Indications and labelling; specific aspects
Cross reference within the SmPC

EMA-Payer Community meeting

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Introduction

- The entire SmPC is ”on label”
- Not only 4.1 includes important information on how to use the product most adequately
- However, we try to avoid ”hidden indications”

4.2 Posology

- **Special populations**
  - Renal/hepatic impairment, elderly, children

Elderly (≥ 65 years)
In general, no dosage adjustment is recommended based on age. Renal function and risk of volume depletion should be taken into account (see sections 4.4 and 5.2). Due to the limited therapeutic experience in patients 75 years and older, initiation of dapagliflozin therapy is not recommended.

  - SmPc Guideline;

It should be stated in which age groups the product is indicated, specifying the age limits, e.g. 'X is indicated in <adults><neonates><infants><children> <adolescents> <aged x to y <years, months>>.

- Upper age limit only if negative B/R balance in elderly
- Upper age limit may be problmenatic in diseases with childhood onset

4.2 Posology

- Section 4.2 should correlate with section 4.1 in clearly specifying **dose** recommendations for the entire population covered by the indication

- **Duration of treatment**
  - Optimal duration often not known
  - What is ”long term treatment”??
  - Include information on available experience (”X has been used for up to 12 months treatment”)

- **Stopping rules**
  - Eg. if data can support that no effect after X months predict no effect of continued treatment

4.3/4.4/4.5

- 4.3 subgroups with negative B/R balance
- 4.4 Precautions, warnings but B/R not negative
- 4.4/4.5 May specify not recommended combinations (of importance if general indication ”combination with other products for the treatment of disease X)

What should be included in 5.1; SmPC guideline

Sections 5.1 – 5.3 should normally mention information, which is relevant to the prescriber and to other health-care professionals, taking into account the approved therapeutic indication(s) and the potential adverse drug reactions. Statements should be brief and precise.

In the exceptional cases when clinically relevant information from subgroup or post-hoc analyses is presented, it should be identified as such in a balanced manner reflecting the limited robustness of both positive and negative secondary observations.

”Information relevant to other health care professionals”

HTAs; often interested in PROs and comparative data

Where results from subsequent studies provide further definition or information on an authorised indication, such information, provided it does not itself constitute a new indication, may be considered for inclusion in section 5.1.

Conclusion

- Other sections than 4.1 includes important information but should in general not extend the approved indication