從新藥可近性
談MEA運用之國際趨勢

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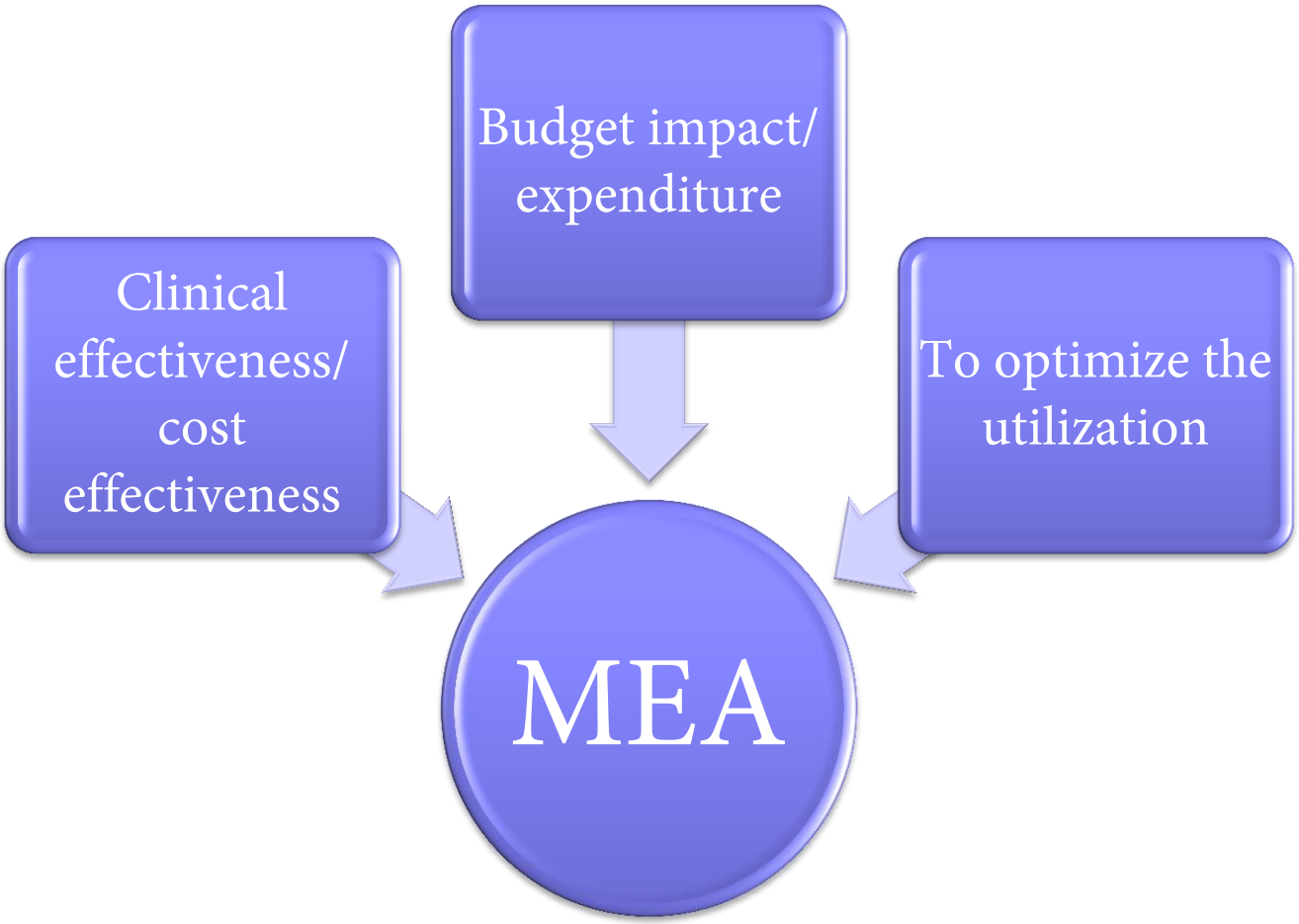
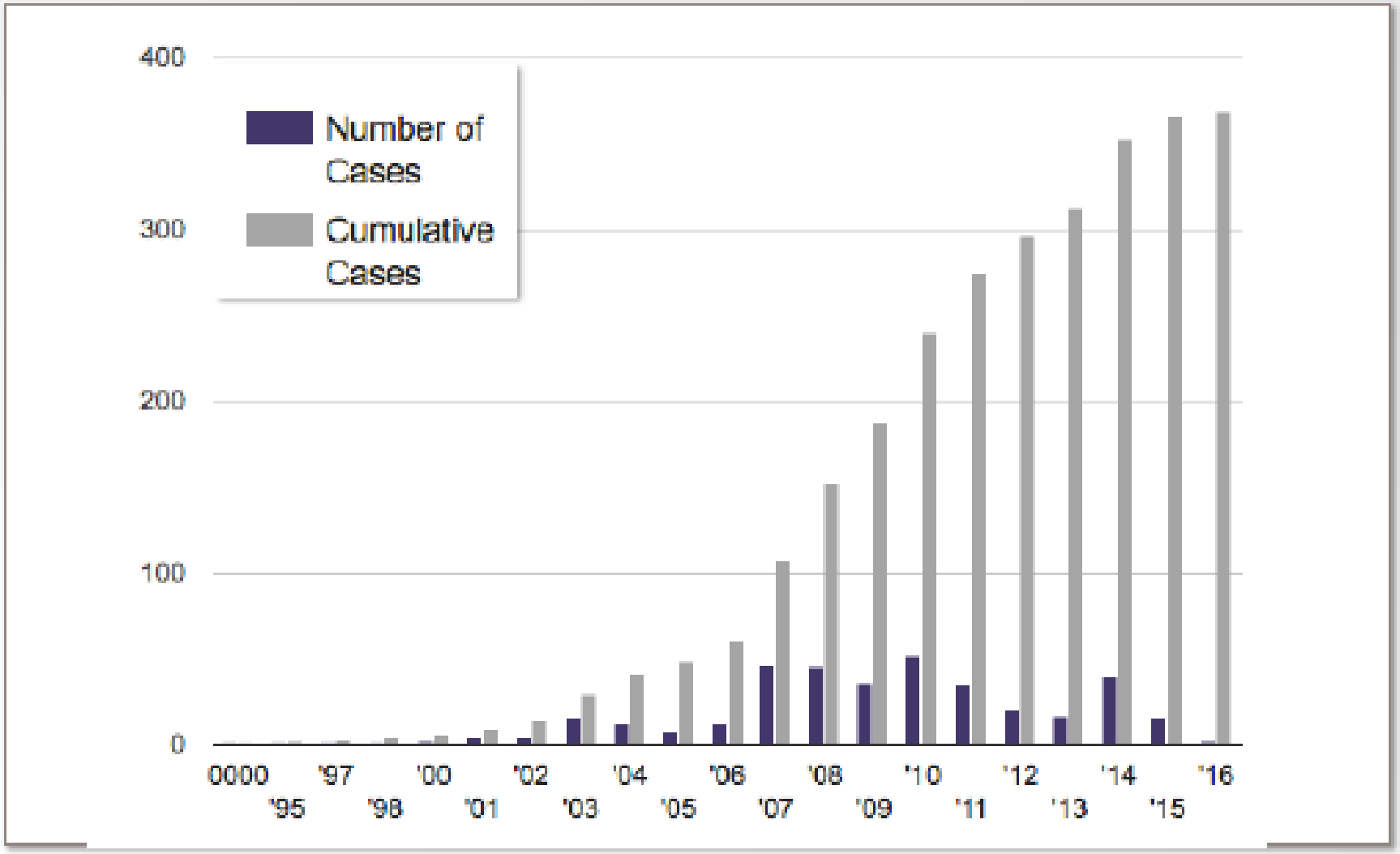
為什麼需要MEA

對於一些創新藥品可藉由提供MEA的方式，加速病患取得使用給付新藥的機會

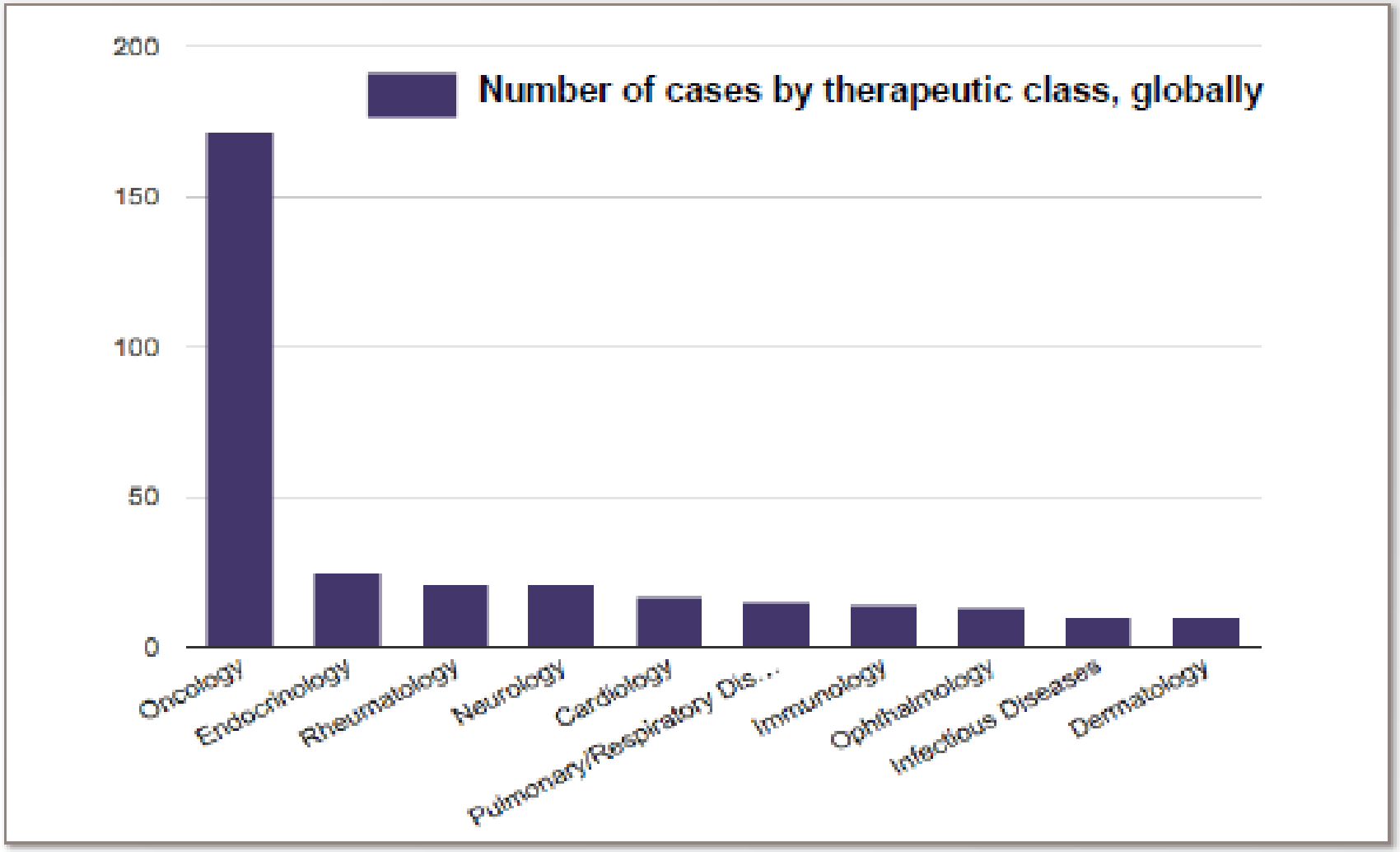


The number of "risk sharing" schemes globally has been growing since the mid-2000's



Source: University of Washington PBRSA Database

Globally, a large majority "risk sharing" schemes to-date are for oncology therapies



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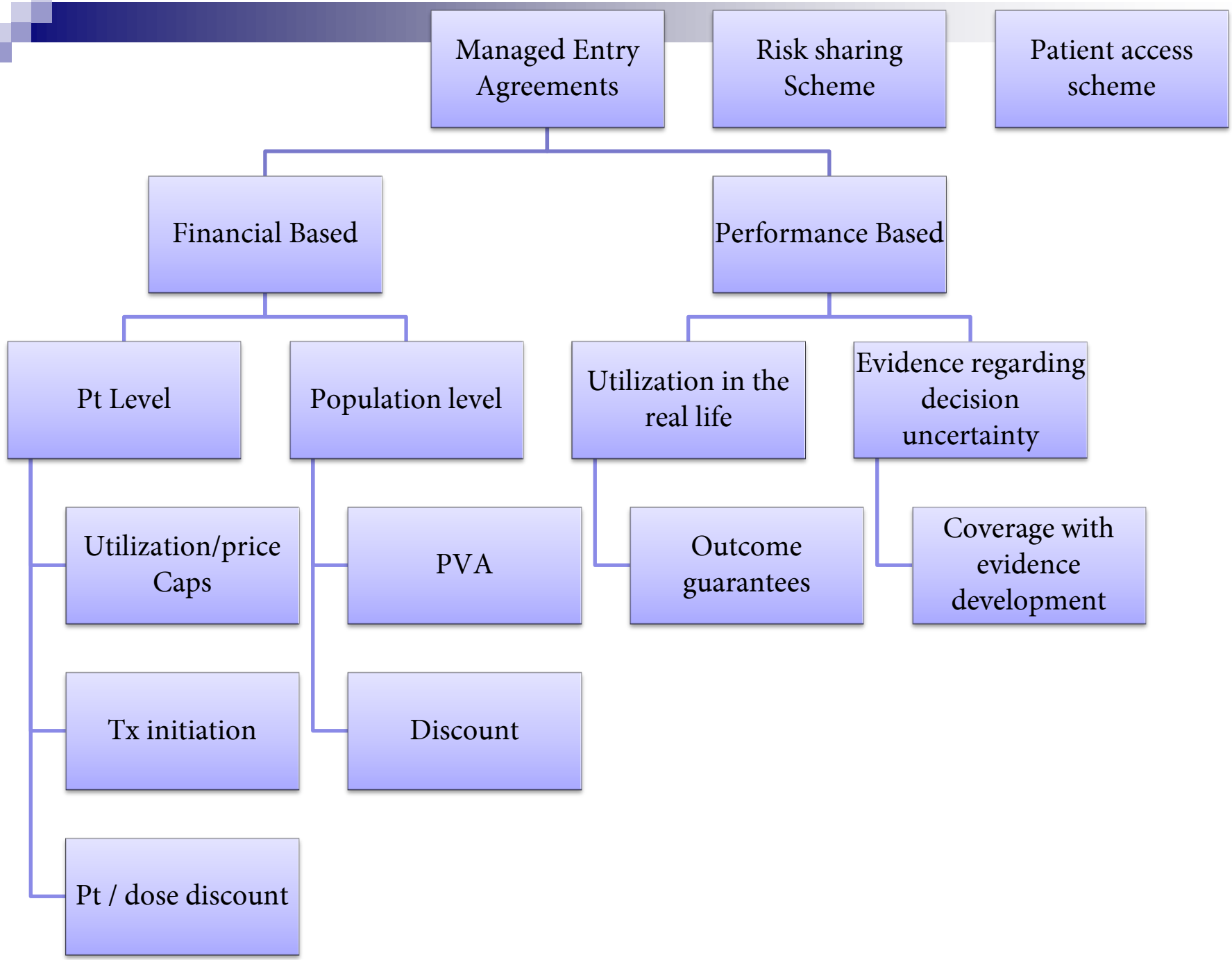
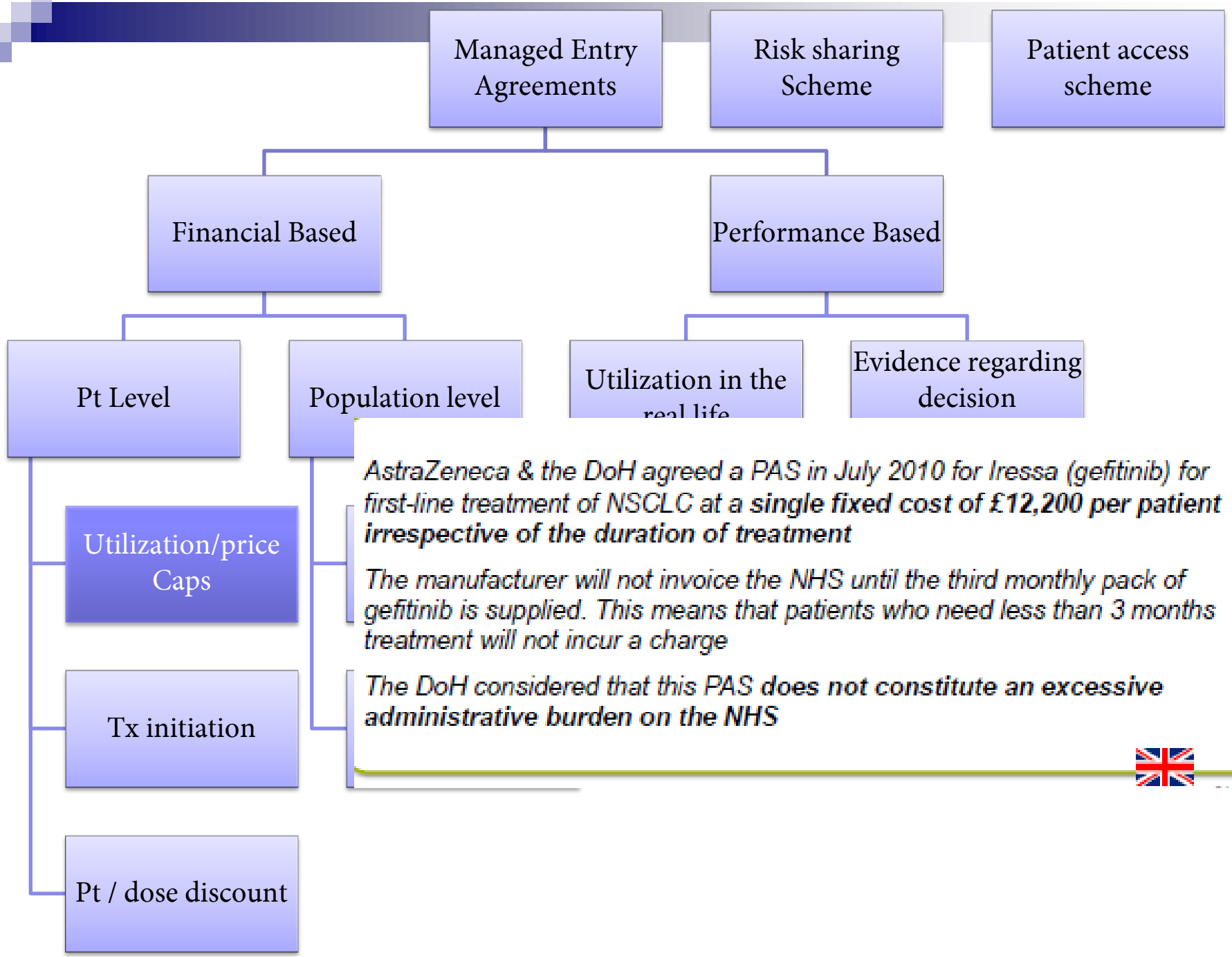

Managed Entry Agreements
Risk sharing Scheme
Patient access scheme
Financial Based
Performance Based
Pt Level
Population level
Utilization in the real life
Evidence regarding decision uncertainty
Utilization/price Caps
PVA
Outcome guarantees
Coverage with evidence development
Tx initiation
Discount
Pt / dose discount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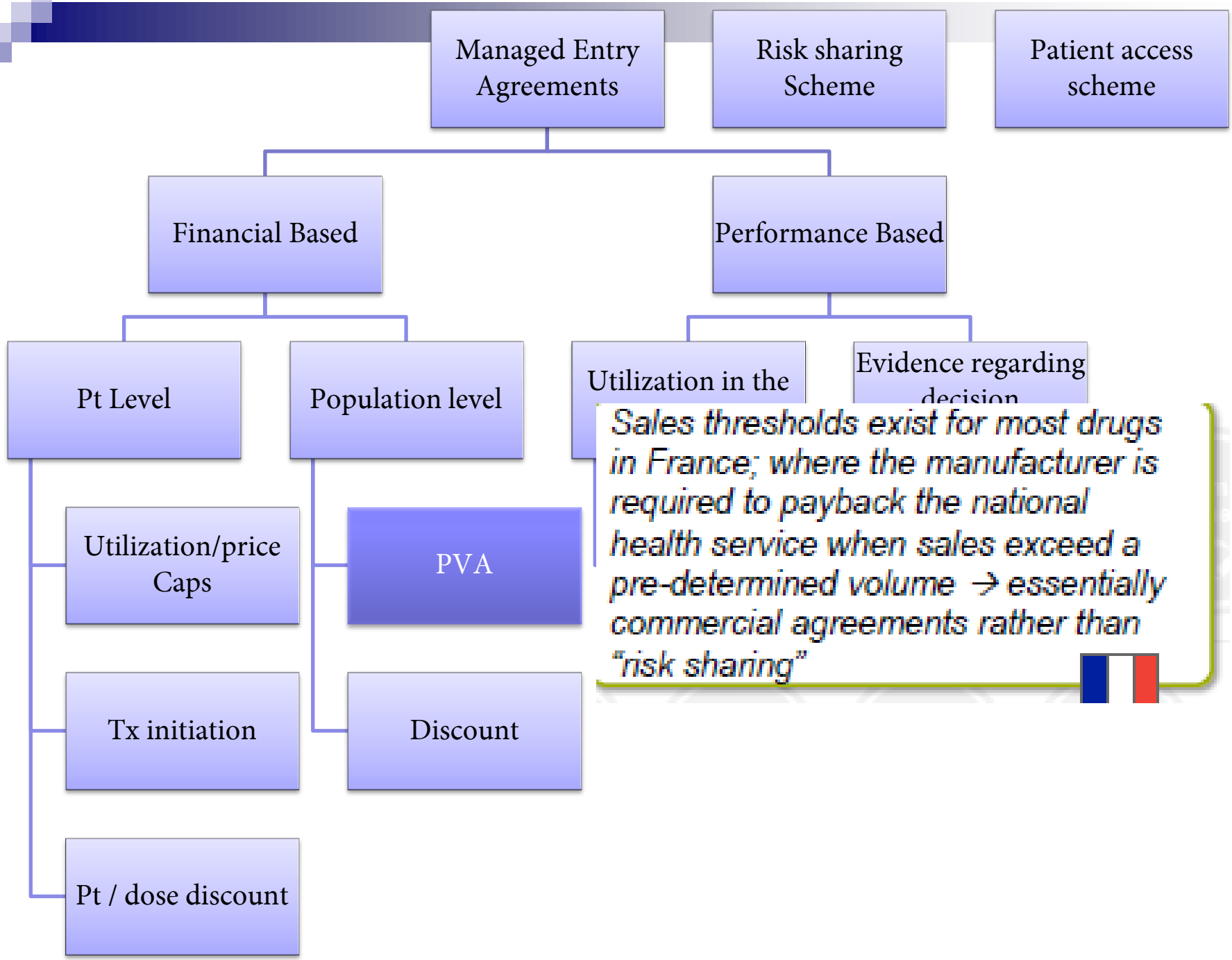
AstraZeneca & the DoH agreed a PAS in July 2010 for Iressa (gefitinib) for first-line treatment of NSCLC at a single fixed cost of £12,200 per patient irrespective of the duration of treatment
The manufacturer will not invoice the NHS until the third monthly pack of gefitinib is supplied. This means that patients who need less than 3 months treatment will not incur a charge
The DoH considered that this PAS does not constitute an excessive administrative burden on the NHS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Sales thresholds exist for most drugs in France; where the manufacturer is required to payback the national health service when sales exceed a pre-determined volume → essentially commercial agreements rather than "risk sharing"

Managed Entry Agreements

Risk sharing Scheme

Patient access scheme

Fina

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Pt Level

Evidence regarding decision uncertainty

Utilization/ Caps

Coverage with evidence development

Tx initiat

Pt / dose dis

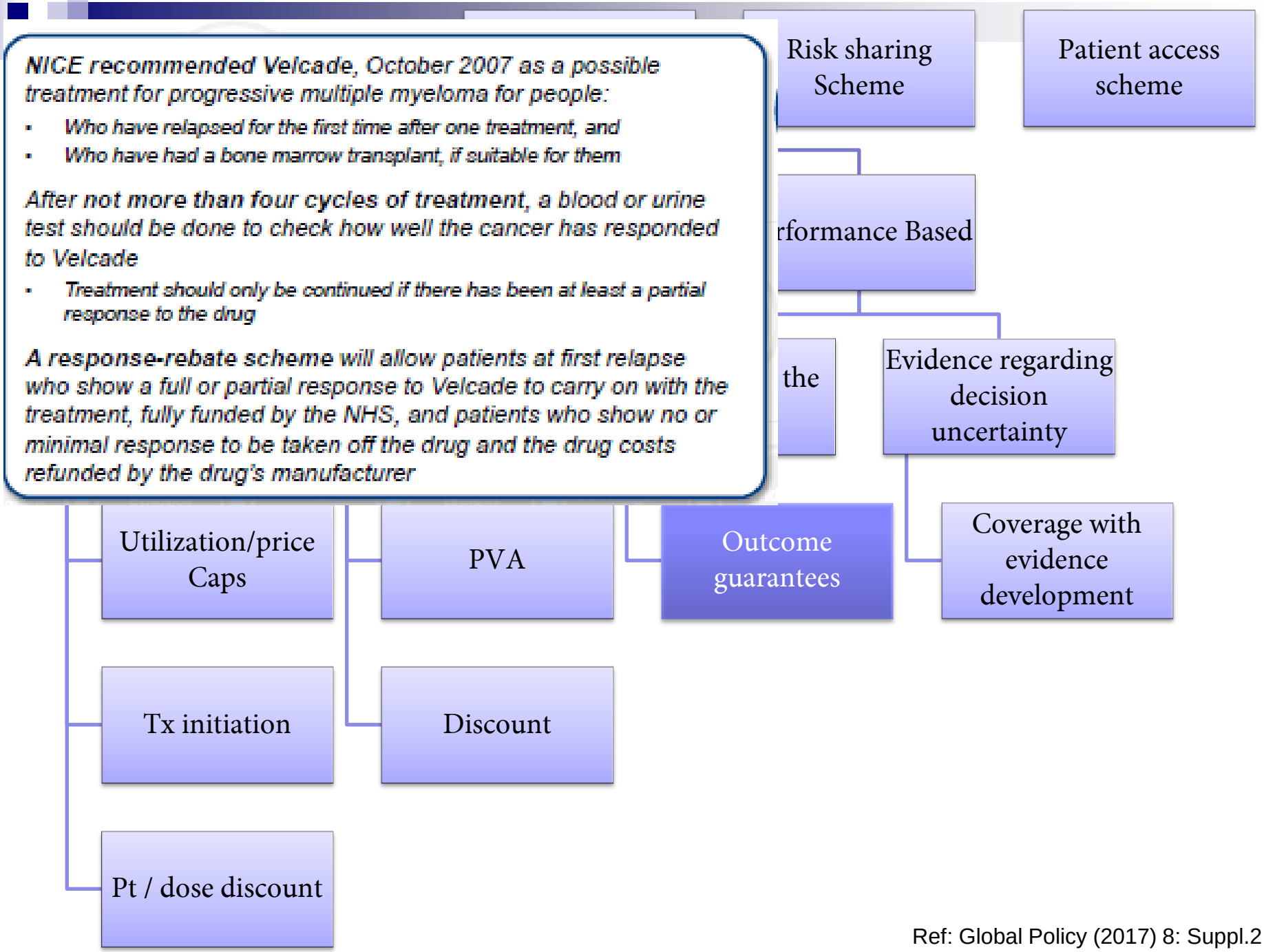
Almost the cost of entry, particularly for oncology therapies and many are CED whereby the company pays for first month+, 50% discount for first month+, etc. and then the SSN takes over if patient responds

Data collected through cancer registries [Italian oncology drug registry (RFOM)], which will soon be made publicly available

Italian oncology drug registry (RFOM) (all oncology drugs monitored and list below had or has a risk sharing deal)	
Avastin	Halaven
Sutent	Torisel
Sprycel	Removab
Tarceva	Mozobil
Tasigna	Jelvaina
Revlimid	Herceptin
Vectibix	Votriant
Tyverb	Jevtor
Nexavar	Arzerra
Torisel	Vidaza
Yondelis	Afinitor
Velcade	Thalidomide
Erbitux	Inossa
Alimta	...
Arranon	

And more...

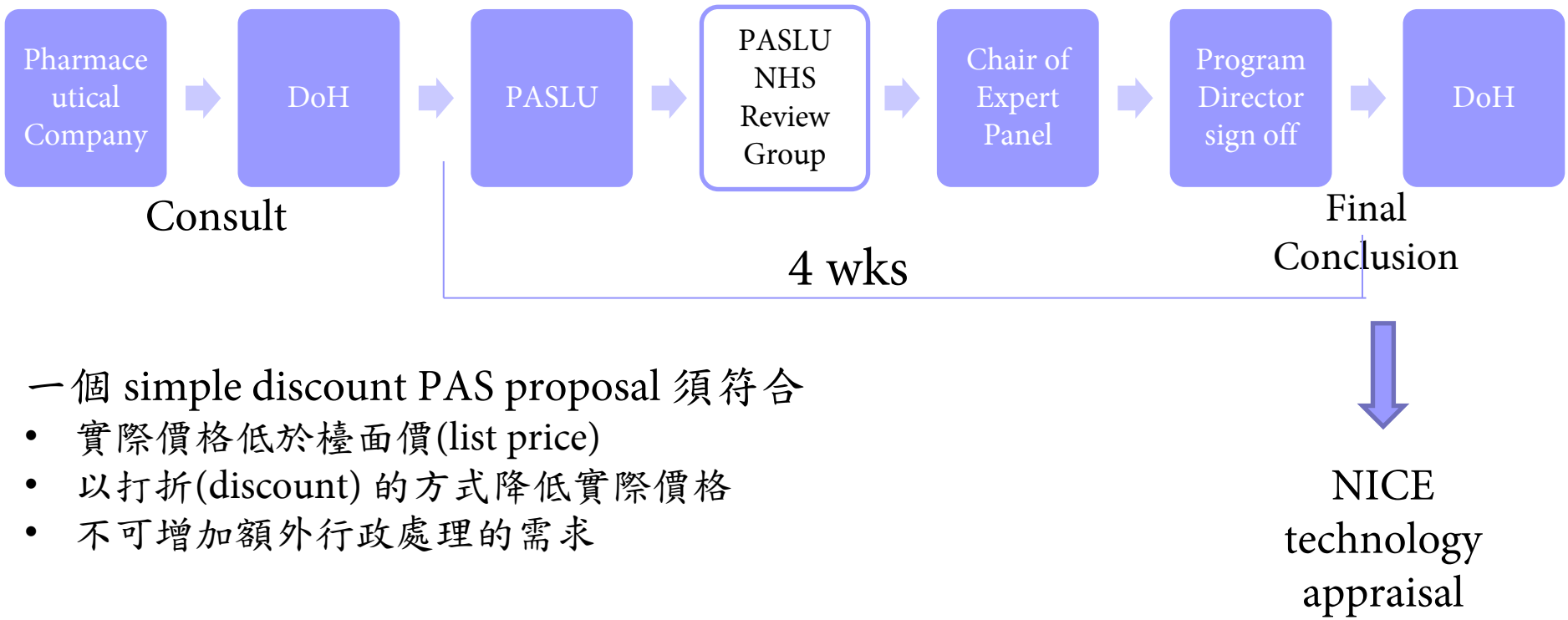
ource: http://antineoplastici.agenziafarmaco.it/info_generali.htm



Ref: Global Policy (2017) 8: Suppl.2

UK - PAS IMPLEMENTATION

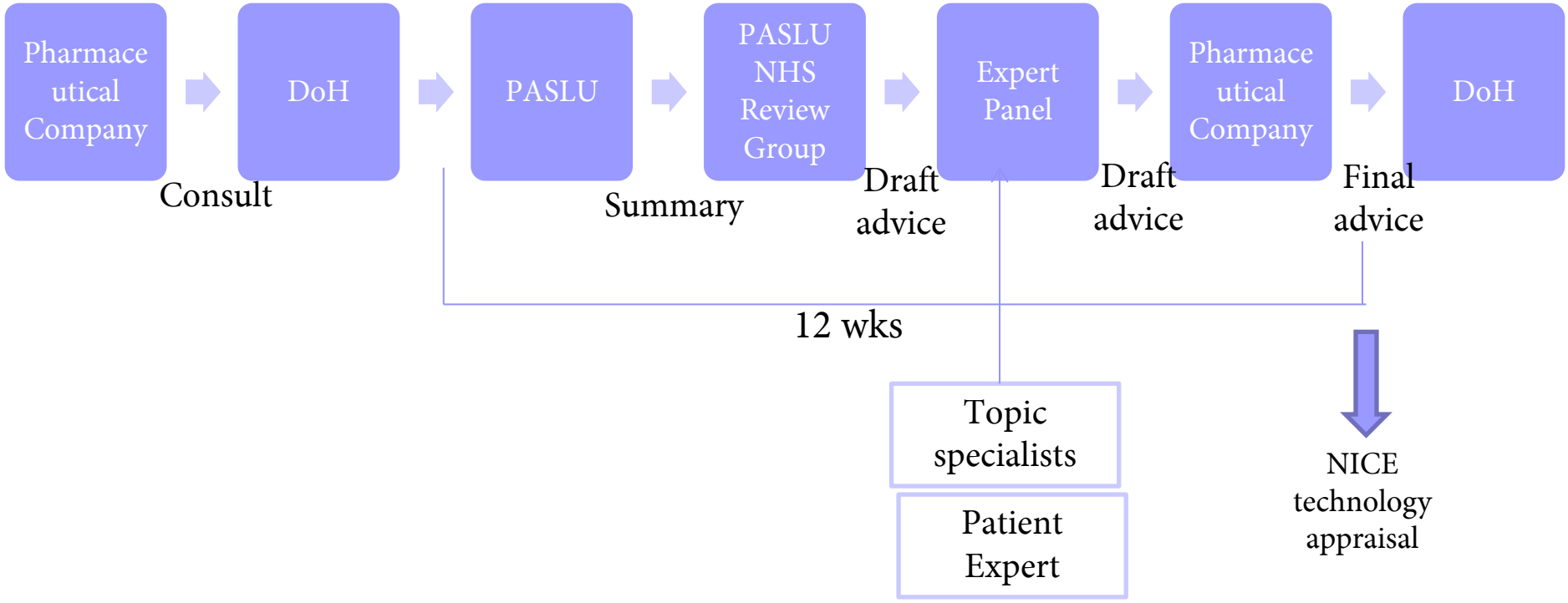
PAS Procedure
– Simple Discount PAS proposal



一個 simple discount PAS proposal 須符合

- 實際價格低於檯面價(list price)
- 以打折(discount) 的方式降低實際價格
- 不可增加額外行政處理的需求

PAS Procedure
– Complex PAS proposal

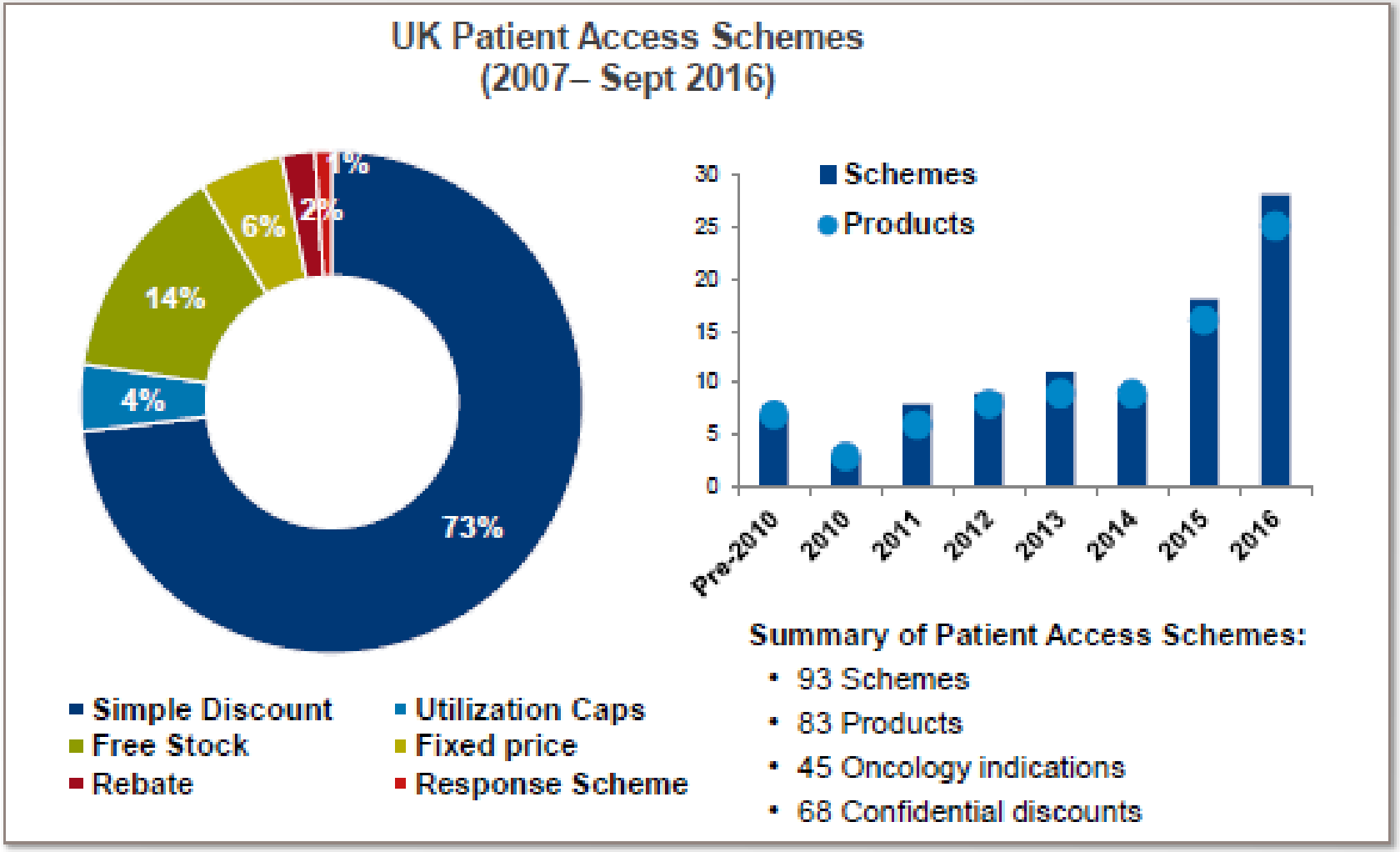


評估的目的：確實了解所提方案是否可在NHS的系統下執行

主要參與評估人員

- NHS Review Group:
  - 各領域專家(clinical, pharmacy, NHS finance, NHS commissioning)
  - 參與評估所提之方案並釐清相關問題
- Expert Panel:
  - 以個人身分參與，不代表任何組織
  - 了解執行PAS方式的NHS職員
  - 病患代表
  - 藥廠代表

"Risk sharing" schemes in the UK, referred to as patient access schemes (PASs), are typically financial-based & majority in oncology



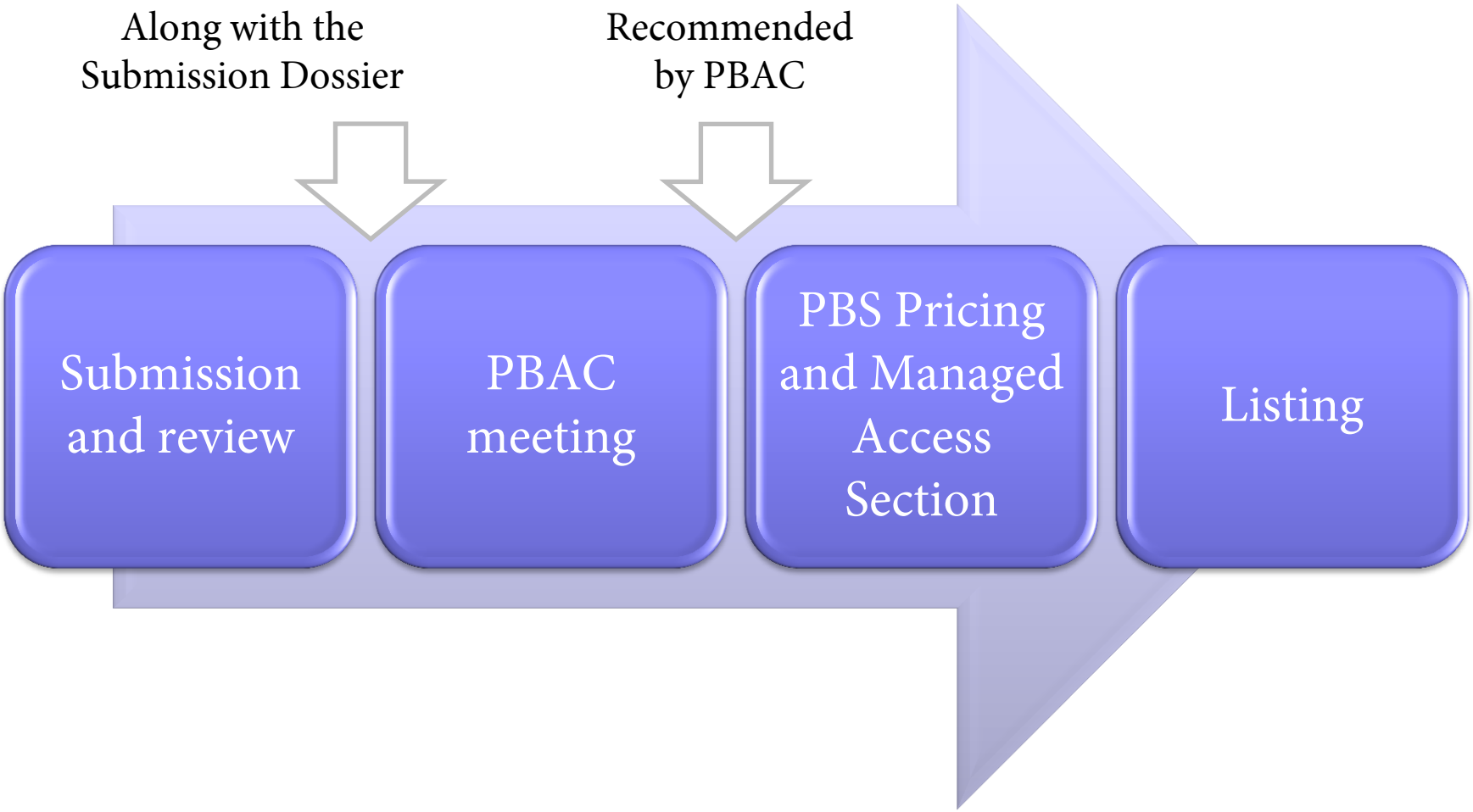
Source: Analysis of NICE Website

MAA: Managed Access Agreement

- 通常是針對罕藥或癌症用藥
- NHS提供有條件的給付
- 主要是針對藥品仍有額外資料需要收集
- 從2016年7月起，由CDF給付的藥品須有MAA
- 合約最長為5年，但可能會依資料收集時間長短調整

AUS - DEEDS OF AGREEMENT IMPLEMENTATION

When to Submit and Kick off the SPA/RSA/MAP Discussion



不同種類的合約用於解決不同的的問題，但皆是期待能使病患能盡早用到創新新藥

SPA: Special pricing arrangement	• 在以不影響其他國家藥價的前提下使澳洲居民可取得藥物給付 • 針對合約內容/方式保密

RSA: Risk sharing Arrangement	• 用以處理給付藥品後可能產生的不確定性，包括
	  • 成本效益
	  • 估計的用量
	  • 估計的整體花費

MAP: Managed Access Programme	• 使具有高度臨床需求，但仍有極高臨床或經濟層面不確定性的藥品可取得給付 將提供更多證據以對不確定的資訊提供解答

MEA 目前面臨的問題－UK 與Aus 處理的方式

	UK	Aus
Confidentiality	- 任何提供給 PASLU 的資料都須被保密 - 需先簽Confidentiality agreement - 有利益衝突的人須被排除在任何評估討論的階段 - MEA 的細節皆不會被公開	若廠商告知若將相關資訊公開會導致公司顯著的財務損失，則相關訊息會被保密
Voluntary	在廠商自己估算且希望符合ICER值下提出	- 由PBAC 或衛生部建議廠商提出 - 由廠商自主提出較為常見
Scheme proposed by	由廠商自行提出方案	由廠商自行提出方案
Review or Negotiation	- PASLU 評估方案的可執行性 - 所提出的PAS會包含於 NICE 的 technology appraisal 中	由衛生部的官員代表政府與廠商討論
Duration of the agreement	持續到下一次guidance 修改時	- 一般是五年 - 會考量原本簽訂合約的因素是否仍舊存在

Risk-Sharing Agreements Can Be Win-Win

Payers	• Reduce uncertainty regarding clinical value, performance and financial impact of a new product
Manufacturers	• Differentiate and demonstrate the value and effectiveness of their product
Consumers	• May gain earlier/easier access to treatments
Society	• Moves towards value-based purchasing

感謝聆聽