Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems

Article 18

Safety and efficacy of medicinal products

1 Where the application for a compulsory licence concerns a medicinal product, the applicant may avail himself of:

a the scientific opinion procedure as provided for under Article 58 of Regulation (EC) No 726/2004, or

b any similar procedures under national law, such as scientific opinions or export certificates intended exclusively for markets outside the Community.

2 If a request for any of the above procedures concerns a product which is a generic of a reference medicinal product which is or has been authorised under Article 6 of Directive 2001/83/EC, the protection periods set out in Article 14(11) of Regulation (EC) No 726/2004 and in Articles 10(1) and 10(5) of Directive 2001/83/EC shall not apply.

Changes to legislation:
There are outstanding changes not yet made to Regulation (EC) No 816/2006 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

– Art. 17-19 omitted by S.I. 2019/801 reg. 49

Changes and effects yet to be applied to the whole legislation item and associated provisions

– Signature words omitted by S.I. 2019/801 reg. 50
– Art. 2(4) words substituted by S.I. 2019/801 reg. 39(2)
– Art. 2(5)(6) inserted by S.I. 2019/801 reg. 39(3)
– Art. 5(a) words substituted by S.I. 2019/801 reg. 41(2)
– Art. 5(c) words omitted by S.I. 2019/801 reg. 41(3)