Pricing and Market Access Considerations in Changing from Vial to Pre-Filled Syringe Packaging: EU5 and beyond

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BACKGROUND

- Changing from a vial-based formulation to a pre-filled syringe (PFS) is an increasingly common part of life cycle management (LCM) in the pharmaceutical industry[1]
- The rationale for launch of a PFS formulation is typically driven by three aspects:

1) **Market Driven** – desire to gain a competitive advantage, gain market share, and/or negotiate a premium price
2) **Customer Driven** – improved safety and accuracy of administration, as well as the possibility to self-administer. Ease of use is valuable for prescribers and healthcare professionals
3) **Product Driven** – LCM, increase of revenue due to less vial wastage

- The ability of a PFS launch for an existing product to drive revenue growth through market share increase and/or price premium makes it a logical LCM consideration

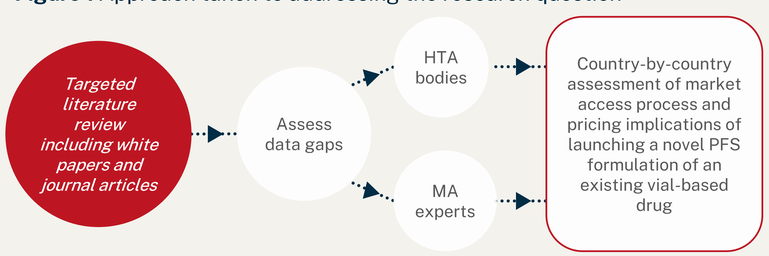
OBJECTIVE

- The objective of this poster is to assess the market access requirements and to analyse the pricing implications for the launch of a PFS formulation of an existing vial-based drug in selected EU markets

METHODS

- A targeted literature review was carried out using Medline, Embase, and Cochrane, as well as internal databases. (Figure 1)
- Email and telephone discussion with HTA bodies and national market access experts provided further insight
- The scope was EU5 (Germany, UK, France, Spain, Italy), as well as a number of additional markets (Netherlands, Sweden, Norway, Czech Republic, Ireland, Finland, Slovakia, Poland)
- Cogentia's internal pricing database was analysed to inform pricing outcomes of a number of case studies across markets. This data analysis was used to support the pricing implications component of the research question
- A range of case studies were analysed, including but not limited to: Nucala®, Lucentis®, Abilify Maintena®, Bydureon®, Xolair®.

Figure 1 Approach taken to addressing the research question



RESULTS

- **EMA / Regulatory level** – moving from a vial to a PFS is likely to be handled as a Type II variation[2]

EU5:

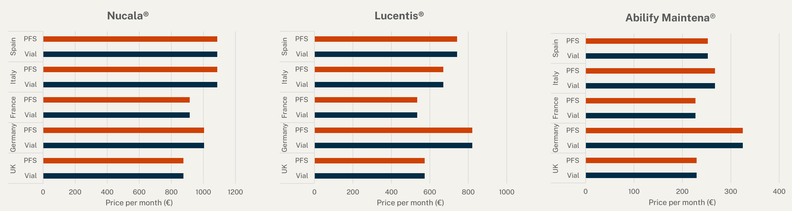
- The procedure for moving from vial to PFS displayed a degree of consistency across the EU5 (Table 1)
- UK, Germany, and France typically do not require HTA submissions for a re-formulation unless a claim of added value is made. If a premium price is sought, added value should be demonstrated in the form of hard outcomes from an RCT. Patient preference studies have little impact on payers

Table 1 Process, risks and considerations when moving from a vial-based formulation to PFS in the EU5

Country	Market access process	Price implication
	A new formulation notification to NHSEngland will be sufficient in most cases. A case would need to be made for price premium, and would have to be considered within the NICE scoping process	Price parity is the expected outcome without added value
	In Germany there is no HTA for new formulations of active ingredients already authorised in the same indication, unless a benefit is supported in RCT. Submit a variation dossier to BfArM	Price parity without the requirement for benefit assessment by the G-BA
	An abbreviated dossier submitted to HAS stating this is a new presentation with no additional value requested. Purely an administrative exercise.	Price parity is the likeliest outcome. For price premium hard outcomes should be demonstrated in RCT
	A light dossier should be submitted to AIFA CTS requesting a new SKU. Likely to be an administrative exercise	Price parity the expected outcome, unless submission coincides with automatic price re-negotiation
	Submit a brief dossier describing the pharmacokinetic studies requesting a new registration number	Vial to PFS is likely to be deemed a simple reformulation resulting in price parity

Abbreviations: AIFA CTS, Agenzia Italiana del Farmaco Commissione Tecnico Scientifica; G-BA, Federal Joint Committee; HAS, Haute Autorité de santé; HTA, Health Technology Assessment; NICE, National Institute for Health and Care Excellence; PFS, Pre-Filled Syringe; RCT, Randomised Controlled Trial; SKU, stock keeping unit.

- The main risk is that the application could be used as a trigger for a re-negotiation of price. Mitigating that is that a better presentation should support the product differentiation.
- **Budget Impact:** an important consideration. Will this new formulation open up a larger market and therefore impact budgets?



Prices extracted from Cogentia's internal pricing database. Accessed 28th April 2020. All prices ex-factory. Sample country case studies used for the demonstration of price parity as a consistent outcome of movement from vial to PFS rather than for the purpose of cross-country comparison.

- Case studies in multiple therapy areas including respiratory, ophthalmology, and psychiatry demonstrate price parity is the most common outcome when launching a PFS formulation of an existing drug
- Interestingly, a number of case studies involved companies withdrawing the vial from the market, likely to promote the move over to the PFS
- This pattern of price parity was consistent across all markets in scope

Table 2 Additional markets follow a similar pattern to the EU5 when assessing a re-formulation

Country	Market access process	Price implication
	Reformulations not usually assessed by TLV if price parity or reduction requested,	Price parity the likeliest outcome on the drug benefit scheme
	An administrative task requesting a new GPK code, no extensive assessment by CieBAG	Price parity the likeliest outcome
	Assuming HSE determine it is a simple reformulation, no rapid review is required	Applying for price parity may avoid the need for a rapid review
	NoMA assess quality aspects and assuming a simple reformulation no need for assessment	Maximum price likely to remain the same as the vial[3]
	SUKL will generally decide within a 30 day timeline on requirement for assessment, but unlikely	Proposed price should be in line with the price of the vial[4]

Abbreviations: CieBAG, Add-on Drugs Assessment Committee; GPK, Generic Product Code; HSE, Health Service Executive; NoMA, Norwegian Medicines Agency; SUKL, State Institute for Drug Control; TLV, Dental and Pharmaceutical Benefits Agency

DISCUSSION

- Price parity was by far the most common pricing outcome when moving from a vial-based formulation to a PFS, likely owing to payers consideration that this is a simple re-formulation based around patient preference.
- Whilst we observed one or two country-specific examples of a price premium being obtained when moving from vial to PFS (e.g. Abilify Maintena in a few markets), there were no examples of a price drop
- Price analysis was based on list price, and so there is no analysis or interpretation of the effect PFS has on confidential discounting

CONCLUSIONS

- The market access process for launching a PFS formulation of an existing vial-based drug appears consistent across Europe, typically requiring a Type II variation at the EMA level followed by an abridged P&R procedure
- Price parity is the most common outcome. This may be as a result of patient preference LCM moves being difficult for payers to value
- Given price premium is relatively rare, commercial reason for launching a PFS should focus on a competitive advantage that drives uptake and market share rather than an increased price
- When forecasting for a PFS launch, recent case studies suggest that UK, Germany, Sweden, Czech Republic, and Norway are markets where launch may be expedited, as demonstrated by Nucala PFS/autoinjector launch
- Further research could be useful to understand whether a price premium could ever be justified moving from vial to PFS, and how this could be achieved

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