FAQs for UK GMP Certification of cosmetics for export to China.

• Note: In all these FAQs, the term <u>GMPC</u> refers to "<u>a UK government-issued GMP certificate for export to China</u>". These FAQs address only those questions relating to GMPCs for UK manufacture. For other queries relating to exporting cosmetics to China, see 'Further information' and 'Useful contacts' at the end of these FAQs.

1. How do I obtain a GMPC to enable me to export my cosmetics to China?

The process for applications is outlined in the attached flowchart. The Responsible Person (RP) as defined under Article 4 of the UK and EU Cosmetics Regulations will need to go to the Import Licensing Branch (ILB) website (www.ilb.trade.gov.uk/) and either register or, if you have previously used the Import Case Management System (ICMS), for example to apply for a Certificate of Free Sale, simply log in. Select the option for GMP Certificate and follow the instructions.

2. If the documents I provide in my application expire in less than three years, will I still receive a three-year GMPC?

Provided you submit either a valid Brand Reputation Compliance Global Standard (BRCGS) certificate for Consumer Products, or a valid ISO 22716 certificate plus a valid ISO 17021 or ISO 17065 certificate showing the auditor is accredited, the GMPC will be issued with an expiry date three years from the date of issue. The Declaration on the GMPC application form makes it clear that if, during that three years, the ISO 22716 certificate is not renewed for whatever reason, the ILB must be notified and the three-year certificate is rendered invalid from that date. Furthermore, when the GMP certificate expires or becomes invalid whichever is sooner, both the applicant (RP) and the Brand are required to notify the competent authority in China immediately unless a new certificate has been issued which is continuous with the previous certificate. The applicant also accepts in signing the Declaration that DIT or OPSS may also notify the competent authority in China of an expired or invalid certificate.

3. Does the GMPC apply to specific products or to all products manufactured at the named facility for a named Brand?

The GMPC is not product-related, but is linked to the manufacturing site. However, the Responsible Person (RP) applying for the GMPC must be able to confirm that all the products the Brand is proposing to export under the GMPC are suitable to be placed on the UK market. This should be confirmed by notifying the products on the UK's cosmetics portal (Submit Cosmetic Product Notifications service). The RP applying for the GMPC should normally be the same as the RP named in that notification and must be established in the UK.

4. Do I need to get a GMPC for each manufacturing facility even though it is for the manufacture of a single product?

Yes. The GMPC is facility/site specific rather than product specific. You will need to apply for a GMPC for each manufacturing site where you manufacture product(s) you wish to export to China.

5. Why is it possible to get a GMPC using only a BRCGS certificate whereas, by the ISO route, two certificates are needed – ISO 22716 plus either ISO 17021 or ISO 17065?

The Brand Reputation Compliance Global Standard (BRCGS) complies with all the requirements of ISO 22716 and BRCGS requires that all its auditors and certification bodies are accredited by UKAS to ISO 17065. Thus, the BRCGS certificate effectively covers both ISO 22716 and ISO 17065.

6. How long will it take for me to receive the GMPC and will there be a fee?

We do not currently anticipate charging a fee for issuing a GMPC. The processing of the applications will depend on how long it takes to verify the evidence submitted and on the volume of applications received. We anticipate the Import Licensing Branch (ILB) will be able to process most uncomplicated applications promptly. However, a sample (random or those raising queries) may be referred to the Review Team at the Office for Product Safety & Standards (OPSS) in which case the application will take longer to process. We recommend submitting your application for a GMPC early in the process of preparing to export to China to prevent this from being a limiting factor in your export process.

Does Brexit affect my ability to obtain a GMPC for products manufactured in the UK?

No. Effective from 1 January 2021, there are two Cosmetics Regimes covering the UK (one covering GB and one, the EU regime, covering NI). The issued GMPC will reference the appropriate legislation dependent on whether the manufacturing facility is located in Great Britain or in Northern Ireland. These GMPC issuing arrangements have therefore fully considered the necessary arrangements reflecting EU Exit.

8. I am a Brand and I do not have a business address in the UK. However, I use a UK third-party manufacturer. Can I obtain a GMPC?

The UK Cosmetics Regulation applies to Great Britain and requires the appointment of a Responsible Person (RP) who must be established in the UK. Although the EU Cosmetics Regulation applies to Northern Ireland and permits the RP to be established in the EU as well as in NI, for the purposes of applying for a GMPC, we require the RP to be established in the UK. Under the UK Cosmetics Regulation, the manufacturer is considered to be the RP unless a written mandate exists between the manufacturer and another party to act as the RP. Since you are using a UK third-party manufacturer, we suggest you contact that manufacturer to establish what arrangements they have in place.

9. Why do I need a Responsible Person to apply for a GMPC on my behalf?

A Responsible Person (RP), who may be a legal or natural entity, is required under the UK Cosmetics Regulation. The RP is responsible for assuring both the safety and efficacy of cosmetics being sold on the UK market and we therefore consider this entity suitable to sign the Declaration in the GMPC application. Only a RP that is established in the UK **and** notified on the UK's cosmetics portal (<u>Submit Cosmetic Product Notifications service</u>) for the relevant product(s) should make the application for a GMPC on behalf of a Brand, regardless of whether the product(s) are being placed on the UK market.

10. Will I need to provide written evidence of the RP mandate if the manufacturer is not the RP?

No. In signing the Declaration in the GMPC application, the applicant agrees to the statement that they are the RP acting on behalf of the Brand. Only a RP that is established in the UK **and** notified on the UK's cosmetics portal (<u>Submit Cosmetic Product Notifications service</u>) for the relevant product(s) should make the application for a GMPC on behalf of a Brand.

11. If I have a product created specifically for the Chinese market, must I also place it on the UK market to comply with the Declaration in the GMPC application?

No. The product must, however, meet the requirements of the UK Cosmetics Regulation **and** be notified on the UK's cosmetics portal (<u>Submit Cosmetic Product Notifications service</u>) thus assuring it is <u>suitable</u> to be placed on the UK market. We require this regardless of whether the product is actually being placed on the UK market.

12. Can I use this GMPC for cosmetics I have manufactured outside the UK?

The UK GMPC will be issued only for UK manufacturing facilities. This is in line with the Chinese regulations which specify the certificate must be issued by the responsible government department in the country/region where the manufacturing takes place.

13. Is the Responsible Person required for the GMPC application the same as the Responsible Person in China identified in CSAR?

We understand the Responsible Person under CSAR (China's Cosmetic Supervision & Administration Regulation) to be a largely administrative role held by a natural or legal entity based in China. The Responsible Person required for the GMPC application must be based in the UK and fulfils that role under the UK Cosmetics Regulation. We recommend you consult the guidance published by OPSS on these Regulations as they apply to cosmetic products being supplied in or into Great Britain (or the equivalent for Northern Ireland) from 1 January 2021 (see 'Further information' at the end of these FAQs).

14. Do I need a GMPC for export to any countries other than China?

At this time, a GMPC is required only for export of general cosmetics to China to gain exemption from otherwise mandatory animal testing requirements. The GMPC is therefore only available to facilitate export to China.

15. How can I obtain an English translation of the CSAR regulations?

CSAR and the relevant regulations are published (in Chinese) on the website of NMPA (China's National Medical Products Administration). For an English translation, you will need to arrange this or subscribe to a commercially available service. For further advice, we suggest you contact DIT and/or CTPA (see 'Useful contacts' at the end of these FAQs).

16. How do I provide evidence of sales in the country of manufacture?

We cannot advise on this aspect since it is unrelated to the issuing of the GMPC. You would need to explore this issue with NMPA. Your Chinese Responsible Person may be able to assist. Alternatively, we suggest you contact DIT and/or CTPA (see 'Useful contacts' at the end of these FAQs).

17. Is a licence from MHRA acceptable as evidence of GMP compliance for cosmetics manufacture?

The Guidelines for Cosmetics GMP in the UK (and in Europe) is ISO 22716. We have therefore limited consideration to these guidelines.

18. Will I need to have my GMPC notarised by a Chinese authority?

We understand that a number of documents submitted as part of an application to import cosmetics into China will have to be translated into Chinese and the translations may need to be notarised. This is likely to include the GMPC. It is envisaged that this will be a responsibility of your Chinese Responsible Person.

19. Will there be a public searchable register of GMPCs issued?

The GMPC will carry a QR code which can be checked against the ILB website. There will be no public register of companies holding a GMPC.

For further information:

For further information relating to the UK Cosmetics Regulation, we recommend you consult the guidance published by OPSS on the regulations as they apply to cosmetic products being supplied from January 2021 in or into Great Britain

(https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/f_ile/968602/Guide-to-cosmetic-products-regulations-2013-tp.pdf_) or the equivalent for Northern Ireland

(https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/f_ile/968604/Guide-to-cosmetic-products-regulations-2013-northern-ireland-tp.pdf_).

Useful contacts:

- Office for Product Safety & Standards (OPSS): www.gov.uk/government/organisations/office-for-product-safety-and-standards
- Department for International Trade (DIT) China: www.gov.uk/world/organisations/department-for-international-trade-china
- Import Licensing Branch (ILB) in DIT: www.ilb.trade.gov.uk/
- Brand Reputation Compliance Global Standard (BRCGS): <u>www.brcgs.com</u> & <u>enquiries@brcgs.com</u>.
- Cosmetic, Toiletry & Perfumery Association (CTPA): www.ctpa.org.uk
- International Accreditation Forum (IAF): www.iaf.nu