A.11	Enzalutamide – metastatic castration-resistant prostate cancer
Does the application adequately address the issue of the public health need for the medicine?	☒ Yes ☐ No ☐ Not applicable Comments:
Briefly summarize the role of the proposed medicine(s) relative to other therapeutic agents currently included in the Model List, or available in the market.	Enzalutamide is an effective medicine for castration-resistant prostate cancer. Efficacy seems to be comparable with abiraterone which is on the EML list, there are no trials with head to head comparisons. The advantage of enzalutamide is that no steroids are needed, and there seems to be somewhat less cardiotoxicity compared to abiraterone. So for subgroups like those where you would prefer steroid-sparing, e.g. those with diabetes, might benefit from enzalutamide, For most patients, abiraterone a good alternative
Have all important studies and all relevant evidence been included in the application?	☒ Yes ☐ No ☐ Not applicable If no, please provide brief comments on any relevant studies or evidence that have not been included:
Does the application provide adequate evidence of efficacy/effectiveness of the medicine for the proposed indication?	☒ Yes ☐ No ☐ Not applicable
Does the application provide adequate evidence of the safety and adverse effects associated with the medicine?	☒ Yes ☐ No ☐ Not applicable Comments:
Are there any adverse effects of concern, or that may require special monitoring?	☐ Yes ☒ No ☐ Not applicable Comments:
Briefly summarize your assessment of the overall benefit to risk ratio of the medicine (e.g. favourable, uncertain, etc.)	It is a good relevant medicine, 4 trials 1. AFFIRM – CRPC after chemotherapy. ESMO-MCBS score 4. Median OS gain 4.8 months. 2. PREVAIL – CRPC before chemotherapy. ESMO-MCBS score 3. Median OS gain 2.2 months. 3. EMZAMET – 1st line metastatic CSPC, in combination with ADT. ESMO-MCBS score 4. Median OS not reached. 4. PROSPER – 1st-line non-metastatic CRPC, in combination with ADT. ESMO-MCBS score 3. Median OS 11 months.

Briefly summarize your assessment of the overall quality of the evidence for the medicine(s) (e.g. high, moderate, low etc.)	The quality of evidence is good
Are there any special requirements for the safe, effective and appropriate use of the medicine(s)**?** (e.g. laboratory diagnostic and/or monitoring tests, specialized training for health providers, etc)	☐ Yes ☒ No ☐ Not applicable Comments:
Are you aware of any issues regarding the registration of the medicine by national regulatory authorities? (e.g. accelerated approval, lack of regulatory approval, off-label indication)	☐ Yes ☒ No ☐ Not applicable Comments:
Is the proposed medicine recommended for use in a current WHO Guideline approved by the Guidelines Review Committee? (refer to: https://www.who.int/publications/who-guidelines)	☐ Yes ☐ No ☐ Not applicable Comments:???
Briefly summarize your assessment of any issues regarding access, cost and affordability of the medicine in different settings.	Abiraterone is widely available as generics. Generic enzalutamide is less widely available. Enzalutamide is an expensive medicine, equally effective as abiraterone. For a subgroup, enzalutamide is preferred, those who would benefit from avoiding steroid use and probably with the cardiovascular risk profile.
Any additional comments	
Based on your assessment of the application, and any additional evidence / relevant information identified during the review process, briefly summarize your proposed recommendation to the Expert Committee, including the supporting rationale for your conclusions, and any doubts/concerns in relation to the listing proposal.	Likely not, unless other views are presented regarding the price of the medicine.
References (if required)	