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New Proposed European Commission Pharmaceutical Regulation – Potential Changes and Impact on Manufacturers with a Focus on Eastern & Southern European Member States

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OBJECTIVES

- To evaluate the proposed pharmaceutical legislation in the EU and assess the practical implications on market access for manufacturers
- To critically assess the new criteria for the Regulation Data Protection period, and their use in practice

METHODS

We compared proposed legislation with the current environment using Harvoni® as a benchmark for its curative potential and cost efficiency in treating hepatitis C, but above all, because it was the biggest drug launch of 2014/15 in terms of revenue. Our focus is Eastern (Bulgaria, Czech Republic, Hungary, Poland, Romania, Slovakia) and Southern (Croatia, Cyprus, Greece, Italy, Malta, Portugal, Slovenia) EU Member States (MS). Data on Harvoni access are current as of Sept' 23.

PROPOSED NEW LEGISLATION[1,2]

- The baseline Regulation Data Protection (RDP) period for pharmaceutical products in the EU is proposed to reduce **from 8 to 6 years**
- Additional RDP extensions may apply based on certain criteria:
  - Products addressing an Unmet Medical Need (UMN) at initial marketing authorization **(+ 6 months**)
  - Products with a new active substance AND comparative clinical trials **(+ 6 months**)
  - Products supplied in sufficient quantity and necessary presentations within 2 years (or 3 years for small and medium-sized enterprises, not-for-profit, and inexperienced companies) of marketing authorization in all Member states (MS) **(+ 2 years**)
  - If a new therapeutic indication with significant clinical benefit is authorized during the RDP period **(+ 1 year**)

RESULTS

Table 1. Harvoni® Market authorization and access across all MS as of Sept'23[3,4,5]

Indication	EMA MA Date	% MS Access overall	% MS Access overall in E/S MS	% MS Access in E/S MS in <2 years
Chronic hepatitis C in adult and paediatric patients ≥ 3y	17/11/2014	75% (21/28)	92% (12/13)	15% (2/13)

- **Supply Issues: Not identified**
- **Addresses UMN** ✓
- **New active substance and comparative trial data:** ✓
- **New therapeutic indication with significant clinical benefit: x** (no new therapeutic indication)

Proposed New Regulations

Under new legislation, if launched now and based on historic performance, Harvoni® would achieve a net RDP of 7 years vs. current option of up to 12 years[5], reducing the opportunity to maximize the return on investments.

Table 2. Potential Harvoni® RDP under new regulations

Elements affecting RDP	Harvoni® RDP
Base level RDP	6 years
Products addressing UMN at initial MA	0.5 years
Products with a new active substance AND comparative clinical trials	0.5 years
Unlikely to achieve the 1-year extension for continuous supply to all MS within 2 years	0 years
A new therapeutic indication with significant clinical benefit is authorized during the RDP period	0 years
Total	**7 years**

E/S MS: Eastern/Southern Member States; MA: Market Access; RDP: Regulation Data Protection; UNM: Unmet medical need

IMPLICATIONS

Member States: Health Systems

- New legislation encourages consistency in drug availability and supply across Eastern and Southern MS, which currently, often experience delayed access vs. other MS
- Potentially have a supply of new innovative medicines within 2 years of launch in the EU for all MS provided HTA procedures are done in a timely manner
- There is an incentive to launch in all MS with no limitation to Western and Northern MS. Equal access is being promoted, but ultimately, it is the MS that determines the timelines of access to innovative therapies across the EU
- Failing to provide continuous supply to all MS could enable generics and biosimilars to be brought to markets earlier

Manufacturer:

- Failing the eligibility criteria for prolonged RDP could result in limited return on investment and unwillingness for investment in Europe
- The extensions will not be confirmed until the MA filing, causing lack of certainty to factor RDP considerations into cost/benefit analyses during the product development
- Manufacturers with no local presence in Southern and Eastern MS may struggle with navigating different drug assessment processes, especially in Eastern and Southern MS with less developed HTA procedures

Key: Negative Impact; Neutral or Mixed Impact; Positive Impact

CONCLUSIONS

It may be difficult to achieve the maximum RDP under the proposed new EU regulations. Our evaluation indicates that, despite meeting some criteria for a prolonged RDP period, Harvoni® would only have attained a maximum of 7 years of exclusivity, forfeiting on an additional 2-year extension for continuous supply to all MS, particularly as in most Southern and Eastern MS, the process of achieving pricing and reimbursement for Harvoni® exceeded 2 years. If Harvoni®, which is arguably one of the biggest treatment innovations in recent years, does not attain the full 10-year RDP exclusivity, lesser treatments may also fall short of attaining the RDP exclusivity. Manufacturers of other impactful medicines may feel the need to offset the reduced time to maximize the return on their investment by potentially increasing prices. Some manufacturers may be more cautious about investing in Europe, potentially delaying or limiting access to innovative drugs for European patients. Launching of innovative drugs should be incentivized across all MS, and both payers and manufacturers need to work collaboratively to provide uniform access to patients in all MS.

The EU will need to consider how policy changes are going to affect both the smaller MS and manufacturers as this will be a challenge for payers and manufacturers alike and could make Europe less attractive for launching new medicines.

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