

SME status Incentive table for Orphan medicinal products



Fee incentives	Orphan medicinal product + applicant non-qualified SME	Orphan medicinal product + applicant qualified SME
Protocol assistance	<ul style="list-style-type: none"> 75% reduction of the total applicable fee (non-paediatric-related*) 100% reduction of the total applicable fee (paediatric-related*) 	100% reduction of the total applicable fee
Inspection (pre-authorisation)	100% reduction of the total applicable fee	100% reduction of the total applicable fee
Application for a marketing authorisation	10% reduction of the total applicable fee	100% reduction of the total applicable fee
Scientific services	Not applicable	100% reduction of the total applicable fee
Post-authorisation activities, including annual fees, during the first year after marketing authorisation	Not applicable	100% reduction of the total applicable fee
Inspection (post-authorisation)	Not applicable	90% reduction to the total applicable fee

* There is an obligation to submit the results of studies conducted in compliance with an agreed paediatric investigation plan (PIP). If not available, your application for a new marketing authorisation cannot be validated, and consequently, its assessment cannot be initiated.

* Given the time and cost involved in developing a medicinal product, the benefits and incentives available to SMEs are considered significant, and we believe Manufactures would be well advised to take full advantage of them.