

Exemption from Indian Barcoding

How medicines due to serialization produces in India receive a correct coding according Delegated Regulation

Many pharmaceutical companies in the German medicine market receive from associated companies or contract manufacturers prescription medicines which are produced and packed in India. India already introduced several years ago a track and trace system for export medicines, which require amongst others a labelling with a data matrix code on the secondary packaging, in which is coded the product code, batch name, expiry date and a serial number. The data themselves are additionally printed in plain text on the packaging and additionally for the German market with the Pharmazentralnummer (PZN) in code 39 and in plain text as well for reimbursement purposes.

With the commencement of the Delegated Regulation (EU) 2016/161 it may come to conflicts especially on the German market, due to the fact the Indian coding comes close the European requirements, but not fulfill every aspect. The securPharm coding rules require for packages sold on the Germany market only, that the product code, as embedded PZN, is whether printed as a NTIN (National Trade Item Number according GS 1 standard) or as PPN (Pharmacy Product Number according ACS format of the IFA). The Indian coding stipulates a GTIN (according GS 1 standard), which will be rejected by some European countries and also by the Germany system.

If you as pharmaceutical company are affected by this problem, we kindly ask you to get in touch with your Indian partner. There is a solution for the problem:

Please request your Indian partner to apply for an exemption from barcoding in case he still not acted so far.

With this exemption the Indian manufacturer don't have to fulfill the Indian export coding requirements, but only have to realize the Coding Requirements of the EMVO and especially the [Coding rules for the Germany market](#) issued by securpharm.

Contact in India

Pharmaceuticals Export Promotion Council of India (Pharmexcil)

Head Office: 101, Aditya Trade Centre

Ameerpet, Hyderabad 500038

Phone: +91 40 23735462/66

Fax: +91 40 23735464

Email: [info\(at\)pharmexcil.com](mailto:info(at)pharmexcil.com)

Website: www.pharmexcil.com

Additional information regarding barcoding

- [General Informations](#)
- [Form for the application for the exemption](#)