"SUNSET CLAUSE"
REQUEST FOR PUBLIC HEALTH EXEMPTION FROM INVALIDATION OF A MARKETING AUTHORISATION

Please complete and return one copy of this form for each PL number for which you wish to apply for a public health exemption..

The medicinal product listed below have not been marketed in any presentation since the date shown below.

[Product name, PL number, date]

We understand that the Marketing Authorisation will potentially become invalid three years beyond those dates in accordance with Articles 24(4) and 24(5) of the Directive. The Marketing Authorisation holder [company name] _____

requests an exemption from invalidation on the following public health grounds exceptional circumstances (in accordance with Article 24(6). (Please tick at least one box and as many as apply)

	The Marketing Authorisation applies to a product	Period for which MA will continue to be valid
☐	1. Which is a medicine where lack of suitable alternative suppliers or alternative treatments mean there is the potential for adverse impact on public health	3 years
☐	2. Which would be a medicine held as part of emergency preparedness arrangements	3 years
☐	3. Which is a medicine used in a critical care setting	3 years
☐	4. Which is intended for certified export for the use of patients in third countries	3 years
☐	5. For which there is an on-going procedure affecting the marketing authorisation critical for placing the product on the market	1 year
☐	6. For which there is an on-going planned change in manufacturing site or process and continued authorisation is required to ensure future supply to patients	1 year
☐	7. Which is subject to regulatory activity related to company mergers and acquisitions or to change of ownership of the marketing authorisation (both companies involved need to apply)	2 years
☐	8. Which is required to ensure future availability from a choice of suppliers of the same medicine for the NHS.□	1 year
☐	9. Which is a product that cannot be placed on the market for Intellectual Property reasons	Up to 3 years
☐	10. Which has been used as the cross-reference product for parallel import products and is required to support continuity of supply	1 years

☐	11. Which has been used as the reference product for use in clinical trials as a non-investigational medicinal product	2 years

It is the responsibility of the applicant to ensure that the above information is a true representation of the situation and to inform the MHRA if any of the exceptional circumstances should change.

Declaration of the applicant

I declare that above information is correct and that evidence justifying the above claims will be provided within one week of any request by the Licensing Authority.

Name and company position:	
Date:	