EAMS: The NHS England perspective

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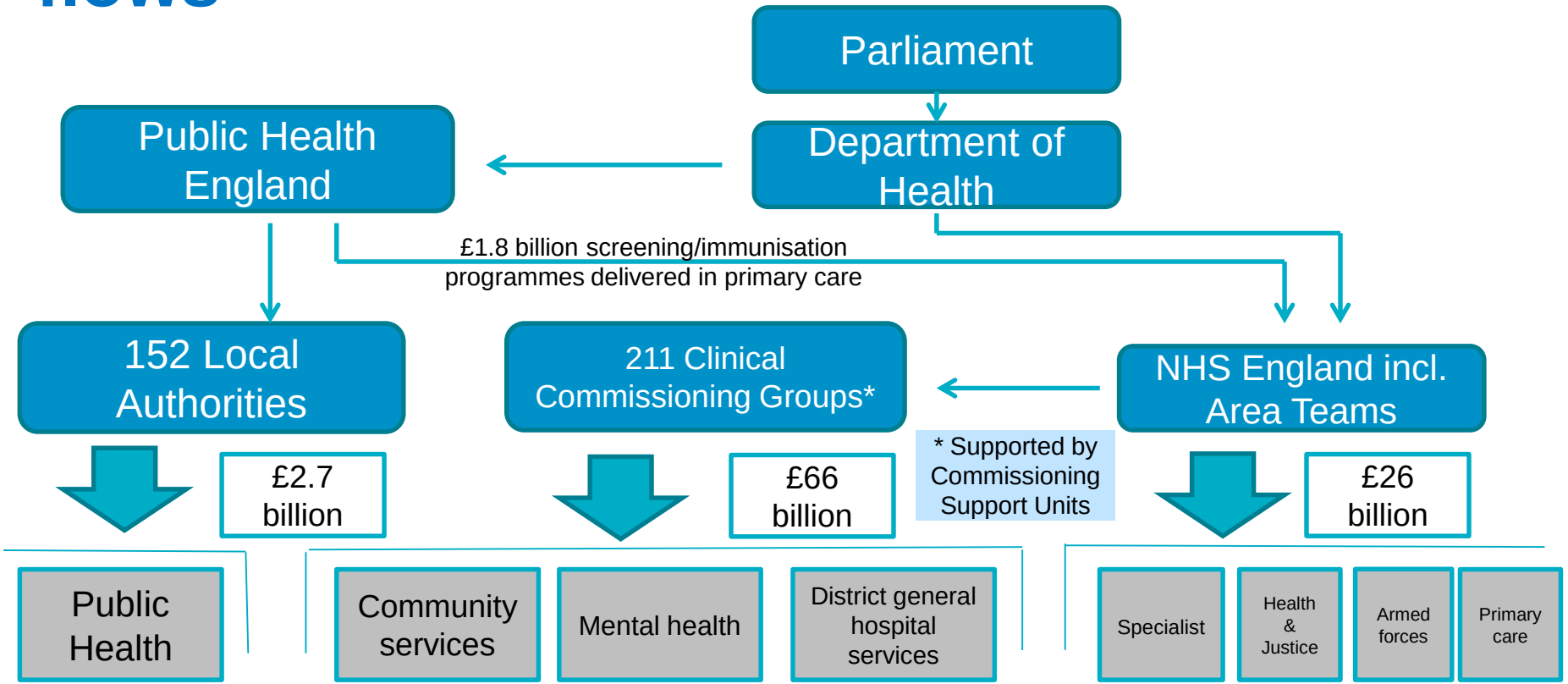
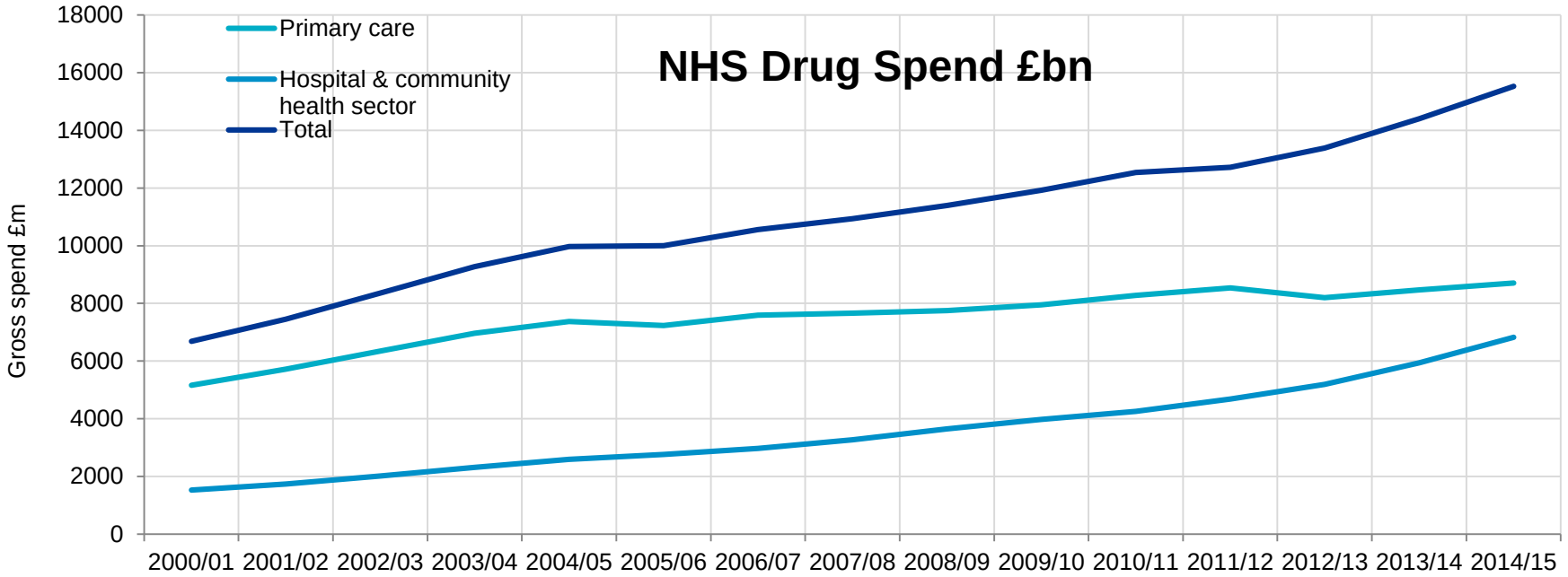
Background to funding and budgets

Commissioning - how the money flows



Medicines Utilisation in Practice



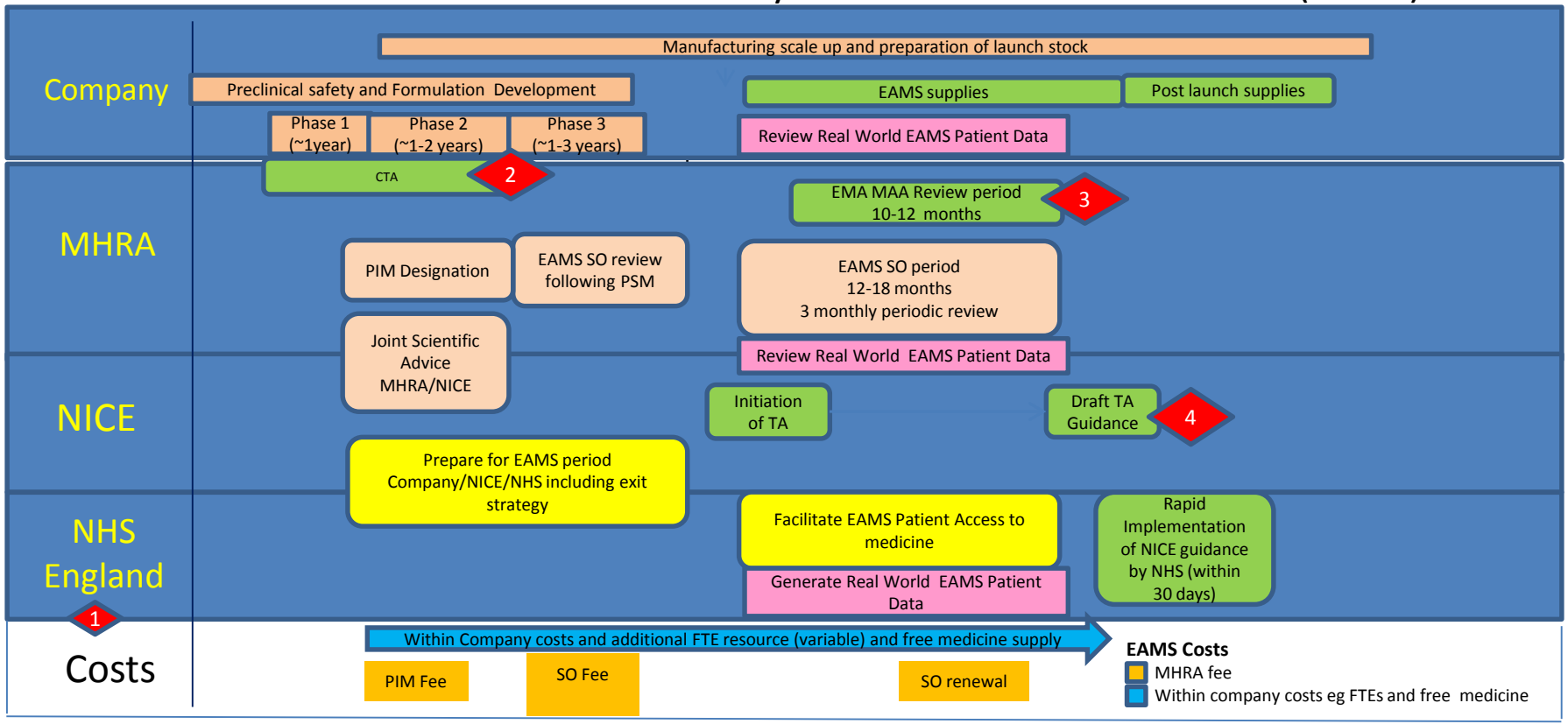
Data source: HSCIC: Hospital Prescribing: England, 2015-16

The story so far…


NHS
England
….much
promise….

But!

Schematic Overview of the Early Access to Medicines Scheme (EAMS)



Key Events and Interactions

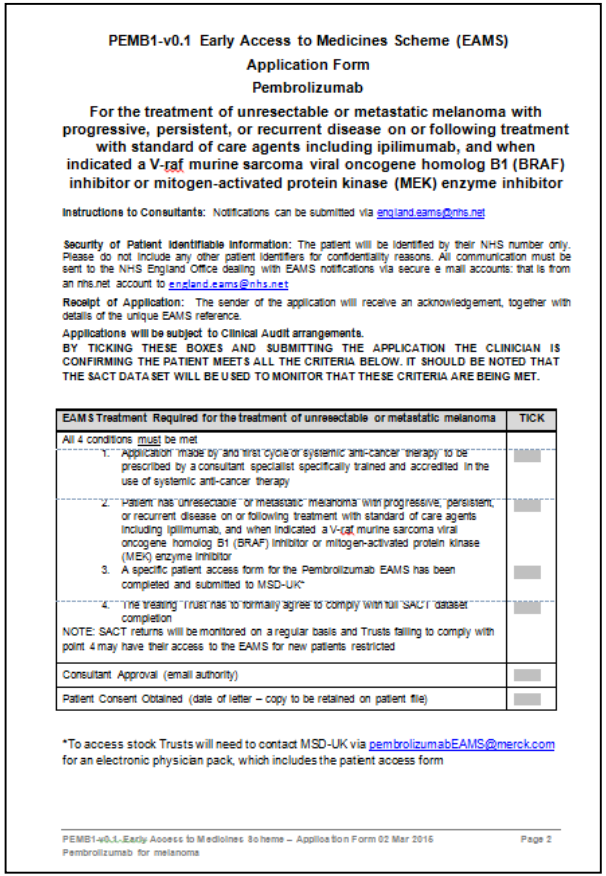
1= DAs also need input to EAMS forecasting and Planning but have a different process to NHS England; 2 = Company submits MAA to EMA
3 = EC grants MA; 4 = NICE HTA recommendation
SO = Scientific Opinion, PIM = Promising Innovative Medicine, PSM – Presubmission meeting, DA = devolved administrations, MAA = Marketing authorisation application, EMA = European Medicines Agency, FTE = Full Time Equivalent, MHRA = Medicines & Healthcare products Regulatory Agency, NICE= National Institute for Health and Care Excellence

Timelines (1)

- PIM announced
- 45 day warning of SO
- SO published
- MA received


NHS
England
Early Access to Medicines
Impact Assessment Report:
Pembrolizumab for unresectable or
metastatic melanoma
February 2015

- Indication
- Place in therapy
- Key trials
- Financial impact
  - Cost of standard care
  - Cost to implement
  - Cost of data collection



PEMB1-v0.1 Early Access to Medicines Scheme (EAMS)

Application Form

Pembrolizumab

For the treatment of unresectable or metastatic melanoma with progressive, persistent, or recurrent disease on or following treatment with standard of care agents including ipilimumab, and when indicated a V-raf murine sarcoma viral oncogene homolog B1 (BRAF) inhibitor or mitogen-activated protein kinase (MEK) enzyme inhibitor

Instructions to Consultants: Notifications can be submitted via england.eams@nhs.net

Security of Patient Identifiable Information: The patient will be identified by their NHS number only. Please do not include any other patient identifiers for confidentiality reasons. All communication must be sent to the NHS England Office dealing with EAMS notifications via secure e mail accounts: that is from an nhs.net account to england.eams@nhs.net

Receipt of Application: The sender of the application will receive an acknowledgement, together with details of the unique EAMS reference.

Applications will be subject to Clinical Audit arrangements.

BY TICKING THESE BOXES AND SUBMITTING THE APPLICATION THE CLINICIAN IS CONFIRMING THE PATIENT MEETS ALL THE CRITERIA BELOW. IT SHOULD BE NOTED THAT THE SACT DATA SET WILL BE USED TO MONITOR THAT THESE CRITERIA ARE BEING MET.

EAMS Treatment Required for the treatment of unresectable or metastatic melanoma	TICK
All 4 conditions must be met	
1. Application made by and first cycle of systemic anti-cancer therapy to be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy	
2. Patient has unresectable or metastatic melanoma with progressive, persistent, or recurrent disease on or following treatment with standard of care agents including ipilimumab, and when indicated a V-raf murine sarcoma viral oncogene homolog B1 (BRAF) inhibitor or mitogen-activated protein kinase (MEK) enzyme inhibitor	
3. A specific patient access form for the Pembrolizumab EAMS has been completed and submitted to MSD-UK*	
4. The treating Trust has to formally agree to comply with full SACT dataset completion NOTE: SACT returns will be monitored on a regular basis and Trusts failing to comply with point 4 may have their access to the EAMS for new patients restricted	
Consultant Approval (email authority)	
Patient Consent Obtained (date of letter – copy to be retained on patient file)	

*To access stock Trusts will need to contact MSD-UK via pembrolizumabEAMS@merck.com for an electronic physician pack, which includes the patient access form

PEMB1-v0.1-Early Access to Medicines Scheme – Application Form 02 Mar 2015 Page 2
Pembrolizumab for melanoma

- All patients must be registered
- Trusts not registering will not be allowed access
- Forms will be used to follow up patients via SACT

The PIM drugs

Drug	PIM received	Indication
Drug A	Sep-14	Cancer
Drug B	Oct-14	Cancer
Drug C	Jan-15	Cancer
Drug D	Mar-15	Cancer
Drug E	Mar-15	Cancer
Drug F	Mar-15	Cancer
Drug G	Mar-15	Cancer
Drug H	Mar-15	Heart disease
Drug I	Aug-15	Cancer
Drug J	Oct-15	Cancer
Drug K	Nov-15	Cancer
Drug L	Nov-15	Cancer
Drug M	Dec-15	Dermatology
Drug N	Dec-15	Cancer
Drug O	Apr-16	Cancer
Drug P	Apr-16	Vascular disease

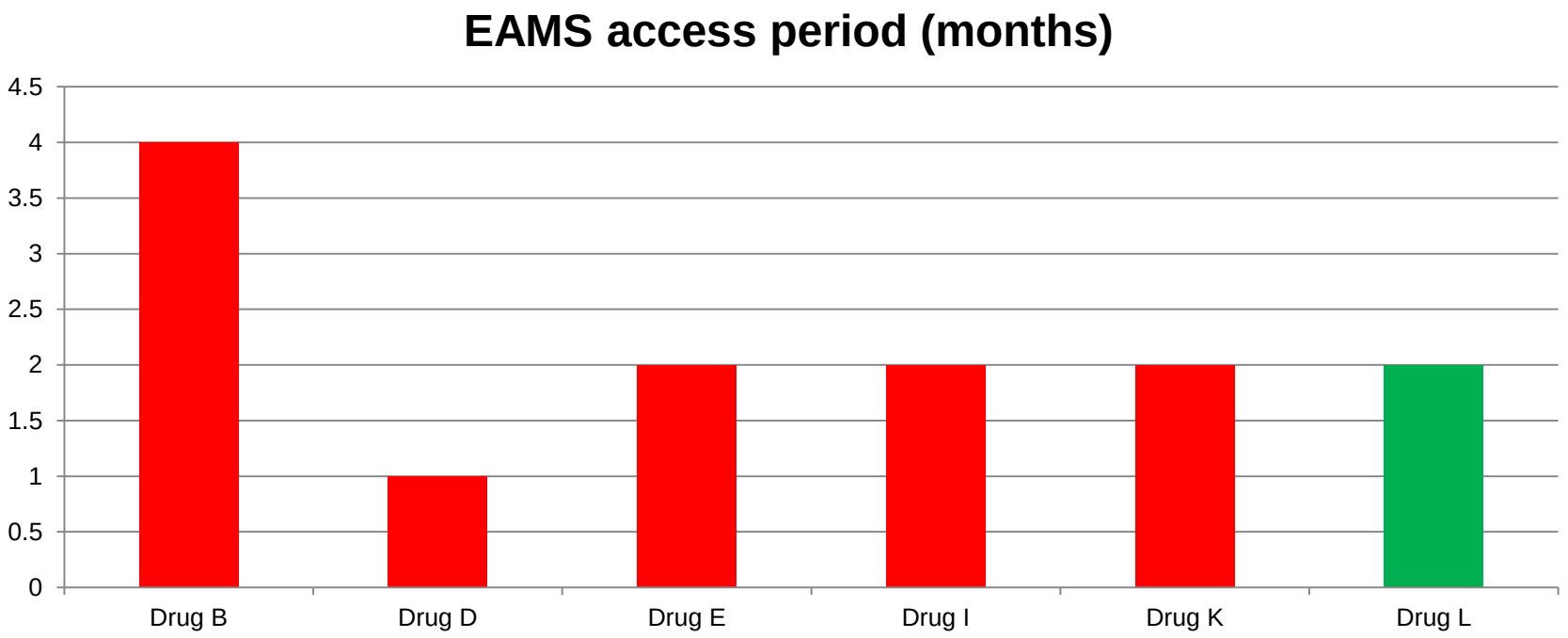
What happened?

Drug	PIM received	Indication	SO status	EAMS implemented	MA received
Drug A	Sep-14	Cancer	TBC		
Drug B	Oct-14	Cancer	Mar-15	Mar-15	Jul-15
Drug C	Jan-15	Cancer	May-15		Jun-15
Drug D	Mar-15	Cancer	Jul-15	Jul-15	Aug-15
Drug E	Mar-15	Cancer	Feb-16	Feb-16	Apr-16
Drug F	Mar-15	Cancer			Sep-15
Drug G	Mar-15	Cancer	TBC		
Drug H	Mar-15	Heart disease	Aug-15	CCG	Jan-16
Drug I	Aug-15	Cancer	Dec-15	Dec-15	Feb-16
Drug J	Oct-15	Cancer	TBC		
Drug K	Nov-15	Cancer	Feb-16	Feb-16	Apr-16
Drug L	Nov-15	Cancer	Mar-16	Mar-16	n/a
Drug M	Dec-15	Dermatology	TBC		
Drug N	Dec-15	Cancer	TBC		
Drug O	Apr-16	Cancer	TBC		
Drug P	Apr-16	Vascular disease	TBC		

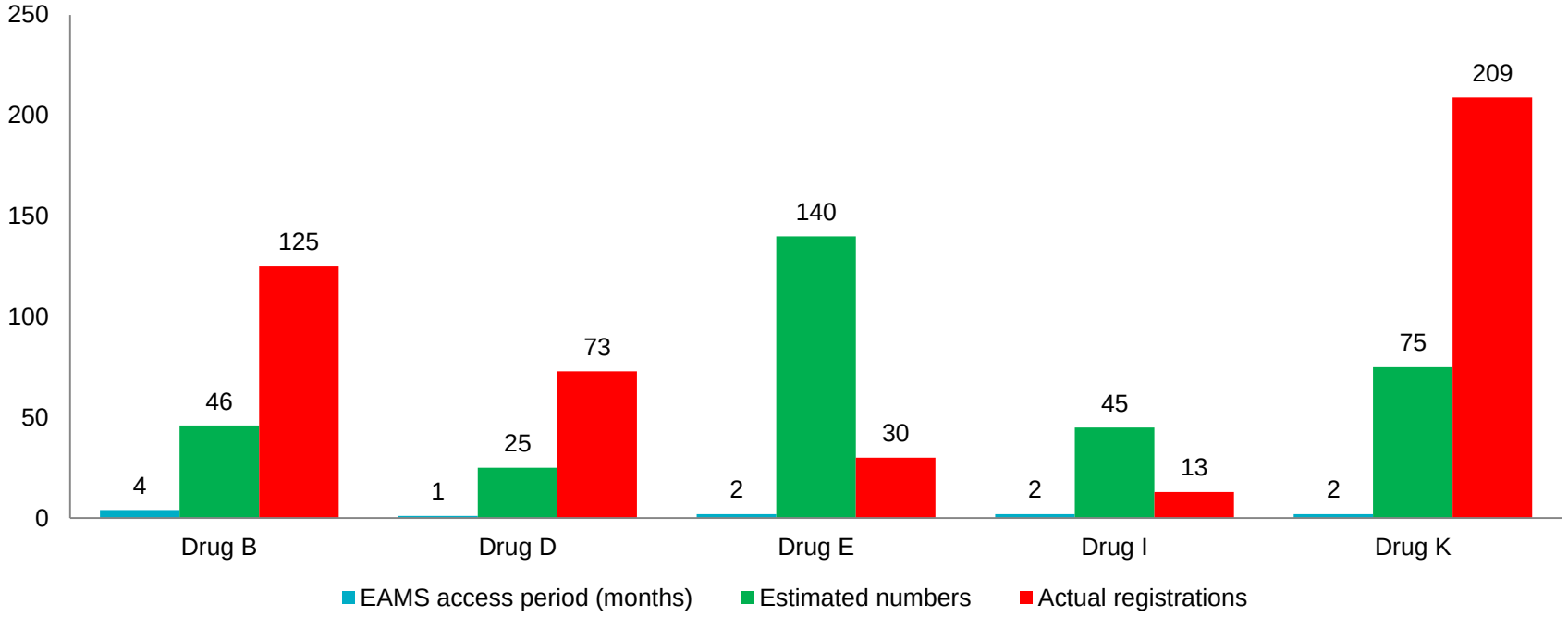
Access

Drug	PIM received	Indication	SO status	EAMS implemented	MA received	EAMS Access Period
Drug B	Oct-14	Cancer	Mar-15	Mar-15	Jul-15	4 months
Drug C	Jan-15	Cancer	May-15	Not implemented	Jun-15	0 months
Drug D	Mar-15	Cancer	Jul-15	Jul-15	Aug-15	1 month
Drug E	Mar-15	Cancer	Feb-16	Feb-16	Apr-16	2 months
Drug H	Mar-15	Heart disease	Aug-15	CCG	Jan-16	n/a
Drug I	Aug-15	Cancer	Dec-15	Dec-15	Feb-16	2 months
Drug K	Nov-15	Cancer	Feb-16	Feb-16	Apr-16	2 months
Drug L	Nov-15	Cancer	Mar-16	Mar-16	n/a	2+ months

Access


EAMS access period (months)
4.5
4
3.5
3
2.5
2
1.5
1
0.5
0
Drug B
Drug D
Drug E
Drug I
Drug K
Drug L

Access (completed EAMS period)



What works well

- Early communication from MHRA regarding PIM and SO status
- Pharma support to identify potential NHS costs
- Joint working with NICE

Feedback from end users

- Improved timely communication that schemes are open, including how to apply.
- Improved timely communication that a scheme has closed to reduce risk that a clinician offers a patient a therapy that is no longer available.
- Walkthrough of the application process before the scheme goes live
- Clear communication if free drug is time limited as this could pose a financial risk to providers
- Some EAMS have been extremely short which appears to go against one of the reasons for EAMS in the first place - i.e. to collect data

Final thoughts

- EAMS provides an early access method which should be embraced by the NHS
- Communication to end users needs to be earlier in the system
- Ideally the SO should provide sufficient time for relevant and meaningful data collection
- There should be a smooth transition (for cancer drugs) from EAMS through to the new CDF