Impact of Brexit on Regulation and availability of Medicines

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The MHRA today

Medicines and Healthcare Products Regulatory Agency

CPRD

Pharmaco-epidemiology
Clinical trials

NIBSC

Biologicals, vaccines and standards

MHRA

Licensing & post-licensing

- Trading agency of the Department of Health
- Employs 1270 staff
- Annual turnover £170 Million

The Commission for Human Medicines (CHM)

- Provides advice on safety and efficacy of medicines
  - Licensing Authority (MHRA)
  - Ministers
- Committee of 19 members with range of expertise
- Further expertise from Expert Advisory Groups
  - Chemistry, Pharmacy and Standards EAG
  - Clinical Trials, Biologicals and Vaccines EAG
  - Pharmacovigilance EAG
  - 8 other EAGs

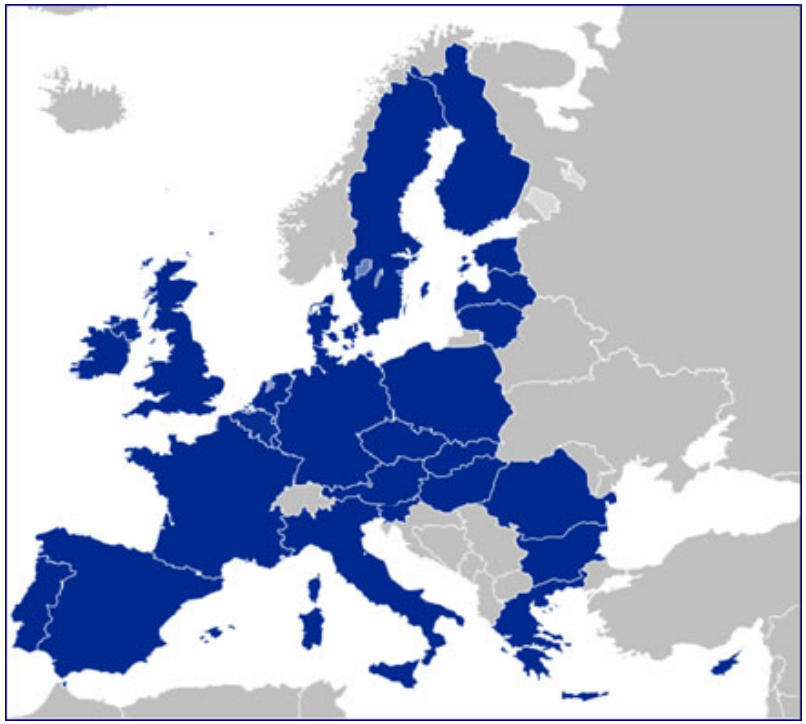
Where is the MHRA?

MHRA – 10th floor

10 South Colonnade
Canary Wharf

The European Regulatory Network

- European Medicines Agency (EMA)
  - Legislation at EU level
- 28 member states
- 3 EEA-EFTA states
  - Norway
  - Iceland
  - Liechtenstein
    - No voting rights
    - No influence on policy



European Pharmaceutical Law

- Allows a single market in pharmaceuticals
- All citizens have an equal chance to benefit

Scope of the European Medicines Agency

- Evaluation and licensing of new drugs
  - Committee for Medicinal Products for Human Use (CHMP)
- Facilitates broadening drug licenses across Europe
  - Co-ordination group (CMDh)
    - Mutual recognition
    - Decentralised procedures
- Post-licensing
  - Pharmacovigilance Risk Assessment Committee (PRAC)

European Licensing Procedures

- Centralised procedure (CP)
  - Single application
  - Unified evaluation
  - Single authorisation in all EU member states
  - Authorisation granted by European Commission
- Mutual Recognition
- Decentralised Procedure

European Licensing Procedures

Centralised procedure

Mandatory

- Biotech products
- Cancer
- Neurodegenerative diseases
- HIV
- Diabetes
- Auto-immune disease
- Viral Disease

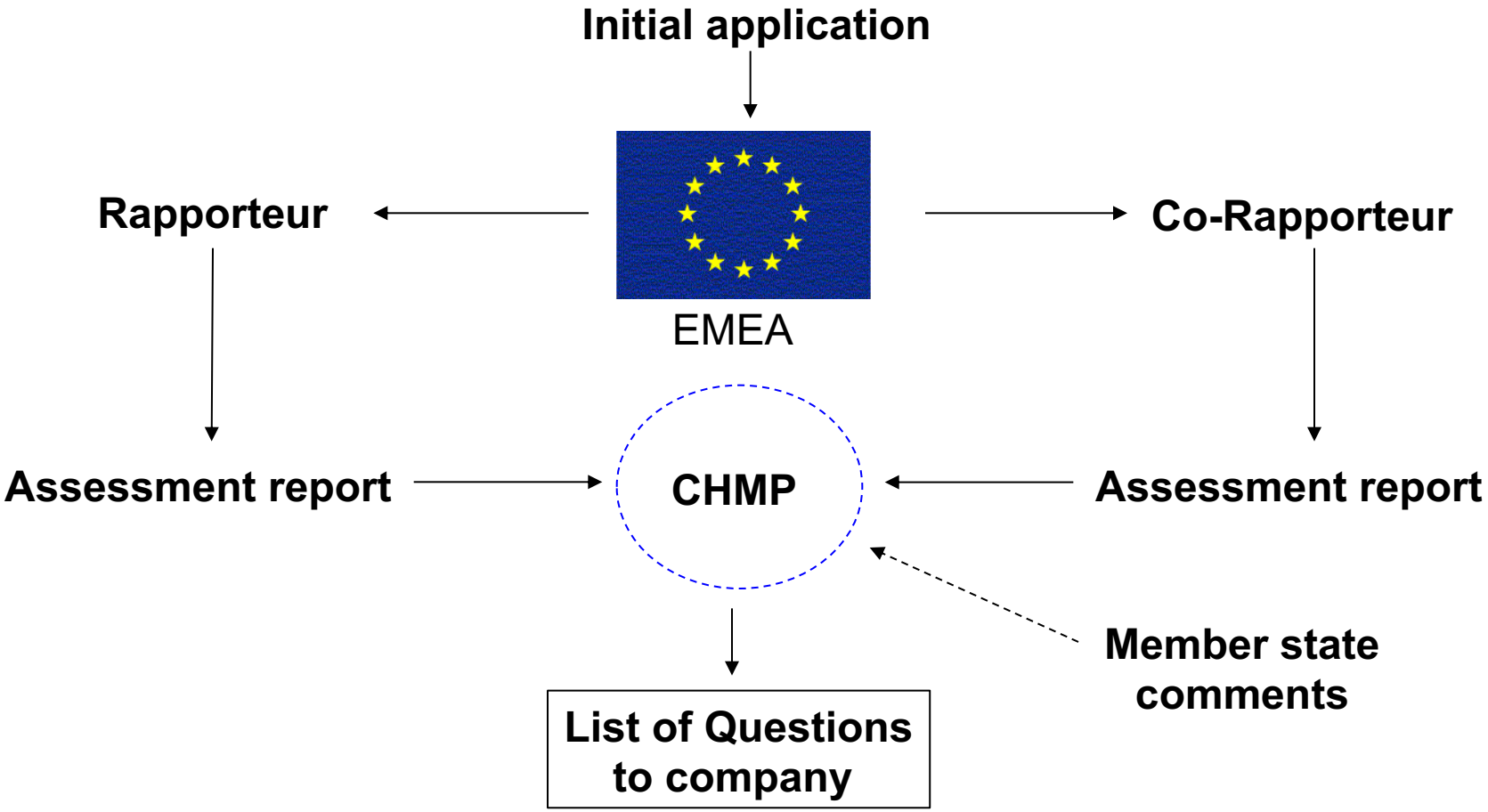
Voluntary

- All new actives
- Practically anything else of ‘proven’ community interest
- Generics of centrally authorised ref. products

European Licensing Procedures

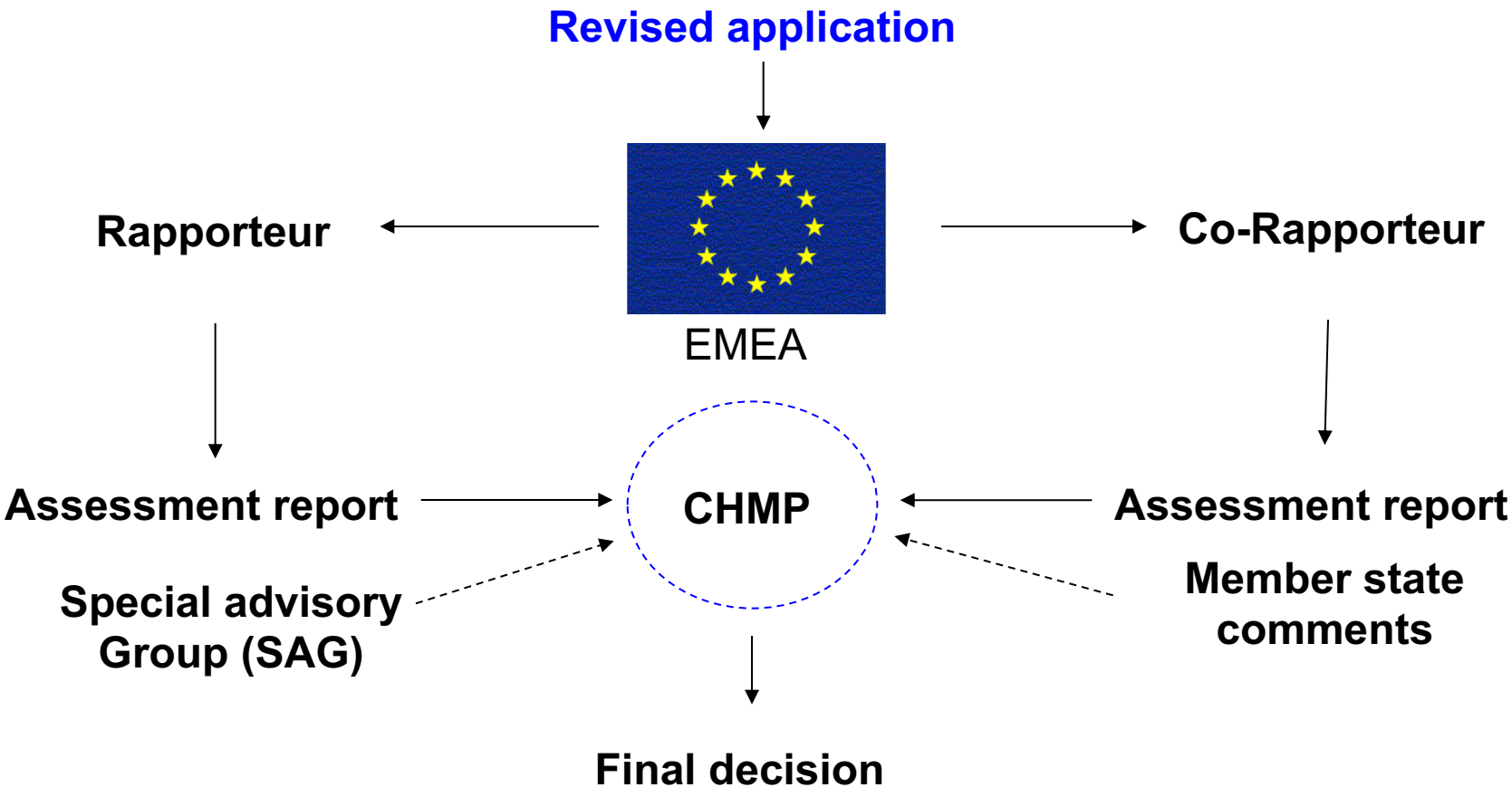
- Mutual recognition
  - For products that also have a licence in EU member state
    - Both new drugs and generics
- Decentralised Procedure
  - Mostly generic drugs
    - Application submitted to one reference member state (RMS)
    - Consults with concerned member state(s) (CMS),
    - Licence granted (or not) in RMS and CMS
- National
  - Mostly generic drugs, single member state

Centralised procedure for marketing authorisation



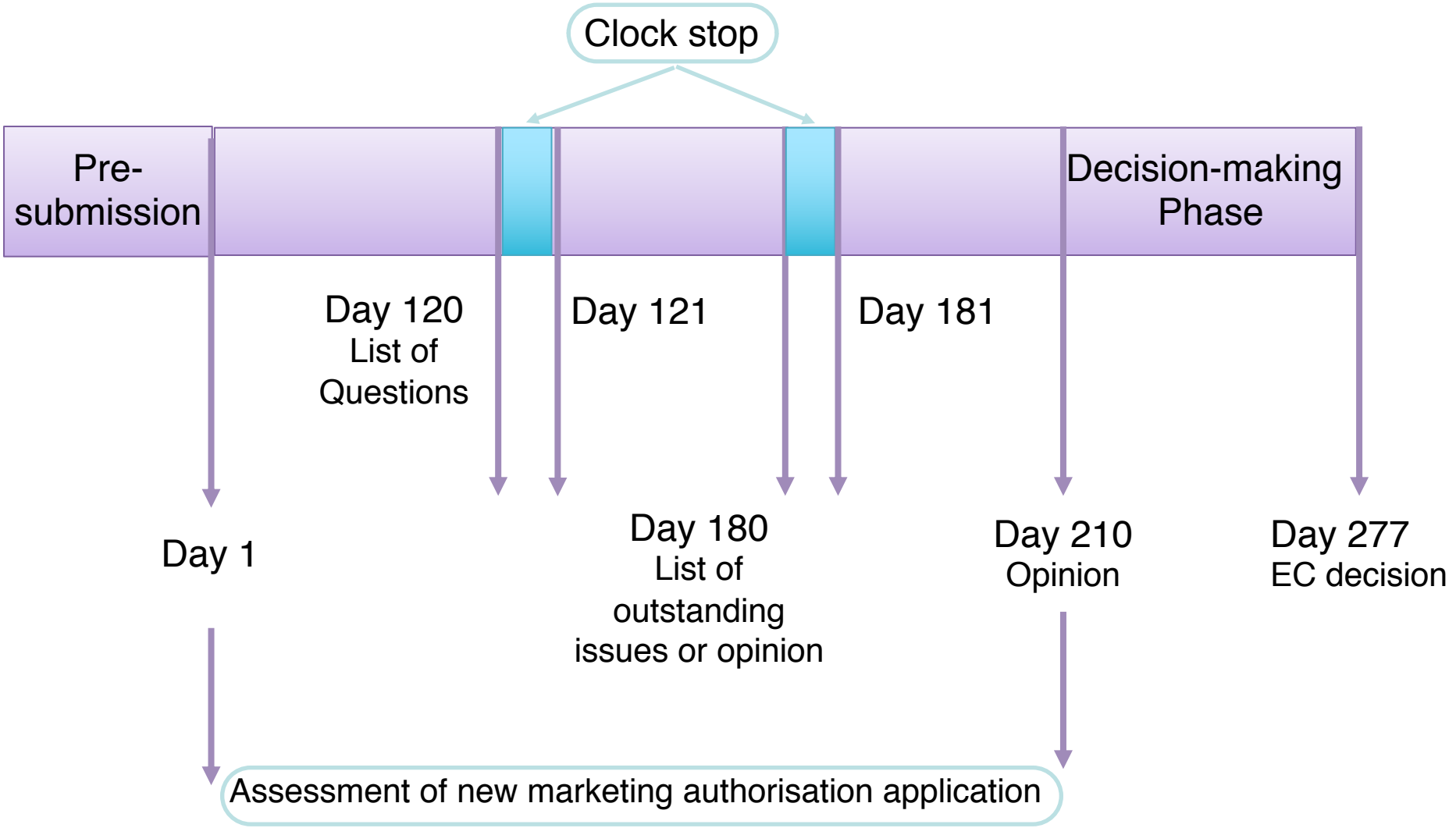
CHMP = Committee for Medicinal Products for Human Use

Centralised procedure for marketing authorisation

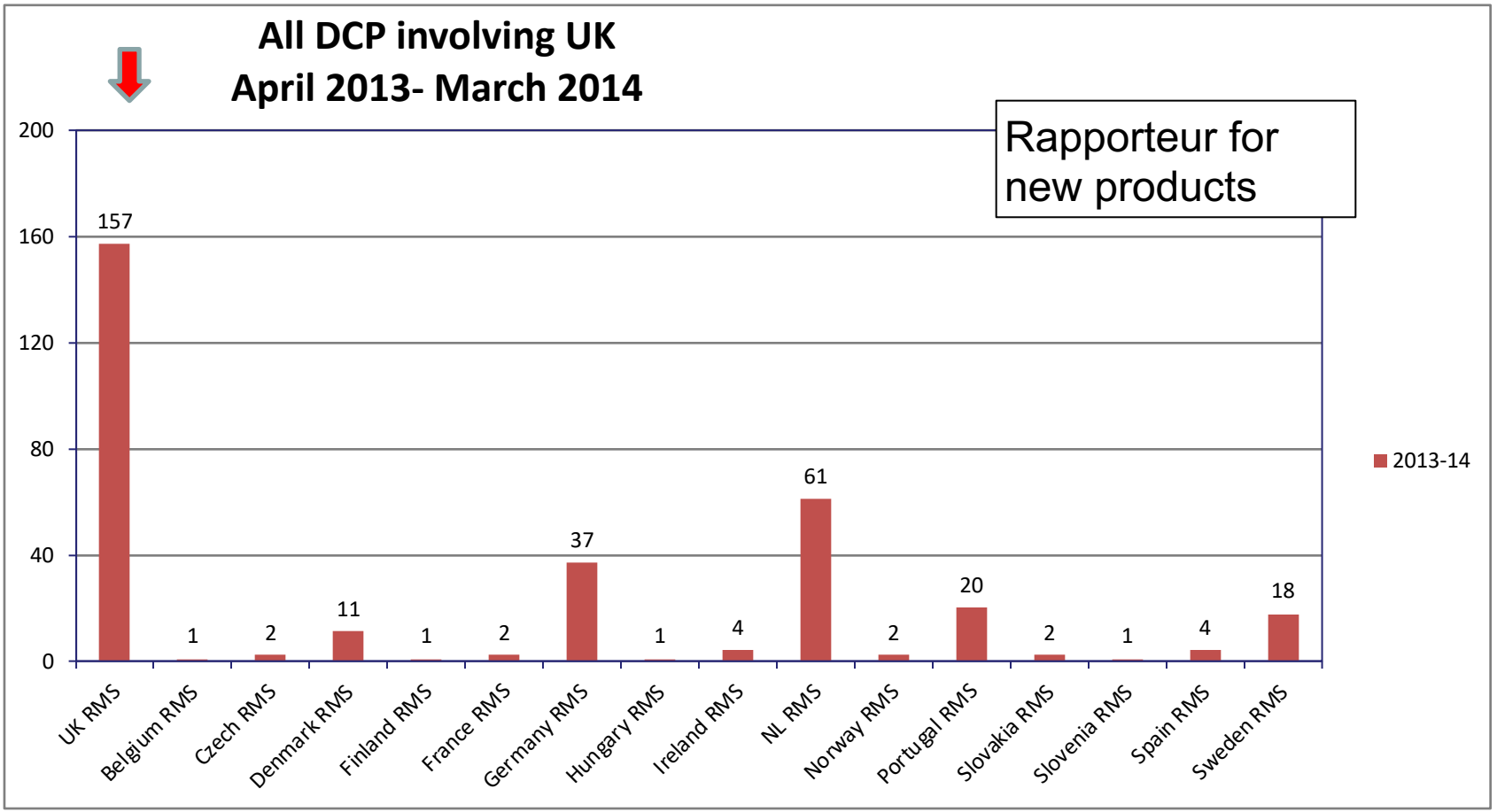


CHMP = Committee for Medicinal Products for Human Use

Timescale for Centralised Procedure

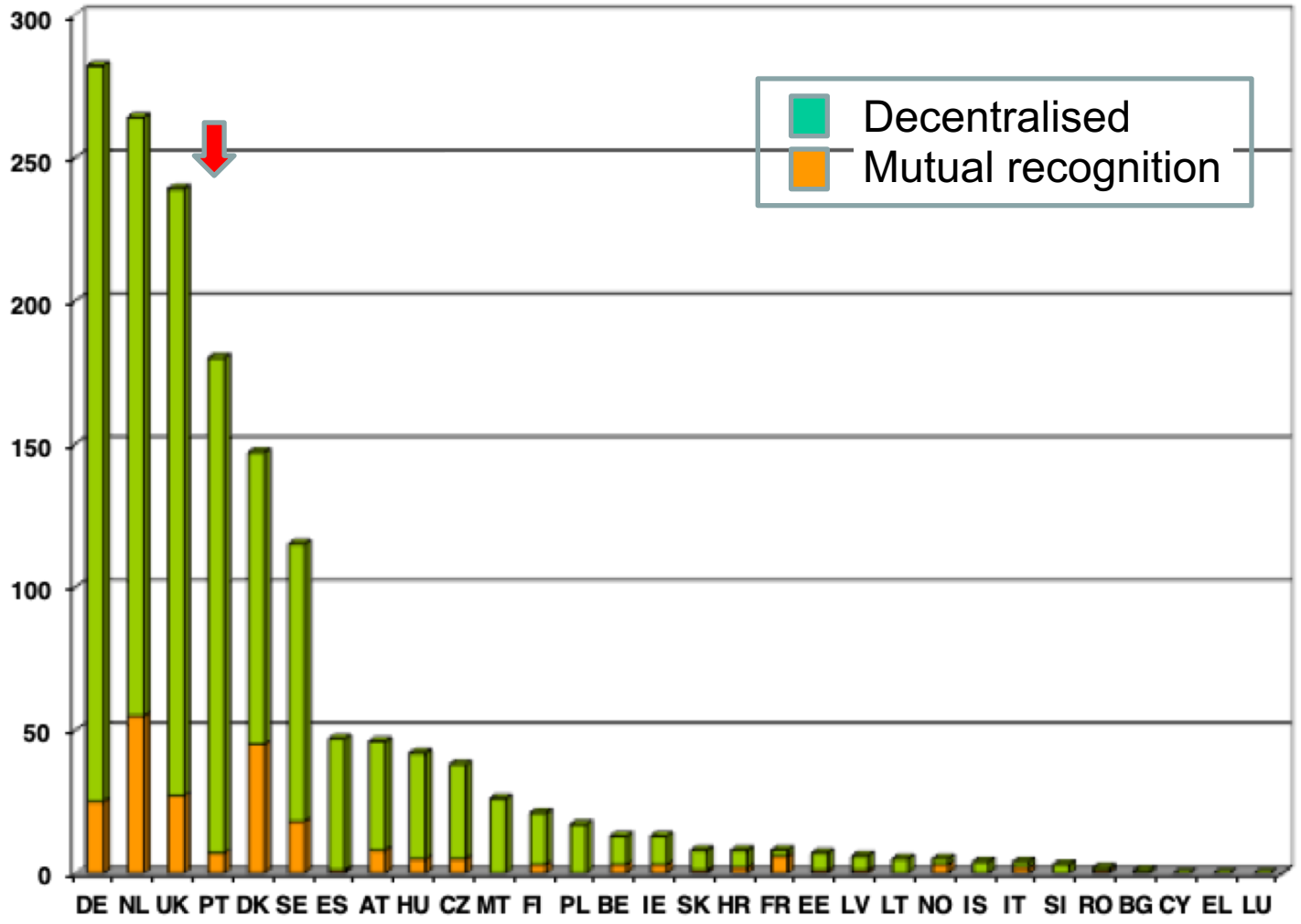


UK played a leading role in the Centralised Procedure



Data from 2013-2014

UK played a leading role in DCP and MR procedures

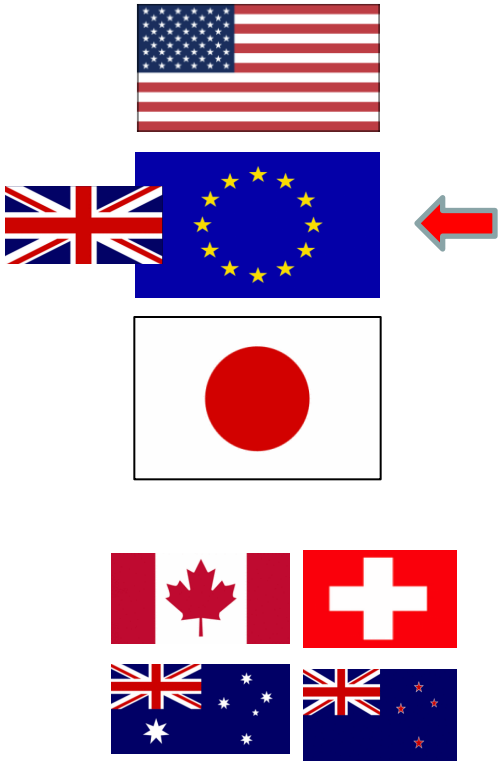


Medicines regulation with current scenarios

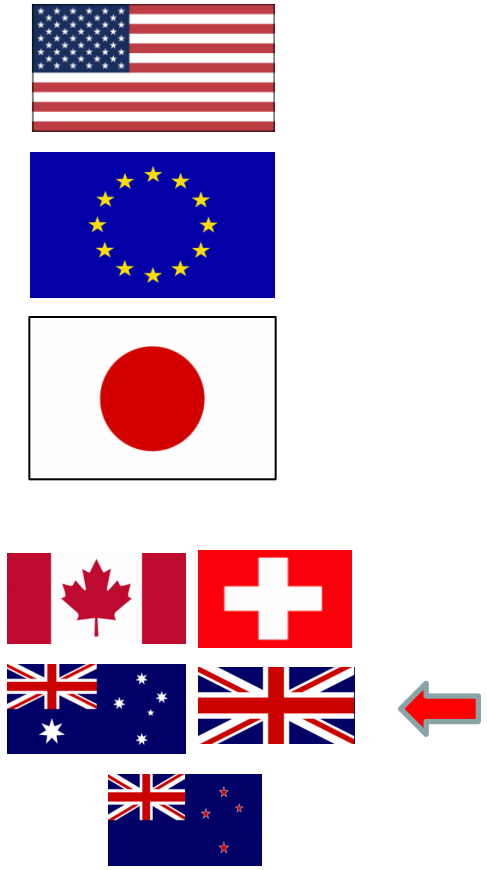
- Mrs May's current deal to 2020
  - Accept EMA decisions: passive role; no say in process
- No deal Brexit
  - Move back to licensing medicines on a National basis
  - Massive increase in workload for MHRA and CHM
- Norwegian model
  - Accept EMA decisions, take part in discussions, act as rapporteur but no influence on policy or legislation

Brexit has the potential to delay UK access to medicines

Now



No deal Brexit

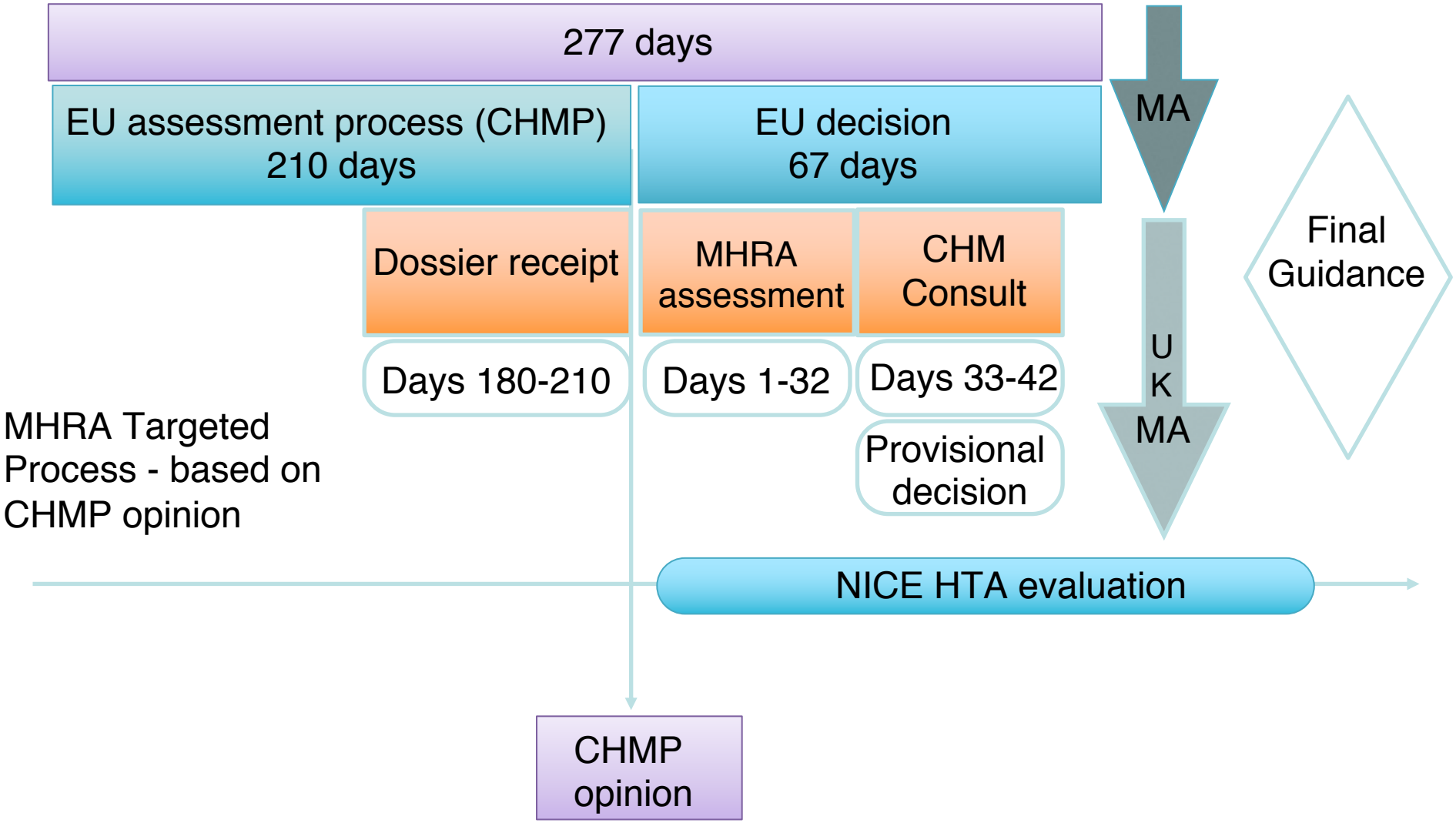


MHRA Targeted Assessment Procedure (TA)

- Eligibility
  - For New Active Substances and Biosimilars
  - CHMP Positive Opinion
- Timelines
  - MHRA decision within 67 days of CHMP opinion
    - Same timeframe as for EU decision to grant EU MA
- Assessment Principles
  - MHRA assessment based on
    - CHMP assessment reports
    - Interactions/responses from company and CHMP

TA timelines and Process

- Submission of a valid application
  - Same dossiers (as EU)
  - All available CHMP assessment reports and responses
  - MHRA will publish submission dates to help planning
    - CHM timelines/dates scheduled to fit process
- Process
  - MHRA completes assessment with CHM/EAG advice
  - Provisional decision by day 42
  - Notification of the recommendation on day 42
  - Finalisation with company to grant UK MA by day 67


277 days
EU assessment process (CHMP)
210 days
EU decision
67 days
MA
Final Guidance
Dossier receipt
MHRA assessment
CHM Consult
Days 180-210
Days 1-32
Days 33-42
Provisional decision
UK MA
MHRA Targeted Process - based on CHMP opinion
NICE HTA evaluation
CHMP opinion

MHRA Accelerated Assessment Procedure (AA)

- Eligibility
  - For all new active substances
- Timelines
  - MHRA decision within 150 days following submission
- Assessment Principles
  - 2 phases including Clock-off period
  - Complete, independent evaluation of the dossier
  - Consultation with Expert Advisory Groups

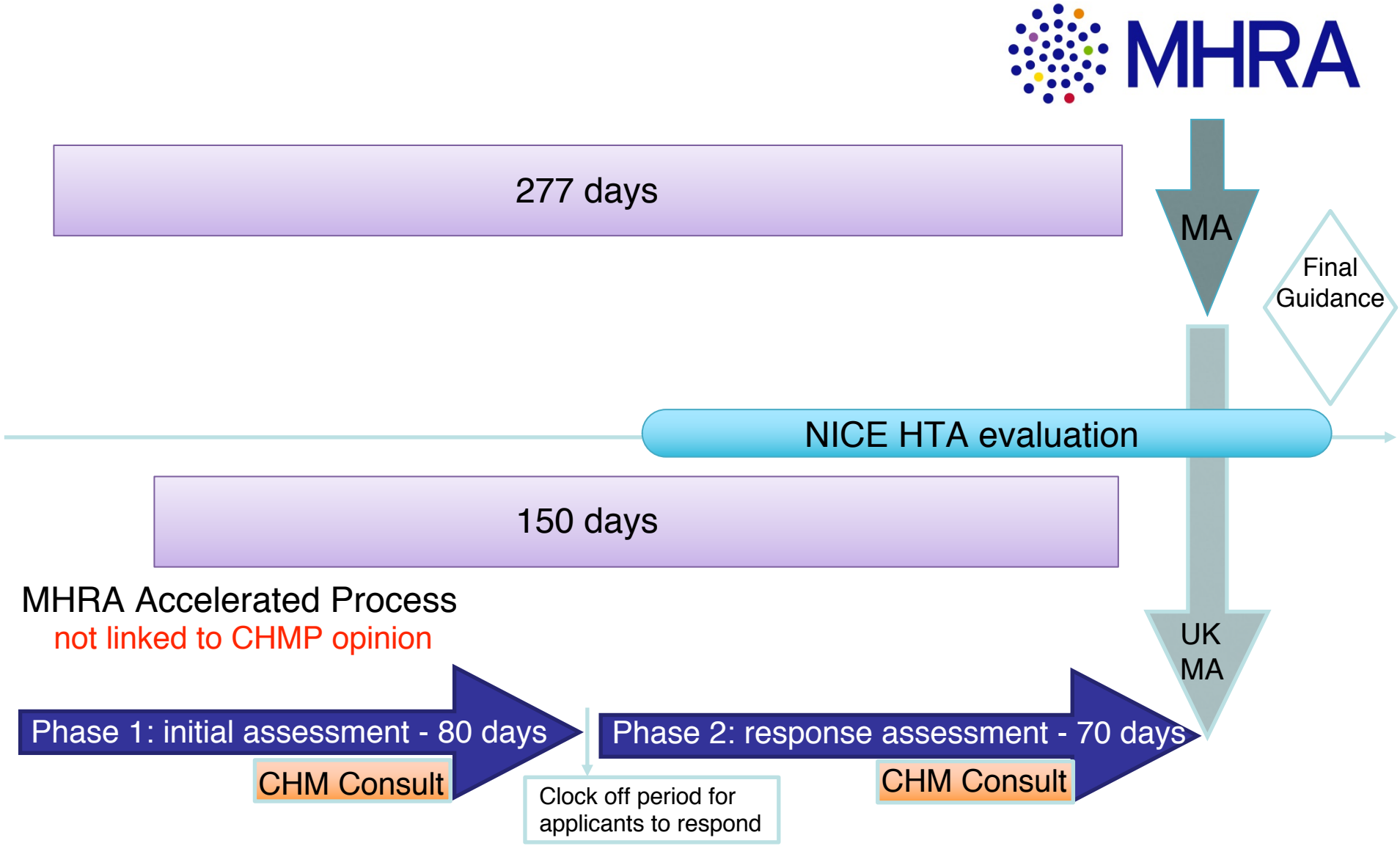
Accelerated Assessment

- Submission of a valid application
  - All Common Technical Document modules
    - Includes the Risk Management Plan and PIP*
  - Pre-submission meeting and early contact with Co-ordinator 90 days prior
  - PIP compliance check - allow sufficient time
  - MHRA will publish submission dates to help planning

*Paediatric Implementation Plan

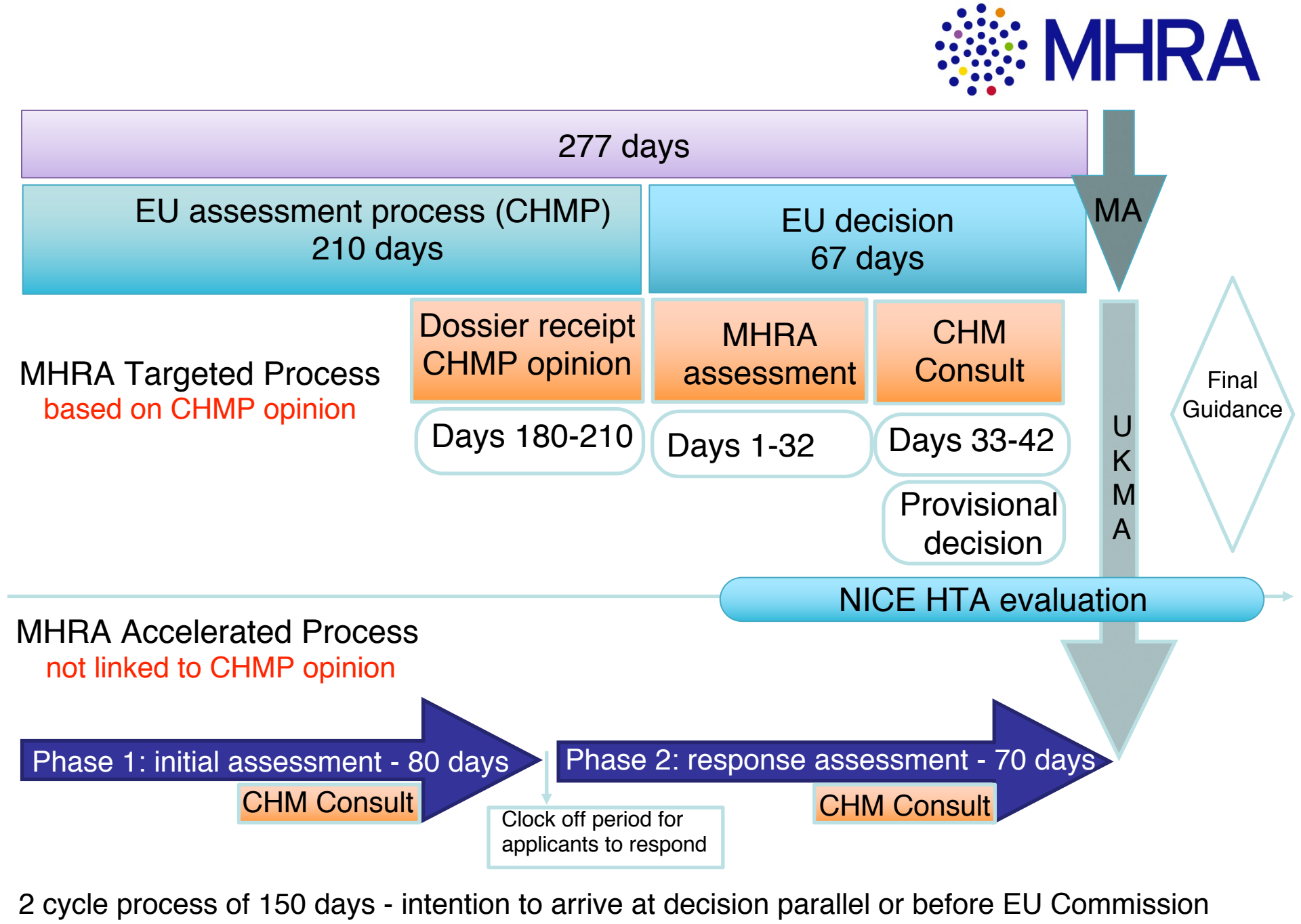
Accelerated Assessment

- Process
  - First cycle
    - MHRA completes assessment by day 80
    - Includes consultation with CHM and EAG
  - Submissions aligned with CHM dates/timelines
  - Clock-off period between phase 1 and phase 2
  - Second cycle
    - Response assessment and consult with CHM/EAGs
  - Decision available by day 150



Independent UK assessment

2 cycle process of 150 days - intention to arrive at decision parallel with or before EU Commission



2 cycle process of 150 days - intention to arrive at decision parallel or before EU Commission

Other potential impacts of Brexit

- Border checks would slow access to medicines
  - 70% of drugs used in UK are produced in the EU
  - DoH advised stockpile 3 months supply of drugs
- Medicinal products for human use in Europe
  - Certified by a qualified person based in EU
  - No legal equivalent in UK

Summary of potential impacts

- MHRA
  - Loss of influence on shaping medicines regulation
  - Loss of income during transition period and then ?
- Pharma
  - To obtain EU and UK licence
    - Duplication of facilities
    - Duplication of effort
- NHS and patients
  - Delayed access to new medicines
  - Barriers to movement of medicines