NICE National Institute for Health and Care Excellence

Early Access to Medicines Scheme: NICE perspective

BIA/MHRA Conference - Accelerated development and access to innovative medicines for patients - 4 May. London

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EAMS Medicines and NICE

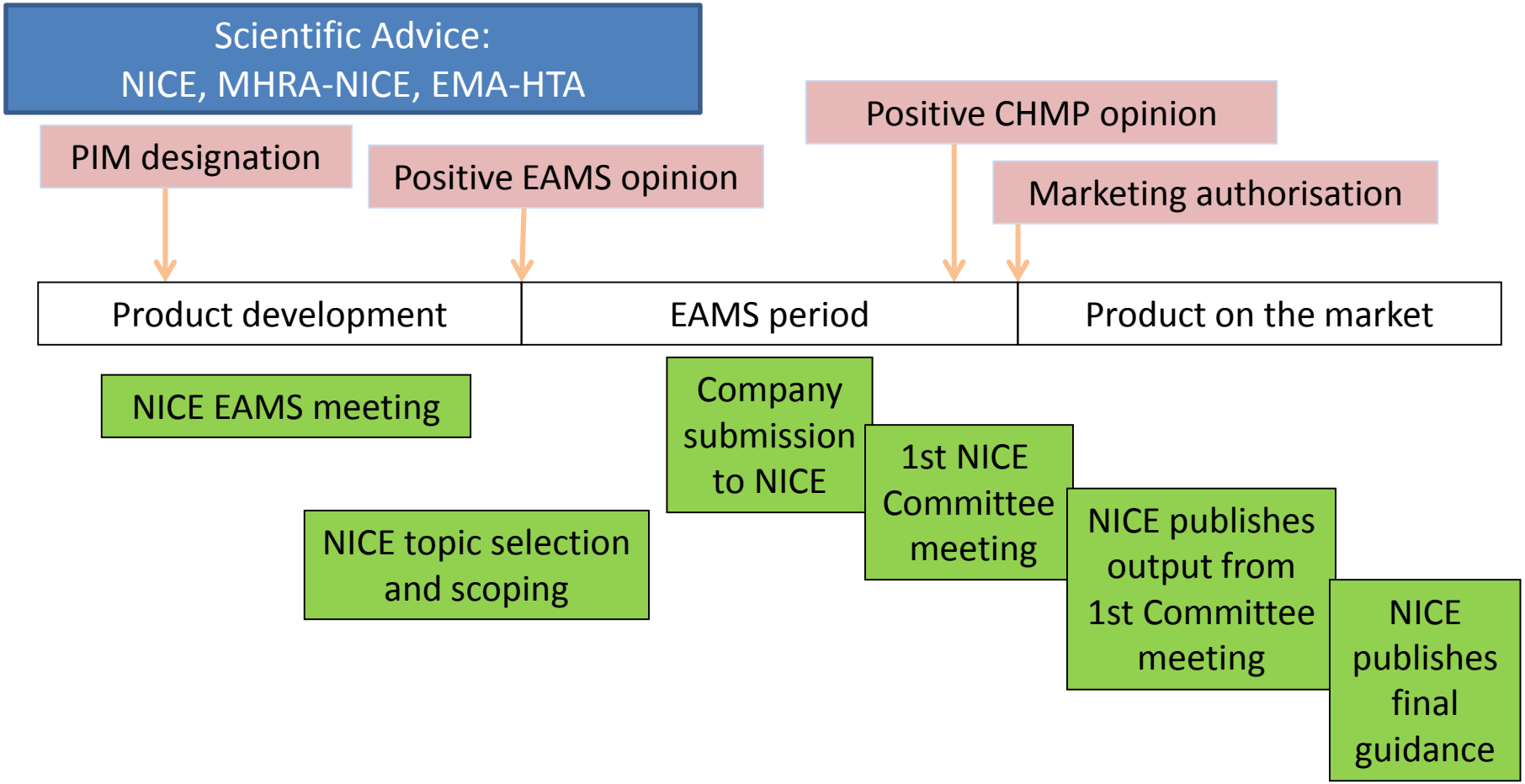
- The Early Access to Medicines Scheme facilitates patient access to innovative medicines addressing unmet need in advance of Marketing Authorisation
- NICE has been working with MHRA, Office for Life Sciences and NHS England to ensure alignment of processes for EAMS medicines
- Most aspects of NICE's Technology Appraisals processes are applicable to EAMS medicines
- To date, most EAMS medicines have been for oncology indications - new Cancer Drugs Fund arrangements relevant to EAMS

Specific arrangements for EAMS medicines

- All EAMS medicines within the TA remit are selected for TA guidance
- Companies encouraged to take up joint MHRA/NICE Scientific Advice
- Companies offered a NICE EAMS meeting
- Scheduling of EAMS medicines is prioritised to allow draft TA guidance to be issued within 1 month of MA
- NHS England implements NICE guidance on EAMS medicines within 30 days of the final guidance (funding direction requires implementation within 90 days for other products)
- NICE EAMS process available from https://www.nice.org.uk/Media/Default/About/Who-we-are/Policies-and-procedures/eams-process-jan-16.pdf

NICE EAMS meeting

- Offered to companies around the same time as their pre-submission meeting with the MHRA
- Allows discussion of any issues to help companies prepare for NICE appraisal including:
  - Potential collection of real world evidence during the EAMS period to address uncertainties in the clinical effectiveness evidence or anticipated resource use
  - Potential patient access schemes or managed access arrangements to support NHS adoption following the EAMS period and NICE appraisal
- NHS England invited to participate so meeting can also include practical arrangements for the EAMS period


Scientific Advice:
NICE, MHRA-NICE, EMA-HTA
PIM designation
Positive EAMS opinion
Positive CHMP opinion
Marketing authorisation
Product development
EAMS period
Product on the market
NICE EAMS meeting
NICE topic selection and scoping
Company submission to NICE
1st NICE Committee meeting
NICE publishes output from 1st Committee meeting
NICE publishes final guidance

Experience with EAMS so far

- ***Additional patient access for >250 patients***
- EAMS periods (time between Scientific Opinion and MA) have been short and insufficient for real world evidence collection e.g.:
  - Pembrolizumab 130 days
  - Nivolumab (melanoma) 21 days
  - Nivolumab (lung cancer) 31 days
  - Sacubitril valsartan 37 days
- Earlier company engagement with EAMS leading to earlier Scientific Opinion and longer EAMS periods would increase patient access and allow full delivery of the anticipated EAMS benefits

EAMS products appraised at NICE

Product	Company	PIM	EAMS Scientific opinion	EMA MA	1st AC Meeting	ACD published	FAD published	Guidance Published
Pembrolizumab - melanoma	MSD	Oct 14	Mar-15	Jul-15	Jul-15	N/A	Oct-15	Oct-15
Pembrolizumab - melanoma					Aug-15	N/A	Oct-15	Nov-15
Nivolumab - Melanoma	BMS	Jan-15	Jun-15	Jul-15	Nov-15	N/A	Jan-16	Feb-16
Nivolumab - Melanoma			Jun-15	Jan-16	Apr-16			
LCZ696 (sacubitril/valsartan) - heart failure	Novartis	Apr-15	Sep-15	Nov-15	Nov-15	Dec-15	March-16	April-16
Ceritinib - NSCLC	Novartis	Apr-15		May-15	Sep-15	Oct-15		
Nivolumab - NSCLC	BMS		Jun-15	Nov-15	Nov-15	Dec-15		

Cancer Drugs Fund

- NICE and NHS England undertook a joint public consultation on proposals for a new Cancer Drugs Fund operating model from November 2015 – February 2016
- Cancer Drugs Fund has become a “managed access fund” to enable patient access to oncology drugs which appear promising but where NICE indicates that there is insufficient evidence to support a recommendation for routine commissioning
- Arrangements implemented in April 2016 and apply to new oncology drugs referred to NICE from that date

Arrangements for oncology drugs – key features

- All oncology drugs expected to receive a marketing authorisation (MA) to be appraised by NICE
- Draft guidance to be issued prior to MA and final guidance within 90 days of MA
- NICE recommendation options:
  - Recommended for routine use
  - Not recommended for routine use
  - Recommended for use within the Cancer Drugs Fund
- From the point of MA, the Cancer Drugs Fund to cover:
  - Drugs recommended for use within the Cancer Drugs Fund
  - Drugs recommended for routine use in draft guidance