Pharmaceutical contracting and price negotiations

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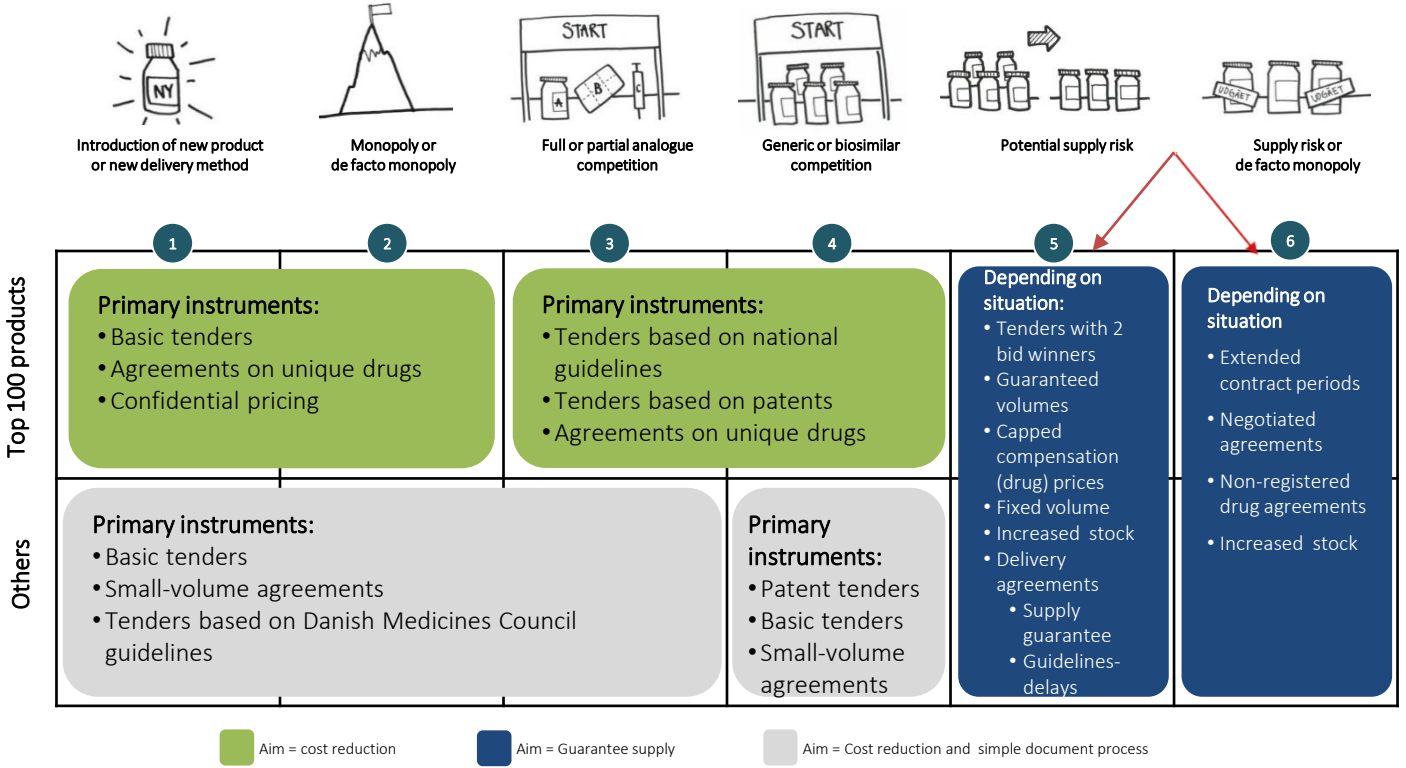
Different contracting mechanisms applied based on competitive market dynamics…



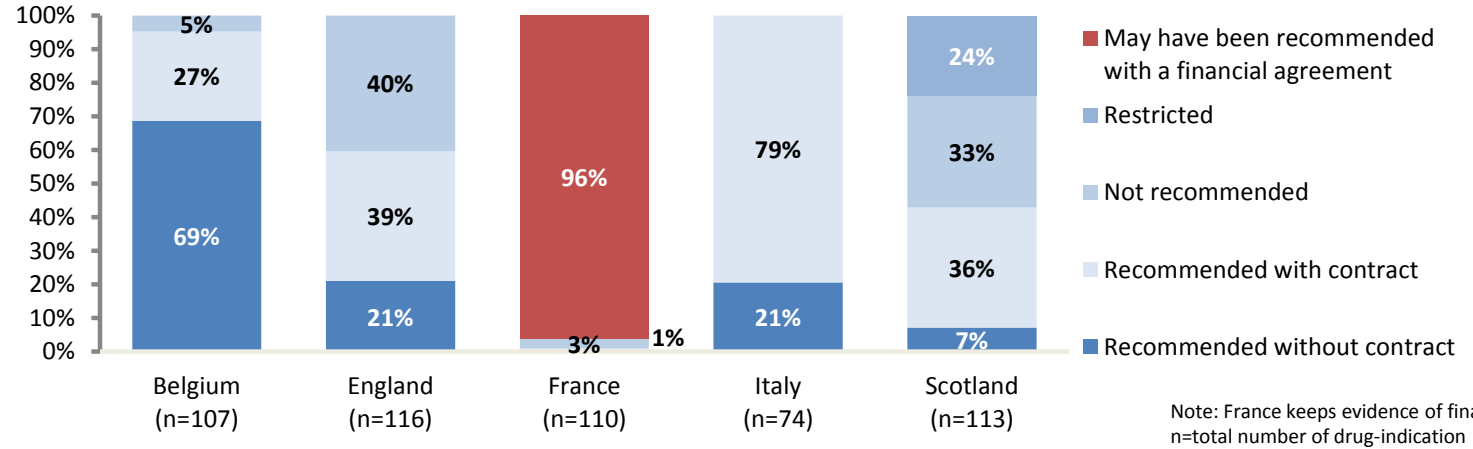
Source: Amgros, unpublished presentation at the WHO consultation on strategic procurement (Sept 22-23, 2016) in Copenhagen, Denmark

…and HTA uncertainties over evidence

- Health Technology Assessment (HTA) agencies have concerns over the clinical impact (product profile), actual patient need, and economic impact of new drugs
- Government agencies rely on various contracting mechanisms to protect national budgets
- Financial arrangements account for most contracts due to simplicity and lower administration costs

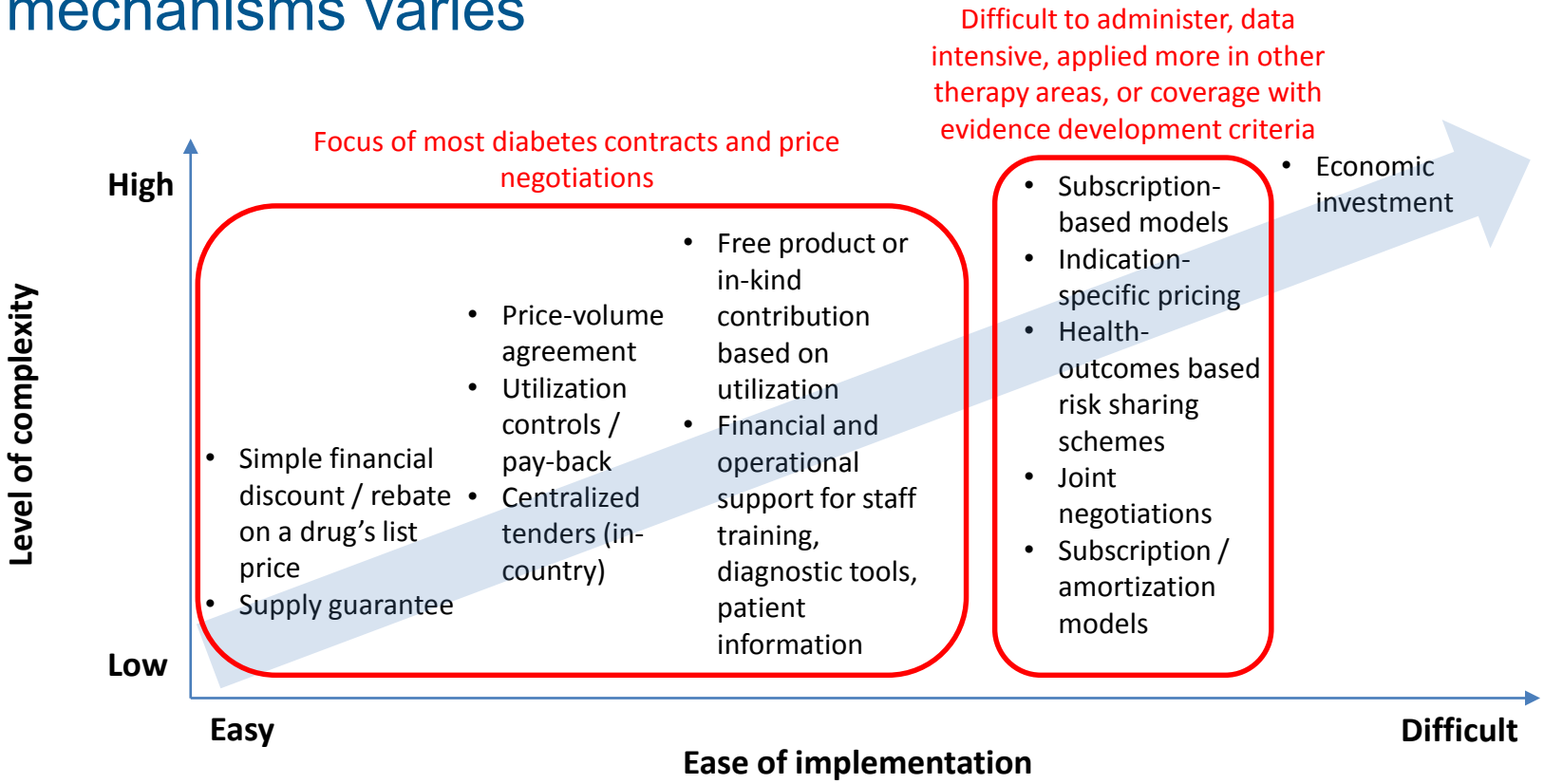
Most HTA agencies recommend fewer drugs or have confidential financial contracts

(Percentage respondents)



Note: France keeps evidence of financial contracts confidential / n=total number of drug-indication pairs studied 2012-2016.
Source: LSE, March 2017.

Complexity and ease of implementation of contracting mechanisms varies



*Contracting mechanisms also called managed entry agreements "MEA"

Tender approaches – select country criteria and practices

Poland (encouragement of generics and biosimilars use):

- Tenders are mandatory (hospital and outpatient) and cover a group of drugs with the same active ingredient. EU tender thresholds apply
- Non-exclusive tenders result in inclusion of both the reference medicine and its generic/biosimilar into the formulary, enabling physician and patient choice

Denmark (small market):

- Centralized pharmaceutical procurement for the five regional authorities on a voluntary basis
- All tenders are issued by a public-sector organization owned by the regions
- Created economies of scale achieving administrative savings approx. DKK 2.8 billion annually (2016)

Hungary (create a competitive market):

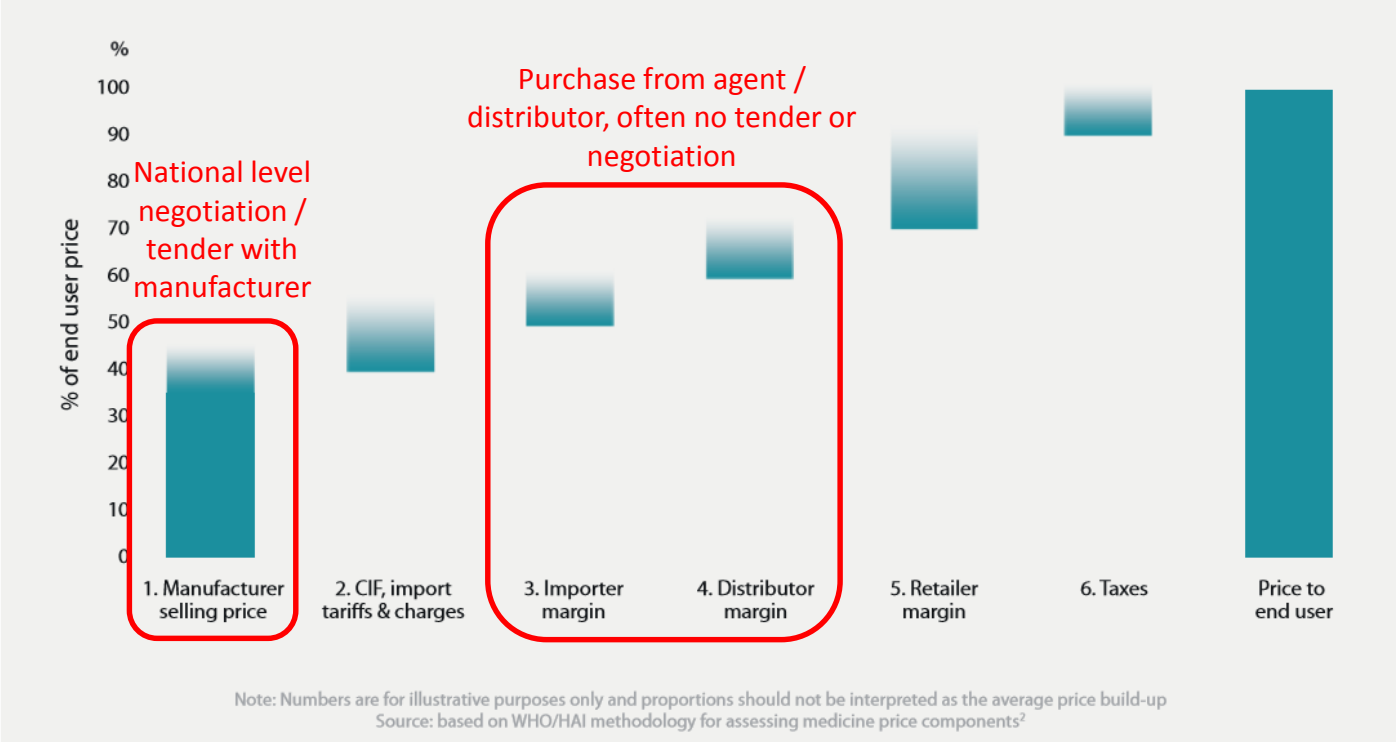
- 2011 – Introduced blind bidding through an electronic system (biolicit process) for a biologics tender – up to two winners; different co-payments for other medicines depending on price

Italy (promote competition):

- A new tender must be made within 60 days of first biosimilar market entry

Source: - IGBA and - Vogler S, Gombocz M, Zimmermann N.: Tendering for off-patent outpatient medicines: lessons learned from experiences in Belgium, Denmark and the Netherlands. In: Journal of Pharmaceutical Health Services Research, 2017

Where along the value chain you are purchasing from / negotiating with impacts negotiation opportunity



Contract and negotiation preparation

Key considerations

Internal (Member State)

1. Health system

- How is healthcare financed and budget determined
- Treatment dynamics (e.g. standard clinical guideline) or changes to policies / clinical practice expected

2. Strategic importance of medicine to population

- Patient population targeted, financial value of contract, budget impact, reimbursement level expected

3. Legal

- What are the existing laws / regulations related to ability to conduct negotiations?
- Prioritization - is there a legal requirement to review each medicine proposed for pricing and reimbursement?
- Procurement approach (centralized, decentralized, donation) and by whom

4. Capabilities

- Internal capabilities (technical, data collection, and administrative), governance

Contract and negotiation preparation

Key considerations

External (Market Environment)

- Payer power and market attractiveness of Member State to the manufacturer (financial value of contracts)
- Market situation of medicine proposed for pricing and reimbursement (e.g. competing therapies to late stage pipeline, product going off patent, availability of generics / biosimilars, line extension)
- Entity (e.g. manufacturer, intermediaries – wholesaler) that is selling the medicine directly to the payer / hospital / pharmacy
- Target listing objective (e.g. reference pricing) and destination of medicine (public and/or private market) by the manufacturer

Opportunities in eastern Europe and central Asia

- **Review diabetes portfolio of medicines** – analogues/human insulin; biosimilar availability and alternatives; alignment to WHO essential list of medicines; supplier options
- **Enhance negotiating power through centralized procurement and tenders / negotiations** – decentralized procurement in some countries at regional/pharmacy level in supply agreements with wholesalers for inpatient/outpatient medicines
- **Determine ability to create a competitive market** – few suppliers for this region inclusive of domestic and international manufacturers.
- **Apply other available pricing / reimbursement policies and tools as it influences negotiation approach and outcome** (e.g. governance – medicine appraisal and price negotiations, price controls, price revisions, reimbursement levels vs out of pocket spend)

Price negotiation considerations and manufacturer objection handling for insulins

Key considerations	Manufacturer pricing implication and potential response	
Level of market competitiveness and guarantee of supply	Key price benchmark in therapy area / indication	Promote biosimilar competition of insulins through abbreviated pathways; duration of agreement
Impact of formulation and dosing on pricing (e.g. flat / tiered pricing)	Need to explore options to narrow the list price gap	Determine additional value of delivery mechanism and dosing options in the population for various human / analogue insulin types
Product with low unmet need, high budget impact, unfavourable cost-effectiveness	Put more pressure on class pricing, especially net price vs individual product	Consider other diabetes management tools beyond the product to reduce focus on class (e.g. insulin, GLP-1, SGLT2) pricing
Narrow indication than intended label due to budget impact	Consider impact of future label expansion	Use of HbA1c level and other endpoint measures to monitor outcomes and financial impact. No commitments
Timing of negotiation	Balance speed to access and optimal price	Delay product review if competitive product will come off-patent, other pipeline products coming to market to increase competition
Internal/external referencing pricing and parallel trade	List price setting and launch sequence optimization	Most EECA countries are not part of core launch plans for pharmaceutical companies – focus on private market or national tender. Consideration to negotiate/procure as a collective under Eurasian Economic Union or other group