



Ministry of Health, Welfare and Sport

# Unmet Medical Need and drug development in policy making

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# Outline

1. Policy work at the Ministry towards Unmet Medical Need
2. Proposals on Unmet Medical Need in the pharmaceutical legislation

**Is society clear  
about what  
medicines it  
needs and what  
it is willing to  
pay for them?**

## **Starting point**

- Medicine development has become much more complex
- Many different parties are involved
- Financial transactions take place along the development path

**Question:** can we create a better understanding of the financial ecosystem that drives the development of novel medicines?

# Dutch **Ministry of Health** commissioned three research reports



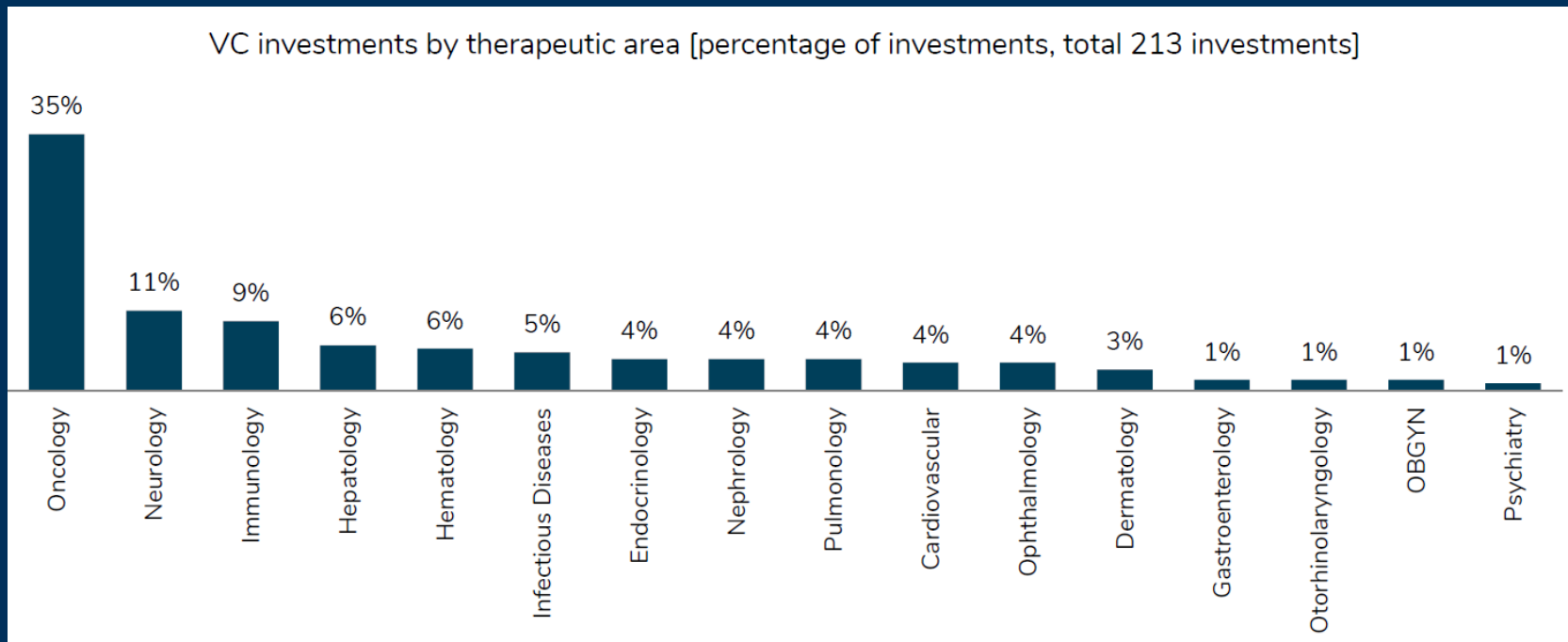
1. Map the financial ecosystem of pharmaceutical R&D – who are the players and what drives decision making?
2. What is the output of the current R&D ecosystem? Which medicines have been developed in the last 25 years?
3. Can we determine where the need for new medicines is the greatest?



# First report **key conclusions**

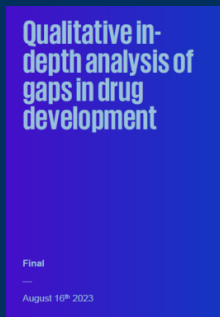
- Pharmaceutical R&D is a multistakeholder and increasingly complex \$300bn global market
- Public funding is important for early discovery, but **private investment drives drug development** in the later stages
- A medicine's **expected financial return** ultimately determines whether it is developed up to launch.
- Global governments and (private) insurance companies' **expected willingness to pay** for new drugs considerably influences the development of novel drugs and the distribution across therapeutic areas.

# What **investment behaviour** do we see?



# Determine **Unmet Medical Need**

- To prioritize medicine development for certain areas is a public and political question that requires societal debate
- The NEED project can be a very helpful tool
- NL commissioned a report that selected 6 indications with an unmet medical need and scientific potential for medicine development



## Does society know what medicines it needs most?



# UMN in the new pharmaceutical legislation



On April 26, 2023, the European Commission adopted a proposal for a new Directive and a new Regulation, which revise and replace the existing general pharmaceutical legislation.

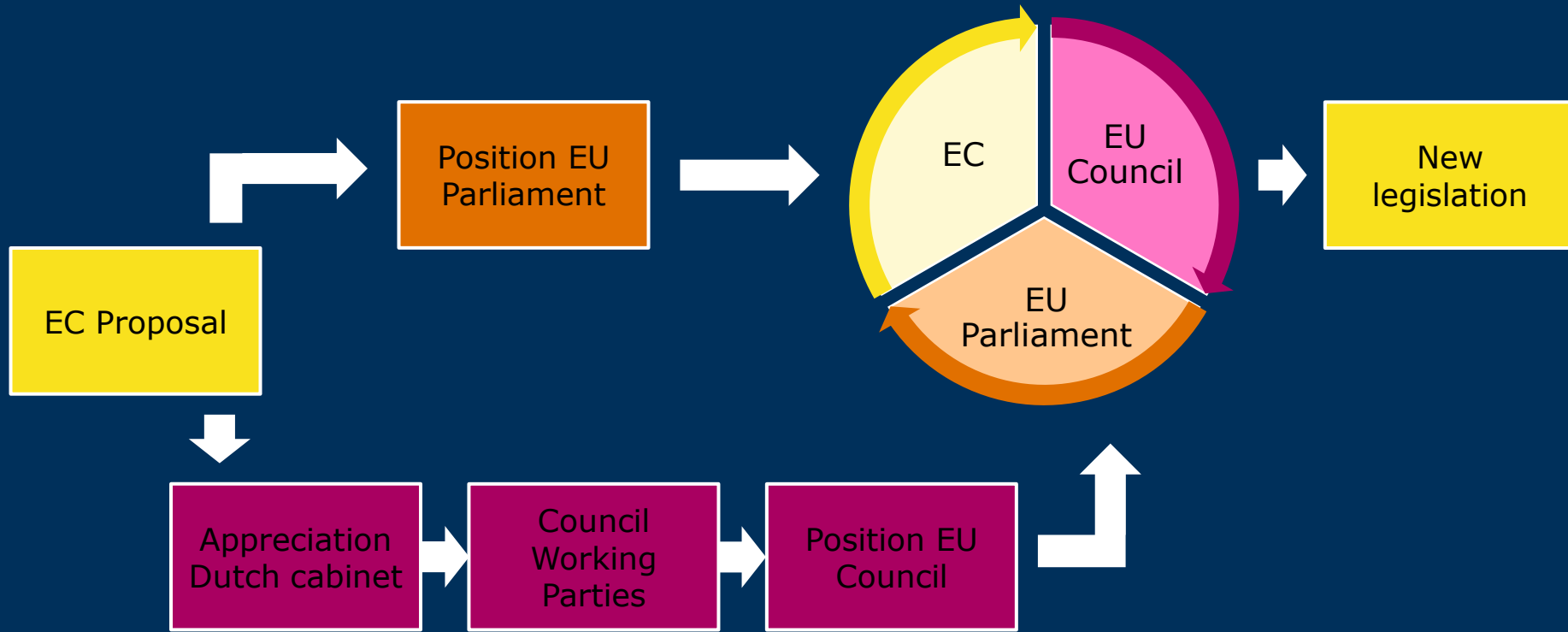
The proposal defines specific criteria for Unmet Medical Need

It offers a set of incentives to stimulate medicine development for diseases that lack appropriate treatment

Lower baseline of regulatory protection with higher protection when certain conditions are met (modulation)



# Proces of **EU** legislation



# Key elements on **UMN** in EC Proposal

Companies receive +6 months of regulatory data protection if they develop a medicine that meets the UMN criteria

All orphan medicines are considered to address an UMN

Orphan medicines that meet the criteria for highUMN will receive +12 months of market exclusivity

Developers of medicines for highUMN or promising medicines for UMN will receive enhanced scientific support and accelerated assessment by EMA (PRIME)

**EC introduces a legal definition of UMN and a new concept of high UMN for orphan diseases**

# Dutch cabinet position



- Formal position is published in BNC-Fiche and publically available
- NL supports the proposal to steer medicine development more towards UMN
- NL support the modulation of incentives for medicine development, where the baseline of regulatory protection is lowered to 6 years, and an additional period is awarded to products that meet UMN criteria

But:

- Criteria must be clear
- Doubts that 6 months of regulatory protection is sufficient
- Concerns on increased administrative burden on both companies and authorities
- Overall package must be in balance to maintain an attractive market for pharmaceutical companies to invest in medicine development



European Parliament

## Position **European Parliament**

Companies that develop a medicine that addresses an UMN are eligible for +12 months of regulatory data protection

Orphan drugs would benefit from up to 11 years of market exclusivity if they address a “high Unmet Medical Need”

**Can we move from  
a supply driven  
pharmaceutical  
ecosystem to a  
more demand  
driven system?**

**Our policy goal**



Ministry of Health, Welfare and Sport

# Thank you for your time

*Working together for health, wellbeing and resilience*