"Circulation"

Re: coding every medicinal pack with serial number inside 2D (Data matrix) and printing it with other information

Circulation No.: 21046, Date: 30/3/2016 (21/6/1437H)

Further to the circulation No. 24569 Date: 14/4/2014 (copy attached) about the SFDA plan for the printing of the 2D data matrix coding, that includes the implementation of the second stage of the plan with the addition of serial number coding for each medicinal pack inside the 2D data matrix and printing it with other information is mandatory, starting from 12th of March 2017 (12/6/1438Hj).

SFDA is seeking through this procedure to provide technical mechanism to facilitate the track and trace process of the pharmaceutical products in the supply chain, so we hope that all pharmaceutical companies will comply with the mentioned due dates considering the following in the implementation:

- The pharmaceutical company must add the serial number, with no need to coordinate with a third party to obtain this number.

- The serial number must not exceed 20 digits; the manufacturing company may use combination from letters and digits (Alphanumeric).

- The serial number must be unique for each pack, as no duplication of the serial number with another pack for the same product is allowed.

- The serial number must be printed on the pack, in addition to encoding it in the 2D data matrix as the scanned code must match with the printed serial number on the pack, the figure below demonstrats the required information to be printed:

GTIN:	62800000000000
EXPIRY:	YYMMDD
BATCH/LOT:	ABCD1234
SN:	7894563214569AB

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٣٢٩٢ الطريق الدائرى الشمالى — حي الربيع — الرياض ١٣٣١٢ — ٦٢٨٨ — المملكة العربية السعودية — هاتف ٩٦٦١٢٧٥٩٢٢٢ + فاكس ٩٦٦١٢٠٥٧٦٣٥ +
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SFDA will update the guidelines for "Saudi Drug Code (SDC) and Drug Bar-coding Specifications" accordingly, and in case of any inquiries we hope you can contact us through the email: (Drug.informatics@sfda.gov.sa)

Thanks for your cooperation…

Executive VP of Drug sector

Dr. Ibrahim Bin AbdulRahman AlGaffaly

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WWW.sfda.gov.sa

"Circulation"

Re: Current linear Drug Bar-coding development to 2D (Data matrix)

Circulation No.: 24569, Date: 14/4/2014 (14/6/1435H)

Further to the circulation No. 19293 Date: 27/4/2013 about the SFDA plan for the printing of the 2D bar-code, with pleasure, the SFDA wants to share with the pharmaceutical companies and drug agents our time plan regarding developing the drug bar-code and the encoded information inside it, and this is for implementation in the drug information system for the other future projects like Trace and Track system for anti-counterfeiting of medications.

The implementation will be on two main stages as follows:

First: starting from 21/3/2015 medications clearance from customs ports will be according to the requirements contained in "Saudi Drug Code (SDC), and Drug Bar-coding Specifications" guidelines as following:

a- To print on the outer pack the 2D (Data-matrix) bar-code including the following data:

    1- *(GTIN)* number for the medication that issued from (GS1) international organization that represented by the Saudi Bar-code Centre in the Council of Saudi Chambers of commerce.

    2- *Expiry date* of the product.

    3- *Batch/Lot* Number.

    4- *Pack size*.

b- To print the encoded data in the 2D bar-code in a clear and readable way beside the 2D bar-code as presented below:

```
GTIN: 62800000000000
EXPIIRY:YYMMDD
BATCH: ABC1234
PACKAGESZE: 30 TAB
```

And it is sufficient to print the *(GTIN)* number only beside the 2D bar-code if the *Expiry date, Batch/Lot* Number and *Pack size* are printed by writing on the pack somewhere else.

Second: starting from 12/3/2017, each medicinal pack coding must be with a unique serial number encoded inside the bar-code and to be printed with the other data, which supplied during the manufacturing process according to the international drug coding requirements , which will be published in a specific and detailed guidelines by Drug Sector, example:

```
GTIN: 62800000000000
EXPIIRY:YYMMDD
BATCH: ABC1234
PACKAGESZE: 30 TAB
SN: 2154687549
```

Based on the above, SFDA advise all pharmaceutical companies and their agents to comply with the due dates for the implementation of the bar-coding new specifications, and for more information and guidance about this subject you can refer to "Saudi Drug Code (SDC), and Drug Bar-coding Specifications" guidelines which is published on the SFDA website or to contact (GS1) Saudi Bar-code Centre in the Council of Saudi Chambers of commerce, noted that the Drug Sector will arrange guidance workshops about this subject that will be announced on the SFDA website and by email.

Thanks for your cooperation…

VP of Drug sector

Prof. Dr. Saleh Bin-Abdullah Bawazeer

٣٢٩٢ الطريق الدائرى الشمالي – حي الربيع – الرياض ١٣٣١٢ – ٦٢٨٨ – المملكة العربية السعودية – هاتف ٩٦٦١٢٧٥٩٢٢٢ + فاكس ٩٦٦١٢٠٥٧٦٣٥ +

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