Example 2

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**
0095	Posology/dosage
2556	Side effects (without restrictionsof side effects)
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.

place, date, signature of marketing authorisation holder

Table of Comparison

Present	Proposed
Posology	
[previous text] Use of Banjosan 100 mg in children under 2 years of age is not recommended. [previous text]	[previous text] Use of Banjosan 100 mg in children under 2 years of age or below 13 kg of body weight is not recommended since the dose strength is not suitable for this age group. Suitable dose strengths and dosage forms are available for this age group [previous text]
Note: The entire text of the Posology section has to be included in both columns. To keep this example as clear and simple as possible it only refers to the "previous text".	
Side effects (without restrictions in side effects)	
[previous text] **Diseases of the immune system** Very rarely may allergic reactions occur, from simple skin rash or urticaria to shock reactions. [previous text]	[previous text] **Diseases of the immune system** Very rarely may allergic reactions occur, from simple skin rash or urticaria to shock reactions. Also very rarely were cases of respiratory constriction (analgesic asthma) in sensitive individuals. [previous text]
Note: The entire text of the Posology section has to be included in both columns. To keep this example as clear and simple as possible it only refers to the "previous text".	

Explanatory remarks:

The marketing authorisation holder intends to report changes in the sections "posology" and "side effects". In the latter case the previous statement will not be restricted.

The following categories of change should be listed in the table:
0095 – Dosage
2556 – Side effects (without restrictions in side effects)

Since the changes are reflected in the informative texts the following positions should 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

Only the positions 0095 and 2556 are relevant for the calculation of fees. 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