PRESS RELEASE
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Tamper Evidence pharmaceutical packages with a Serial Number: GE Pharmaceuticals Ltd. and Wörwag start the series production

After completion of the test stage there begins a series production in accordance with FMD – three years before expiry of transition period for the new EU guideline

In the beginning of April the starting period for the regular production of Tamper Evidence pharmaceutical packs with serial number was launched. On behalf of the pilot customer Wörwag Pharma GmbH & Co. KG the Austrian-Bulgarian service contractor GE produced on 5 April 2016 the first batches for the European market. With that said the partners Wörwag and GE joined are among the first companies in Europe that produce in a series production of packs combined with tamper-proof fastener in accordance with EU-Directive 2011/62/EU that becomes valid from 2019. Three years before the end of transition period they thereby marked the technical scale in Europe. From 9 February 2019 all pharmaceutical producers are obliged to produce Tamper Evidence and serial numbered packs in accordance with the EU-Directive known as the one for Falsified Medicines (FMD). "Along with Wörwag we already have the first user who is well ahead in the series production and conforms to the FMD directive", pointed out Dr. Günter Datz, Manager of GE Pharmaceuticals. "Owing to our sufficient technical solutions from now on we are able to offer to all pharmaceutical producers that are interested in their FMD-conforming products with secondary packs". The specialists in packing GE are working out in their new expanded factory in Botevgrad near Sofia by introducing six production lines and they are still to expand the capacities further on. Already two lines in conformity with FMD-products are ready and some other FMD-lines are under construction.

In anticipation of the FMD-Directive the GE Pharmaceuticals Ltd. along with the pilot client Wörwag had to make alignments for the new production. From the beginning along with all there were the German service providers Baumer hhs, that are specialized in machine building, and the folding box provider Kroha. Under the leadership of the German-Bulgarian Management duet of GE, Dr. Günter Datz and Angel Angelov, the Project team developed a new packing design and implemented new requirements to the production technology. "The new building in Botevgrad gave the possibility from the beginning to introduce under optimal conditions a State-of-the-art technology to a FMD-conformist production", stressed Dr. Günter Datz, the German manager of GE. "We decided along with our production service provider GE at an early stage to acquire the necessary Know-how for the pilot project", added Michael Kulmann, Manager of Operative Sales with Wörwag Pharma GmbH & Co. KG. "On these grounds we become familiar with the new standards and have the possibility for our product portfolio to be timely re-organized with valid requirements from 2019 on".

On 5 April 2016 took place the series production of the first batch of serialized medicines with GE Pharmaceuticals. 1.000 packs of stomachic Pantoprazol 40mg came off the line on behalf of Wörwag. Both the adhesive and printing technologies ensure all requirements for the first production campaign and the quality management to be met. This year around 150.000 FMD-conformist secondary packs are forecasted to be produced for Wörwag.

Tamper Evidence: Folding box with special adhesive technology

The folding box for the secondary pack shall be user-friendly and secondary closeable. This shall be envisaged for preferentially front opening with an unnoticeable perforation. It is located on the top side of the pack and is obscured by the flap as the latter shall be affixed. After the first opening by pressing and by pulling over alongside the perforation the pack on that side can be conventionally fastened and thus once again the bracket on the top shall be locked. For forgery-proof closure Baumer hhs developed a combined hot- and cold-adhesive technology for the Tamper Evidence closure.

2D-Data-Matrix-Code

The serial number is printed on the back side and for sure bilaterally: It is one over another square-like machine-readable 2D-Matrix-Code deposited and on the other under the abbreviation “SN” in readable scriptum. The latter is valid also for the product code, the batch number and the expiry date. All that data shall be verified in accordance with EU-Directive from 2019: the first time immediately after printing on the secondary pack, the second time with the version on the point of sale (pharmacy, hospital etc.). The first shall be given after successful verification of the valid serial number and the second after approval through an IT-system of the pharmaceutical product by the end user.

Full-Service at the production site

GE Pharmaceuticals offers at the production site in Botevgrad already from 2006 intensive services in relation to packs of tablets and hard gelatin capsules. The portfolio includes from custom clearance through performance of EU-retesting to primary and secondary packaging, as well as manual rework. GE Pharmaceuticals offers of course all necessary laboratory analyses, stability examinations and release of the packed product by Qualified Persons. For the first time GMP-qualified manufacturing facility was certified by the Austrian Examining Institute AGES in the year of 2006. In the years past there followed multiple audits and re-audits by clients, as well as by the Bulgarian Healthcare institution BDA (Bulgarian Drug Agency).

Images: (Source: Bruno Lukas, Press'n'Relations GmbH)

Quality control at the production line

Optical test of the printed serial number

Box with tamper evidence

Serial number printed on the box

2D-Data-Matrix-Code, scanned & shown on smartphone

New GE production plant in Botevgrad

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GE Pharmaceuticals Ltd.

With currently 150 employees GE Pharmaceuticals Ltd in Botevgrad (Bulgaria) produces annually about 60 million blisters and 20 million packages of drugs. With the commissioning of the second manufacturing site in September 2015 the number of production lines increased to six - with the option to launch in future another twelve lines additionally. The Austrian-Bulgarian company was founded in 2005 as a joint venture with 31 employees. It is owned respectively to 50 percent by Ecopharm Ltd. and by Genericon Pharma Ltd, one of Austria's largest manufacturers of generics.