EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 July 2015
EMA/493921/2015
Human Medicines Evaluation Division

Request/declaration form for the provision of information via quick response (QR) codes in the centralised procedure.

[This request form accompanied by relevant information should be submitted to EMA in the context of an authorisation procedure within module 1.3.1 of the dossier.

All sections of the form should be completed. The applicant is required to confirm all the statements highlighted in bold within this form (declarations)] and sign at the end of the document. If not completed in full, the applicant may be requested to re-submit.

Name of the medicinal product / Procedure number	
Active substance	
Name and address of the applicant	
Authorised signatory	

1. Platform hosting the information

- Type of platform that will host the information provided via QR code:

Website ☐ Webpage ☐ Smartphone app ☐ National Agency website ☐ other ☐

- State URL of the platform hosting the information……

- Description of the platform:

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5515
Send a question via our website www.ema.europa.eu/contact

(Detailed description of the platform should be given also addressing the mechanisms to ensure that most patients can benefit from the information provided)

It is hereby declared that:

☐ **The final design of the platform has been provided**

☐ **The design of the platform allows easy access to the information in the EU official languages, as appropriate.**

☐ **The platform hosting the information is exempt of any promotional element (e.g. information relating to the marketing authorisation holder, links to corporate websites, etc.)**

2. Information provided to patients/users

- **Statutory information**…….. …… yes ☐ no ☐

If yes, specify the type of statutory information:

☐ Partial information of the package leaflet (certain sections)

Please specify:

☐ Partial information of the Summary of product characteristics (certain sections)

Please specify:

☐ Package leaflet

☐ Summary of product characteristics

☐ Educational material as outlined in the Risk Management Plan

It is hereby declared that:

☐ **Electronic versions of the statutory information are compliant with the approved version and will remain unchanged after approval except for the updates of the product information resulting from approved modifications.**

☐ **The readability of the information provided in the electronic format is ensured.**

- **Additional information** compliant with Article 62 of Directive 2001/83 …….yes ☐ no ☐

If yes, provide a detailed description of the following:

- Intended information:

[A description of the pieces of information provided via the QR code should be provided (e.g. script of a video for instructions for use, etc.). The URL provided in section 1 should allow the assessor to access the full information]

- Reasons for providing patients/users with additional information via QR code and the expected benefits to patients/users:

- Relation between the additional information proposed and the actual information of the SmPC that supports it:

Purpose of information	**Compliance with SmPC [Specify which section(s) of the SmPC]**

(Add additional rows as necessary)

3. Location of the QR code

- The intended location both in printed material and product information annexes should be described in detail (e.g. inner lid/inner flap or the carton, package leaflet, Annex IIIa, Annex IIIb, etc.).

The following documents should be submitted along with this application form:

- Mock-ups of labelling and/or package leaflet (the location of the QR code should be clearly illustrated)

- Product Information annexes (reference should be made as ['QR code to be included' + <URL>] in the appropriate sections)

4. Implementation of the QR code

It is hereby declared that:

☐ **The applicant will contact the corresponding national competent authorities (NCAs) via the assigned contact points to ensure endorsement of the national version(s) of the content prior to the launch.** ***[THIS STATEMENT IS ONLY APPLICABLE WHEN ADDITIONAL (non statutory) INFORMATION IS PROVIDED; IF NOT APPLICABLE TICK HERE ☐]***

☐ **The national versions of the platform and final content made available to the patients/users will comply with the declared/approved English content as stated in the CHMP Assessment Report.**

☐ **The platform hosting the information and web domain rights will remain valid while the authorisation of the QR code is in place.**

☐ **The platform hosting the information and the content will not be modified without prior authorisation by EMA except for the updates of the product information resulting from the approved modifications which must be automatically implemented in the electronic version. The corresponding national competent authority will be the responsible for granting the authorisation of any modification that is considered country specific (e.g. if it affects only one language, etc.)**

Print name and signature: **Date:**