Example 1

Federal Institute for
Drugs and Medical Devices
Kurt-Georg-Kiesinger-Allee 3
D-53175 Bonn

Marketing authorisation holder
(name and address):
Banjopharm AG
Example street 10
99999 Example town

Phone: **0999 / 99 99 999**

File no. of Application for Renewal:
(pursuant to Section 105 sub-section 2 AMG)

Pharmaceutical company no (PNR):
1234567

Date of last Variation:

Name of medicinal product:
Banjosan 100 mg

Date of last Renewal:

Pharmaceutical form:
Tablet

Marketing Authorisation no/Registration no:
99999.00.00
Processing no. (ENR): **2199999**

☐ Variation due to BfArM-letter dated
File no.:

ATC-Code: E15AX

Notification includes changes requiring approval

yes ☐ no ☒

Notification
of national Variation pursuant to Section 29 and/or Section 105 German Drug Law (AMG)

The following changes are notified (List of changes with the structural numbers and corresponding text provided in the Catalogue of changes published at www.bfarm.de):

SKNo	**Brief description according to Catalogue**
0026	Manufacturer/batch release
1417	Manufacturers, other (not SKNo=0026)
0716	Prolongation of shelf-life of the medicinal product
1002	Package leaflet (PIL) pursuant to Section 11 AMG
0319	Expert information (SPC) pursuant to Section 11a AMG

List the **present** and **proposed** characteristics on the following pages and attach documents where appropriate.

This is to confirm that no other changes relevant to authorisation have been made than those notified above, and further, that the electronically submitted texts coincide literally with paper submission.

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place, date, signature of marketing authorisation holder

Table of Comparison

Present	Proposed
Manufacturer/batch release	
Example Pharm AG Example street 4 44444 Exampletown	Banjopharm AG Example street 10 99999 Example town
Manufacturers, other (not SKNo=0026)	
Example Pharm AG Example street 4 44444 Example town	<u>Manufacture (bulk)</u> Banjobulk GmbH Example street 10a 99999 Example town <u>Packaging and Labelling</u> Banjopack GmbH Example street 10b 99999 Example town
Prolongation of shelf-life of the medicinal product	
2 years	3 years

Explanatory remarks:

The marketing authorisation holder intends to report a change of the manufacturer responsible for batch release, of other manufacturers and a prolongation of product shelf-life.

The following types of change should be listed in the table:

0026	Manufacturer/final release
1417	Manufacturers, other (not SKNR=0026)
0716	Prolongation of product shelf-life

As the PIL is affected by the change of the manufacturer responsible for final release and the SPC by the prolongation of shelf-life the following positions have to be listed on the first page of the form:
1002 – Package leaflet (PIL) pursuant to Section 11 AMG
0319 – Expert information (SPC) pursuant to Section 11a AMG

Positions 0026, 1417 and 0716 are relevant for the calculation of fees only. The changes in the PIL and SPC are the result of these changes and as such they are not charged.

as at 25 Nov 2009