Individual Patient Funding Request (IPFR) and One Wales Interim Commissioning Processes

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NHS WALES GIG CYMRU

AWTTC
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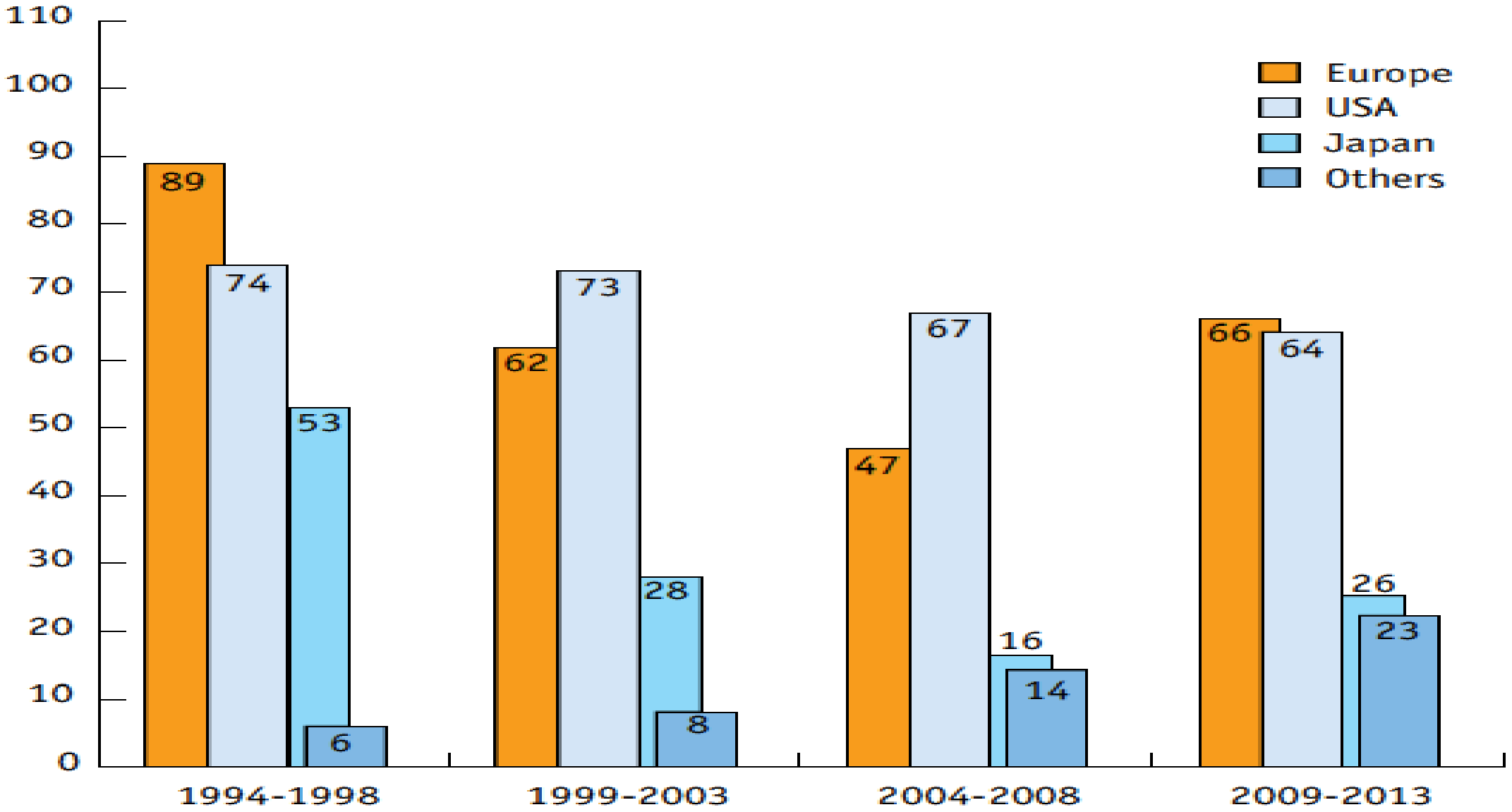
NUMBER OF NEW CHEMICAL OR BIOLOGICAL ENTITIES (1994-2013)



Source: SCRIP – EFPIA calculations (according to nationality of mother company)

http://www.efpia.eu/uploads/Figures_2014_Final.pdf

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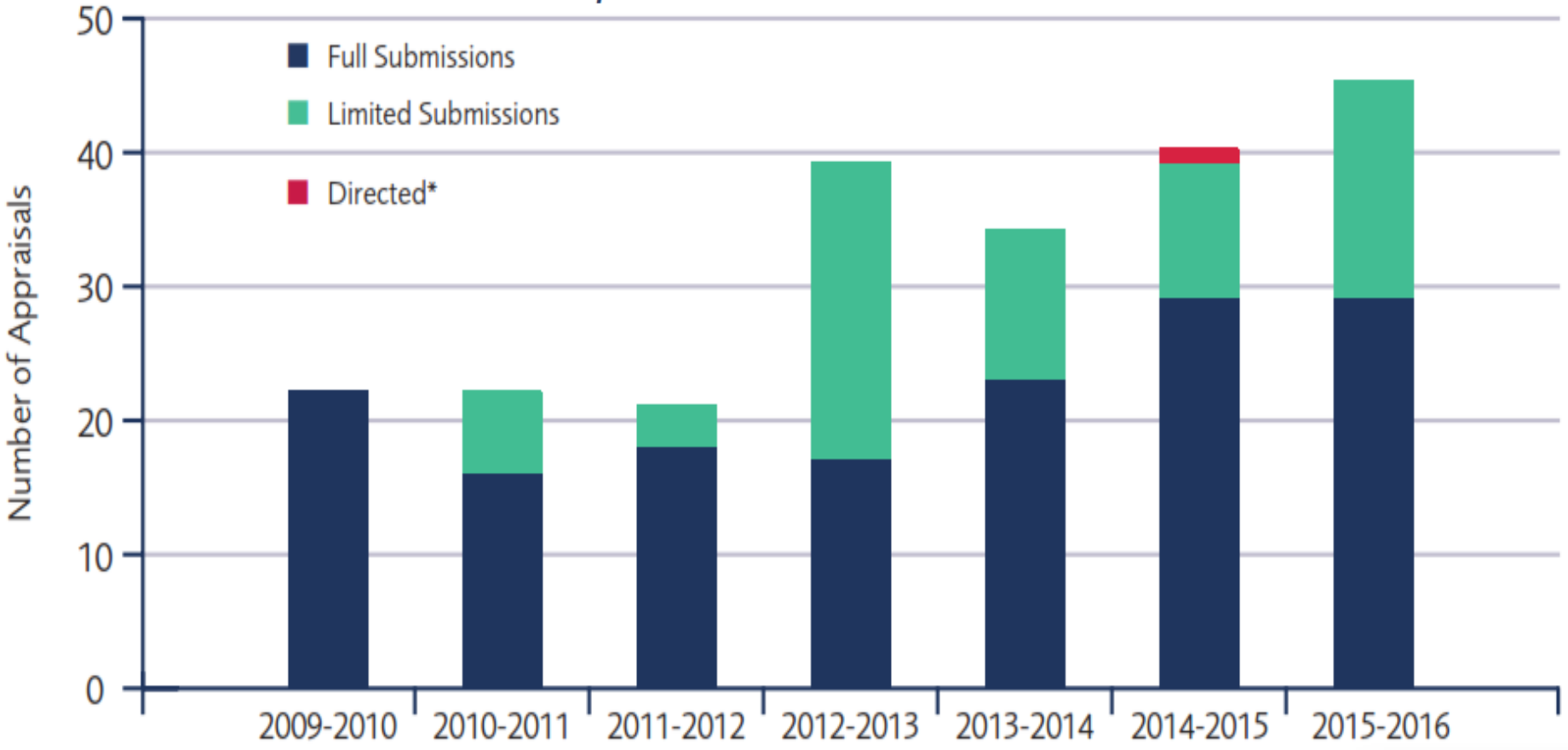
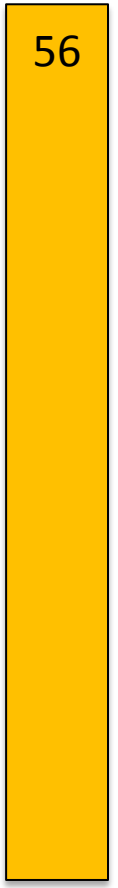
"Getting the best outcomes from medicines for patients in Wales"





Statements of Advice

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Non-engagement notices

- 56 Statements of advice in April 2015-March 2016
- 4 submissions subsequently received (several others expected)
- Reasons (when given): *Not launching in UK, resource constraints,*
- 17/56 submitted to the Scottish Medicines Consortium (SMC)
- 8 approved by SMC by the end of March 2016

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Medicines with Statement of Advice in Wales which were recommended (w/wo restrictions) by the Scottish Medicines Consortium in 2015/16

Medicine	Indication	
Lenvatinib (Lenvima®)	Treatment of adult patients with progressive, locally advanced or metastatic, differentiated (papillary/follicular/Hürthle cell) thyroid carcinoma (DTC), refractory to radioactive iodine (RAI)	
Secukinumab (Cosentyx®)	Alone or in combination with methorexate for the treatment of active psoriatic arthritis in adults when response to previous disease modifying anti rheumatic drug (DMARD) therapy has been inadequate	
Aflibercept (Eylea®)	Treatment of patients with visual impairment due to myopic choroidal neovascularisation	AWMSG Presently in progress
Aflibercept (Eylea®)	Treatment of adults with visual impairment due to macular oedema secondary to branch retinal vein occlusion (BRVO)	
Bevacizumab (Avastin®)	In combination with paclitaxel and cisplatin or, alternatively, paclitaxel and topotecan in patients who cannot receive platinum therapy, for the treatment of adult patients with persistent, recurrent, or metastatic carcinoma of the cervix	AWMSG Presently in progress
Diamorphine hydrochloride (Ayendi®)	Treatment of acute severe nociceptive pain in children and adolescents 2 to 15 years of age in a hospital setting. Diamorphine hydrochloride nasal spray should be administered in the emergency setting by practitioners experienced in the administration of opioids in children and with appropriate monitoring	
Isavuconazole (Cresemba®)	Treatment of invasive aspergillosis and mucormycosis in patients for whom amphotericin B is inappropriate	Recommended as option, Dec ‘16
Febuxostat (Adenuric®)	Prevention and treatment of hyperuricaemia in adult patients undergoing chemotherapy for haematological malignancies at intermediate to high risk of Tumour Lysis Syndrome (TLS)	

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MIND THE "GAPS"!

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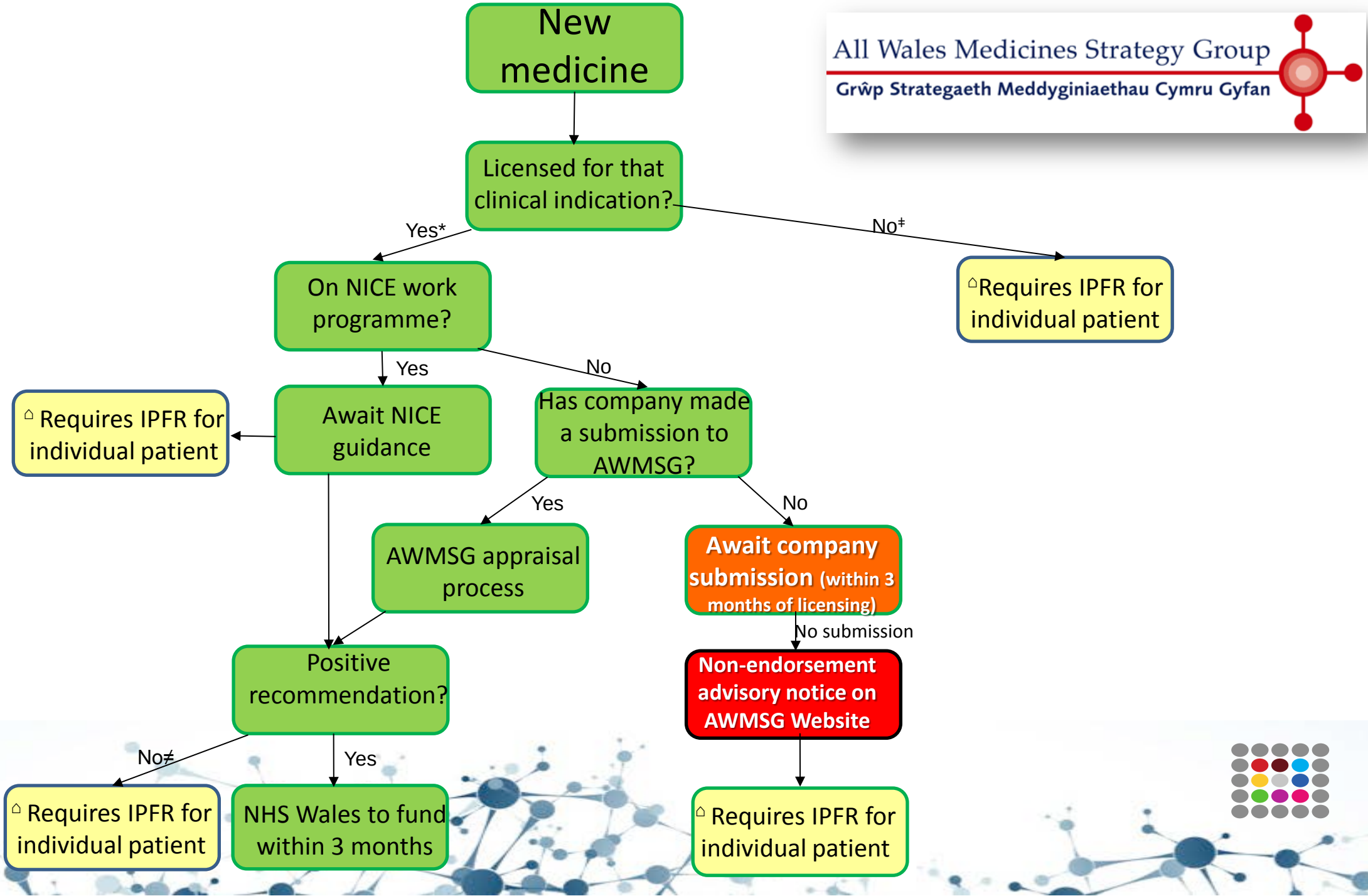
- Negative appraisal of Medicines
- Delayed appraisal of licensed medicines
- Non-appraisal of licensed medicines
- Off-label use of medicines


New medicine
Licensed for that clinical indication?
Yes*
No‡
⌂Requires IPFR for individual patient
On NICE work programme?
Yes
No
⌂ Requires IPFR for individual patient
Await NICE guidance
Has company made a submission to AWMSG?
Yes
No
AWMSG appraisal process
Await company submission (within 3 months of licensing)
No submission
Non-endorsement advisory notice on AWMSG Website
Positive recommendation?
No≠
Yes
⌂ Requires IPFR for individual patient
NHS Wales to fund within 3 months
⌂ Requires IPFR for individual patient

Methods to achieve timely access for patient groups via HTA

- Early HTA
- "Late" HTA (if medicine available in England via a commissioning route)

Generic name	Trade name	AWMSG Status	MINISTERIAL RATIFICATION	NICE STATUS	NICE APPRAISAL DATE
sorafenib	(Nexavar®)	Optimised recommendation	05/04/2016	Not recommended	26/05/2010
aflibercept	(Zaltrap®)	Not recommended	08/06/2015	Not recommended	25/03/2014
eribulin mesilate	(Halaven®)	Optimised recommendation	29/04/2016	Not recommended	01/04/2012
pomalidomide	(Imnovid®)	Recommended	27/08/2015	Not recommended	26/03/2015

IPFR PANELS IN WALES

- 7 Health Board IPFR Panels
- 1 “national panel” (WHSSC)

What is an Individual Patient Funding Request?

IPFR

- A request to a health board to fund NHS healthcare for individual patients who fall outside the range of services and treatments that a health board has agreed to routinely provide

- This can include a request for any type of healthcare including a specific service, treatment, medicine, device or piece of equipment

Categories suitable for IPFR

IPFR

- A treatment that is either new, novel, developing or unproven and is not within the health board's routine schedule of services and treatment (e.g. A drug that has yet to be approved for use in a particular condition)
- A treatment that is provided by the health board in certain clinical circumstances but is not eligible in accordance with the clinical policy criteria for that treatment (e.g. Treatment for varicose veins)
- The patient has a rare or specialist condition that falls within the service remit of the Welsh Health Specialised Services Committee(WHSSC) but is not eligible in accordance with the clinical policy criteria (e.g. Plastic surgery)

IPFR

IPFRs conducted since 2012

Year	2012-13		2013-14		2014-15		2015-16	
	No.	%	No.	%	No.	%	No.	%
IPFR (medicines)	406	60	437	59	348	67	309	45
IPFR (medicines) - approved	216	53	223	51	176	51	176	57
IPFR (treatments)	275	40	303	41	173	33	374	55
IPFR (treatments) – approved	131	48	160	53	86	50	226	60
Total IPFR	681	100	740	100	521	100	683	100
Total IPFR – approved	347	51	383	52	262	50	402	59

IPFR system

2014 IPFR Review

Present Review

2016-17 Review of IPFR Process

"It is right that we have a process in Wales to enable access t treatments and devices which are not normally available via the NHS. Each health service in the UK has such a process, with clinical criteria to determine accessibility"

"The NHS Wales process has been improved following a review in 2013-14. A further review will now take place to ensure better consistency of decisions across Wales and make recommendations about what clinical criteria should be applied when determining eligibility"

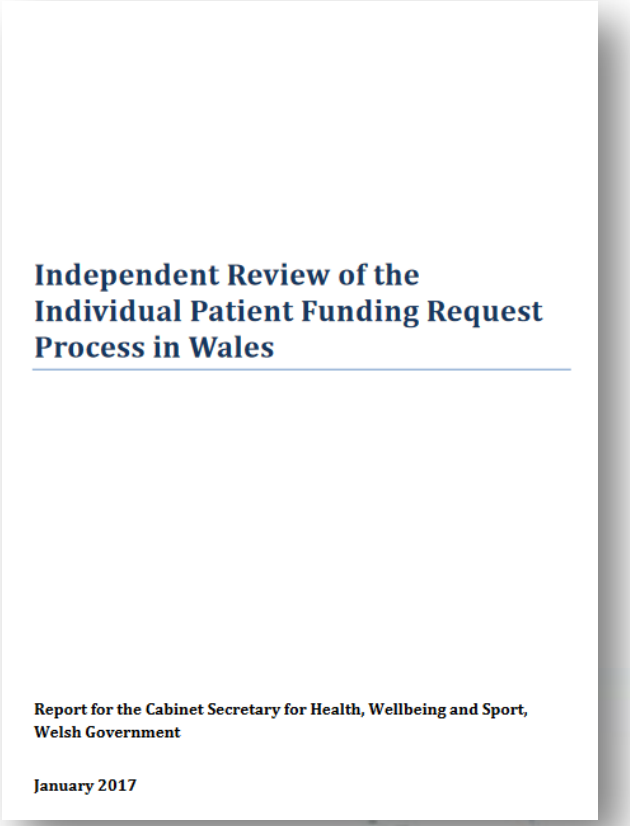
Vaughan Gething AM
Cabinet Secretary for Health, Well-being and Sport

Independent Patient Funding Request Review 2016

Llywodraeth Cymru
Welsh Government

Last updated 17 January 2017

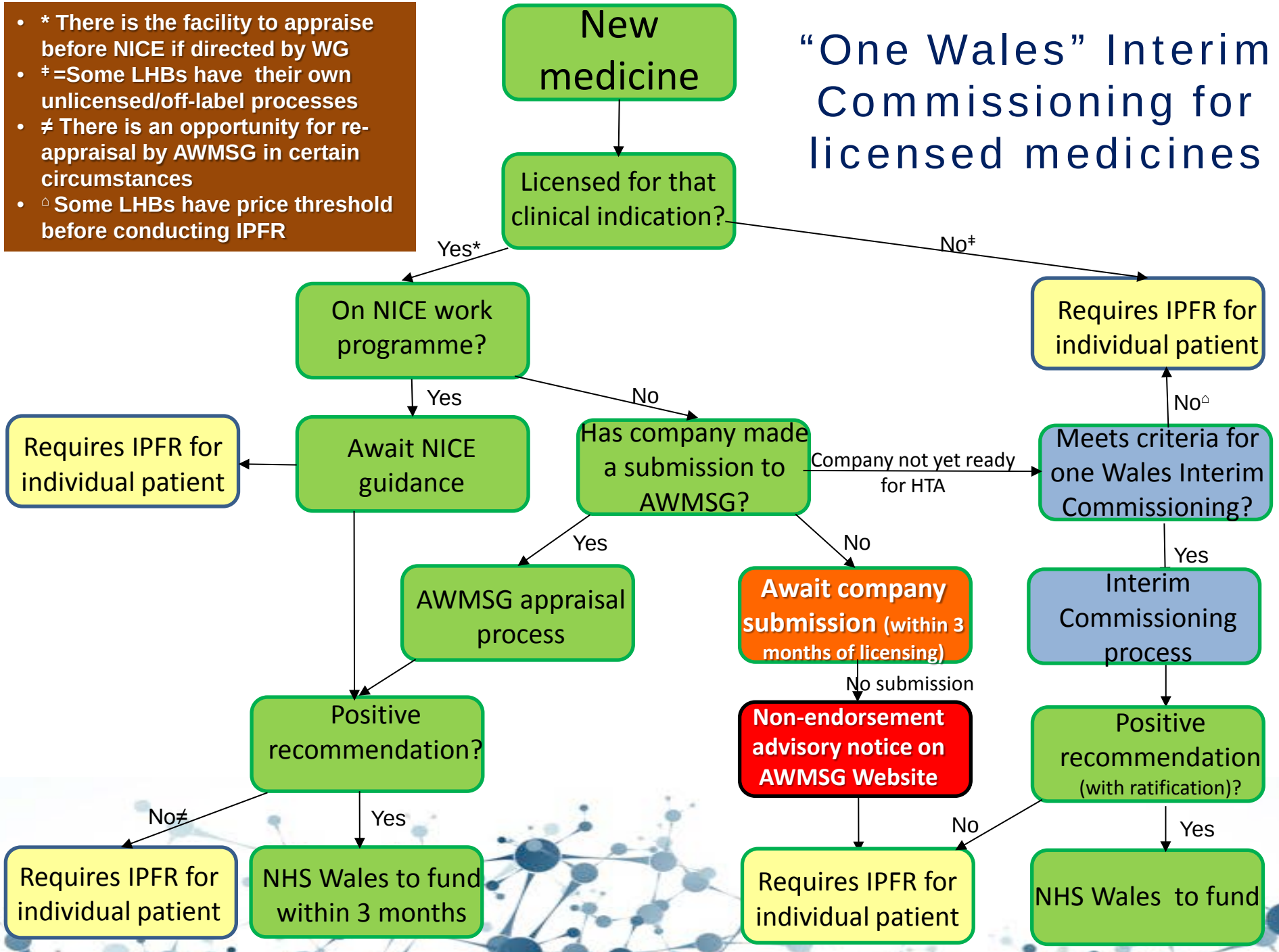
- Contains 27 recommendations relating to 7 important areas:
  - Commissioning
  - Exceptionality
  - Non-clinical factors
  - Consistency and the number of panels
  - Communication
  - Paperwork and the IPFR process
  - Medicines appraisal



http://gov.wales/topics/health/nhswales/funding/?lang=en

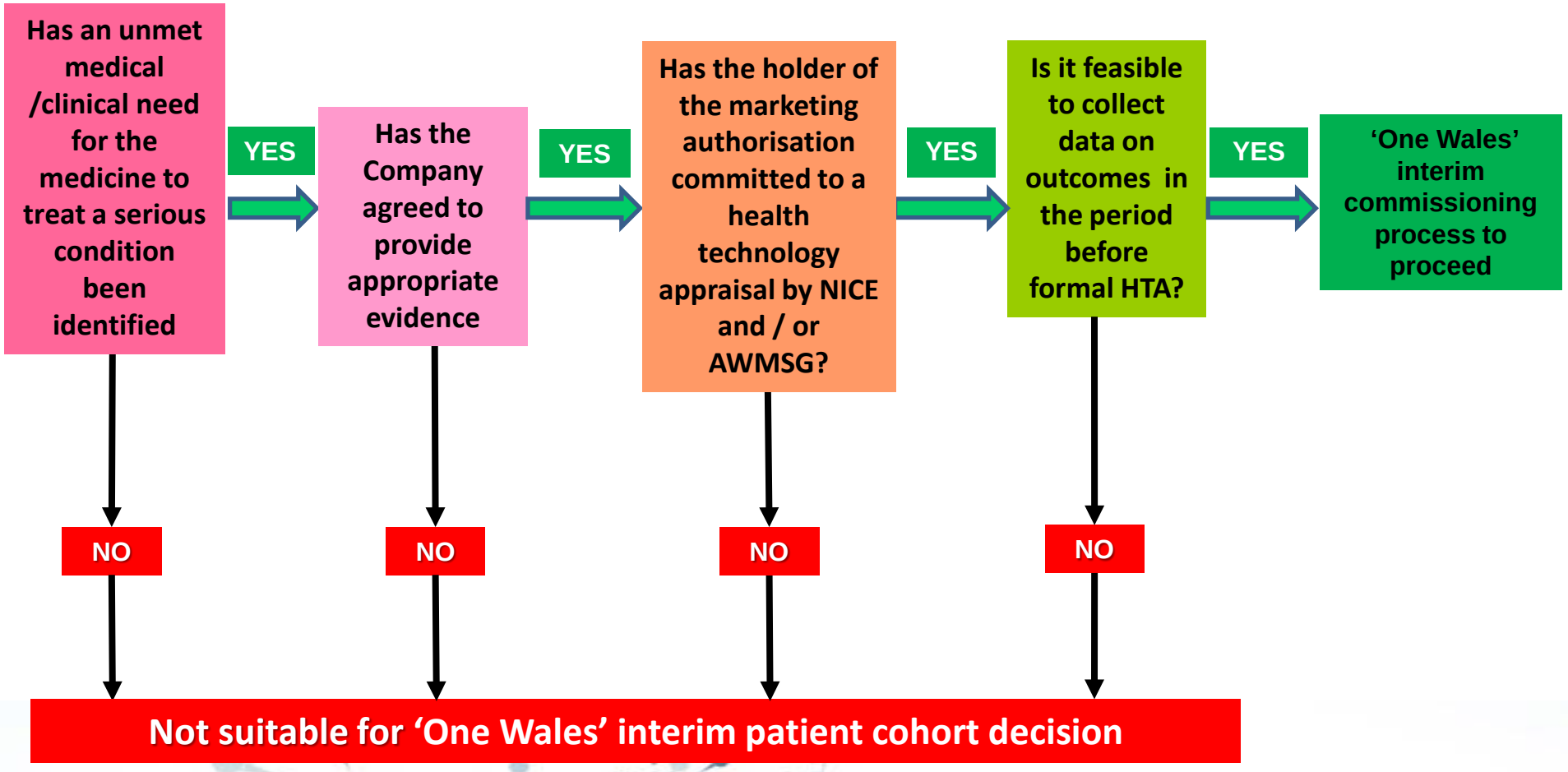
“One Wales” Interim Commissioning for licensed medicines

- * There is the facility to appraise before NICE if directed by WG
- ǂ =Some LHBs have their own unlicensed/off-label processes
- ≠ There is an opportunity for re-appraisal by AWMSG in certain circumstances
- ⌂ Some LHBs have price threshold before conducting IPFR



“One Wales” Decision Tool for licensed medicines

All the conditions in the coloured boxes must be met for the One Wales Process to proceed



Please note this only applies for licensed medicines. Unlicensed medicines or off-label use of a medicine will be considered on a case-by-case basis

“One” Wales Interim Pathway Commissioning Group (IPCG) decisions, May 2016 to date

Medicine, indication and licensed status	IPCG decision
1. Axitinib, post-pazopanib, for advanced renal cell carcinoma (off-label)	Use supported
2. Docetaxel in combination with hormone therapy for the treatment of metastatic prostate cancer (off-label)	Use supported
3. Bevacizumab (7.5 mg) for the 1st line treatment of advanced ovarian cancer in patients at high risk of disease progression (off-label)	Use not supported
4. Adalimumab (Humira®) for the treatment of paediatric patients with severe refractory uveitis (off-label)	Use supported
5. Adalimumab (Humira®) for the treatment of adult patients with severe refractory uveitis (licensed indication)	Use supported
6. Arsenic trioxide (TRISENOX®) for Acute promyelocytic leukaemia - 1st line therapy in patients unsuitable for anthracycline-based therapy(off label)	Use supported

Further medicine-indications for patient cohorts in Wales are being prepared for consideration by IPCG

“One Wales” Interim Commissioning Points to note

- ‘One Wales’ interim commissioning will not apply to medicines that have been appraised by NICE/AWMSG and received a negative recommendation
- The duration of an interim commissioning decision for licensed medicines will be decided on a case by case basis
- For unlicensed medicines the ‘One Wales’ interim commissioning decision will be reviewed annually
- For unlicensed medicines to be considered there must be no suitably licensed alternative
- Patient outcomes are to be monitored following a positive decision for both licensed and unlicensed medicines

New Treatment Fund (NTF) in Wales

- A total of £12 million will be released to health boards with immediate effect, with a further £4 million being made available later to help speed up access to medicines recommended by NICE and AWMSG

- Under the new system, all health boards will be required to make a NICE or AWMSG recommended medicine available no later than two months from the date the final guidance is published, shortening the maximum amount of time before which a health board must make a treatment available by a third

- In respect of NICE recommendations, health boards will now be expected to introduce medicines recommended by NICE at the first publication of the final guidance, rather than waiting for the final Technology Appraisal guidance published after the appeal period

http://gov.wales/newsroom/health-and-social-services/2017/170110fund/?lang=en

Acknowledgements

- **Pharmaceutical Manufacturers**
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- **IPFR and One-Wales implementation Team**: Gail Woodland, Ann-Marie Matthews, Rosie Spears, Jessica Davies, Kath Haines, Tony Williams, Ruth Lang and Karen Samuels
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Diolch yn fawr

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