

Note on Transferable Vouchers

April 2022

The European Commission has been considering introducing novel rewards to incentivise development of orphan and/or paediatric medicines, or to better address unmet medical needs, including for antibiotics. In particular, among different options, the EC has been evaluating the introduction of transferable vouchers for priority review or regulatory rewards¹, potentially complementing existing incentives.

A form of transferable vouchers exists in the US and is being referenced in EU policy discussions for the possible introduction of transferable vouchers in the EU. However, **transferable vouchers in the US are ONLY for priority review** (ie. accelerated approval), **there is NO such voucher extending regulatory or IP exclusivities.**

As explained below and demonstrated in independent studies, the introduction of transferable exclusivity vouchers in the EU would

- **break the founding principle of the relationship between innovation and reward**
- **frustrate the legitimate expectations of generic/biosimilar manufacturers**
- **extend monopolies on more profitable products that would not otherwise qualify for that extension**
- **unduly delay access to generic and biosimilar medicines for patients**
- **dramatically increase costs for healthcare budgets, with significant risk of overcompensation especially if the development for instance of an antimicrobial would have taken place anyway**
- **be unfair towards those patient categories that would bear the financial burden for an innovation they do not use**
- **increase legal uncertainty & unnecessary litigation, including for users of SPC manufacturing waiver, which need predictability for their investment plans**

The US Approach

Transferable vouchers exist in the US under the FD&C Act, section 529. According to the United States FDA guidance for industry on [“Rare Pediatric Disease Priority Review Vouchers”](#), an applicant for a rare paediatric disease product application may be eligible to receive a **transferable priority review voucher and could be used exclusively to accelerate the FDA review process. It does NOT provide regulatory nor IP exclusivity extension.**

The European Union Approach

The European Commission has been assessing the possibility of amending the pharmaceutical legislation as well as [Regulation for rare diseases](#) and [Regulation for medicines for children](#). In particular, for addressing unmet medical needs, including for antibiotics, medicines for children and for rare diseases, the Commission is exploring different options² that would include “novel rewards” comprising transferable data and market protections or potentially other forms of exclusivities.

Such approach would take distance from the US model, whereby transferable vouchers just allow a priority review. **The Commission’s proposal does NOT reflect the FDA approach and suggests that these vouchers may also extend the regulatory exclusivity of a specific product on the market³**, not excluding that the vouchers could complement the existing exclusivities. This approach proposing additional protections to the already existing ones rather than alternative incentives would certainly present serious fundamental concerns around timely and equitable access to treatments for patients and the negative impact on healthcare budgets and the balance of the whole system.

¹ [European Commission, Inception Impact Assessment – Medicines for children & rare diseases](#)

² Ibid

³ Ibid footnote 1

What independent studies say

A [study by the Slovenian Presidency of the EU and the EU-JAMRAI](#), quoted in the [EPSCO Conclusions on strengthening the European Health Union](#), includes transferable exclusivity vouchers among the “**discarded pull incentives**”, since whereas they “*may be straightforward to implement, in the end, the cost of these vouchers to healthcare systems is anticipated to far exceed the cost of revenue guarantees*”⁴.

Another study, “[Pull Incentives for Antibacterial Drug Development: An Analysis by the Transatlantic Task Force on Antimicrobial Resistance](#)”⁵, analysed the best possible incentives for novel antibiotics, stressing that “**a tradable exclusivity voucher would be used to extend the exclusivity period of the most profitable drugs in the market. The price paid for such a voucher would be high, probably in the range of billions of dollars**”, concluding that “*they are an inefficient mechanism for promoting innovation*”, as it “*would be funded by the purchasers of the drug whose monopoly period is extended*”, representing “**a disproportional level of subsidizing one area of healthcare at the expense of another**”. It would have a “**negative impact on patient care, by delaying the generic entry (and therefore lower prices) of more widely used medications. The overall cost of this incentive, from both societal and healthcare perspective, may be too great. Finally, tradable exclusivity vouchers do nothing to ensure appropriate use, because the return on investment of the antibiotic remains directly proportional to its volume sold and/or used.**”

What it would mean in practice

Taking some of the EU most profitable blockbusters of the recent years, an additional period of exclusivity on these products (eg. **1 year**) **would translate in the following additional costs for EU healthcare systems:**⁶

- ✓ **Adalimumab (Humira®): to treat rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis**
Costs in 2018: €3.8 billion – Costs in 2019(after biosimilar competition):€2.8 billion → **€1 billion lost savings**
- ✓ **Trastuzumab (Herceptin®): to treat breast cancer and stomach cancer**
Costs in 2018: €1.6 billion – Costs in 2019 (after biosimilar competition): €1 billion → **€600 mln lost savings**
- ✓ **Rituximab (MabThera®): to treat certain autoimmune diseases and cancers such as non-Hodgkin lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis**
Costs in 2018: €965 mln – Costs in 2019 (after biosimilar competition): €632 mln → **€333 mln lost savings**

Conclusion

While Medicines for Europe supports incentives for medicines for children and rare diseases, the introduction of transferable vouchers extending regulatory or IP exclusivity of (most remunerative) products would:

- i)** break the founding principle of the relationship between innovation and reward
- ii)** frustrate the legitimate expectations of generic/biosimilar manufacturers
- iii)** hinder timely access to market for generic and biosimilar medicines for the most expensive products;
- iv)** dramatically increase healthcare systems expenditures, with significant risk of overcompensation;
- v)** be unfair towards the patient categories that would bear the financial burden for an innovation they do not use;
- vi)** increase legal uncertainty and unnecessary litigation, including for users of SPC manufacturing waiver, which need predictability for their investment plans.

Therefore, it is of utmost importance that the European Commission would consciously evaluate all the different aspects and potential downsides of the introduction of transferable vouchers extending IP/regulatory exclusivities.

⁴ *Improving Access to Essential Antibiotics*, by the Slovenian Presidency of the EU and the EU Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI), available [here](#).

⁵ *Clinical Infectious Diseases*, Volume 65, Issue 8, 15 October 2017, Pages 1378–1382, <https://doi.org/10.1093/cid/cix526>. The study concludes that the best solutions would be market entry rewards, like delinkages or new pricing models.

⁶ Considering available data for 2018. MIDAS Quarterly Audit from Q2/2018 to Q1/2021