

Annex I

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for fluorodopa (18F), the scientific conclusions are as follows:

Based on spontaneous cases identified during the reporting period and based on the fact that burning sensation is already included as an important identified risk for one of the product containing fluorodopa (18F), the PRAC considered that a causal relationship between the adverse drug reaction "burning sensation" and the injection of medicines containing fluorodopa (18F) linked to the pH of these products (pH: 4.0 – 5.5) is likely. Therefore, the product information of all medicinal products containing Fluorodopa should be updated accordingly.

The CMDh agrees with the scientific conclusions made by the PRAC.

Grounds for the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for fluorodopa (18F) the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing fluorodopa (18F) is unchanged subject to the proposed changes to the product information.

The CMDh reaches the position that the marketing authorisation(s) of products in the scope of this single PSUR assessment should be varied. To the extent that additional medicinal products containing fluorodopa (18F) are currently authorised in the EU or are subject to future authorisation procedures in the EU, the CMDh recommends that the concerned Member States and applicant/marketing authorisation holders take due consideration of this CMDh position.

Annex II

Amendments to the product information of the nationally authorised medicinal product(s)

Amendments to be included in the relevant sections of the Product Information (new text **underlined and in bold**, deleted text ~~strike-through~~)

Summary of Product Characteristics

- Section 4.8

The following adverse reaction(s) should be added under the SOC "Nervous system disorders" with a frequency "not known":

Burning sensation

Package Leaflet

- Section 4

Burning sensation, with the frequency 'Not known'.

Annex III

Timetable for the implementation of this position

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Adoption of CMDh position:	November CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	29 December 2018
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	27 February 2019