



*Making Medicines Affordable*

# Practical elements for harmonisation after art. 30 referral

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# Variation C.I.1.b

## ■ Revised product information

- Availability of translations

*Positive experience with BfArM, AGES, CBG where translations are provided on website*

## ■ The EGA would welcome more CAs to take up the initiative

### ■ Advantages:

- Harmonised information for patients
- Reduction of unnecessary workload for the industry and for the authorities (checking translation)