

## **France Assos Santé position on the protection of intellectual property rights in the framework of the revision of the EU pharmaceutical package**

*26 September 2024*

### **1. Limiting basic regulatory data protection**

France Assos Santé supports the following principles :

- Reducing the duration of basic regulatory data protection,
- Conditioning any additional month of data protection to the respect of different rules,
- Limiting the maximum duration of intellectual property rights to 10 + 1 years: 8 years for regulatory data protection + 1 year for a (single) new indication if significant clinical benefit + 2 years for market protection.

### **2. Conditions for extending regulatory data protection**

France Assos Santé supports the extension of regulatory data protection in 3 cases:

- For medicinal products containing a new active substance, when the marketing authorisation application is based on comparative trials with a clinically relevant comparator,
- For medicinal products addressing an unmet medical need,
- When a significant part of the R&D is carried out within the EU and at least in part with public entities.

France Assos Santé supports the effective marketing of medicinal products in all Member States based on the following scheme:

- Obligation for marketing authorisation holders (MAH) to request a price and reimbursement in all Member States that ask for it; AND
- Shortening the regulatory data protection period in countries where the product is not marketed within 2 years after the Member State's request to the MAH.

### **3. Encouraging the development of new priority antimicrobials**

We recognise the need to encourage the development of new 'priority' antimicrobials offering a significant clinical advantage in terms of antimicrobial resistance.

France Assos Santé is opposed to the setting up of transferable exclusivity vouchers for the following reasons:

- They have not been proven to be effective,
- Their cost is unpredictable and potentially very high for social security systems<sup>1</sup>,
- They risk limiting access to the medicines to which they will be transferred.

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<sup>1</sup> The more expensive the medicine to which exclusivity is transferred, the more profitable the sale of the voucher will be.

We propose to set up a system of conditional and phased funding for the development and marketing of priority antibiotics coupled with advance joint purchasing, providing the developer with a revenue guarantee that is partially or totally uncoupled from the volume of sales.

- These bonuses will be paid thanks to an upgrade of the European Commission's resources (in particular the Horizon and Health programmes).
- This mechanism requests the adoption of delegated acts to set up the system of staggered payments.