-way-life/european-health-union_en

3. European Medicine Agency web-site: https://www.ema.europa.eu/en

4. **European Centre of Disease Prevention and Control web-site:**

   https://www.ecdc.europa.eu/en

5. **European Food Safety Authority web-site: https://www.efsa.europa.eu/en**

6. 駐歐盟兼駐比利時代表處衛生組

   https://www.taiwanembassy.org/be/post/513.html