**ABBREVIATED SUBMISSION CHECKLIST (THERAPEUTIC CLASS)**

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| **Date of SMC Executive meeting:** |
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| **1. REGISTRATION DETAILS** |

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| **1.1 Medicine (generic name, strength, form [proprietary name®])** | |
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| **1.2 Submitting company** | |
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| **1.3 Licensed indication under review** | |
| * *Compare the licensed indication with the indication of the other medicines in the same therapeutic class.* | |
| **1.4 Any proposed positioning** | |
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| **1.5.1 Date of licensing** | **1.5.2 Date of availability** |
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| **1.6 Dose** | |
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| **1.7 Is there any relevant SMC advice for the existing medicine, or alternative medicine(s) in the same therapeutic class? If yes refer to appendix 1** | |
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| **1.8 Is there any previous correspondence with submitting company in terms of submission requirements for the medicine under review? If yes, summarise below including any service consultation that may have been undertaken as part of assessment of submission requirements.** | |
| *Summarise any previous correspondence that has taken place with the company regarding submission requirements including service consultation, decision made (and who made the decision [8b, 8c pharmacist or SMC executive team])* | |

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| 2. CONCLUSION |
| **2.1 Summary of the basis for the abbreviated submission including which abbreviated submission criteria have been met** |
| *State which abbreviated submission criteria the company consider have been met and comment on whether these are acceptable.* |
| **2.2 Are there any outstanding issues (e.g. requiring consultation with service, or clarification from the company required) etc. or significant uncertainties?** |
| * *Document any other issues or concerns in the checklist* * *Consider whether to seek further advice from the service through the formulary pharmacists, clinical experts or from the company; these may include*   + Clinical expert views may be required on the medicine, the relevant comparator(s)/market share and the medicine’s likely potential uptake (to provide checks and balances on company’s estimate of net budget impact). Consideration should be given to sending the generic questions (procedure 9) to experts identified from CRM.   + *Pertinent issues to the service should be considered*   + *Current timelines for patent expiry for reference and comparator products should be considered, if appropriate.*   + *Any anticipated withdrawal of the comparator or reference product should be investigated.*   + *Issues around branded generics and combination products can be problematic. Some branded generic products and some combination products will be within the remit of SMC and may be appropriate for either abbreviated or a full submission (see SMC website for information on generic medicines).* * *Consider discussion with NDC committee pharmacist members.* |
| **2.3 If the submission is not suitable to be reviewed under the abbreviated process, please provide details of reason for this decision** |
| *Summarise reasons for decision and who made the decision (8b pharmacists / 8c pharmacists / SMC executive team)* |

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| **3. FACTORS RELEVANT TO THE DECISION** | |
| 3.1 SIMILAR CLINICAL EFFECTIVENESS or NON-INFERIORITY | |
| **3.1.1 Has the formulation/product under consideration been compared with:**   * **an appropriate reference product(s)/parent compound with the same indication** * **appropriate route, dose and treatment period?** | |
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| **3.1.2 Has similar clinical effectiveness or non-inferiority been demonstrated in clinically relevant outcomes or can bioequivalence be inferred from relevant pharmacokinetic data?** | |
| * *Clinical non-inferiority or bioequivalence must be capable of being demonstrated briefly, in simple terms.*    + *Given that bioequivalence or clinical non-inferiority will have been assessed prior to licensing this may not require in-depth review* * *If required further data or evidence should be requested from the company; for example if non inferiority cannot be demonstrated from the data submitted*   + *If this is still inconclusive then discuss with 8c pharmacists or exec team* * *If required, further advice may be sought on the interpretation of the available data, through contacting the service or clinical experts when necessary.* * *Consider discussion with NDC committee pharmacist members.* | |
| **3.1.3 If no direct comparison is available can similar clinical effectiveness be presumed?** | |
| * *The company may provide an indirect treatment comparison (published or in-house analysis) to demonstrate similar clinical effectiveness within class. However, there will be limited critique of indirect data (i.e. the indirect comparison checklist will not be completed). Where necessary, specialists’ views may be sought on the medicine, the relevant comparator(s)/market share and also the medicine’s likely potential uptake (to provide checks and balances on company’s estimate of net budget impact).* | |
| **3.2 RELEVANT COSTS** | |
| **3.2.1 Has the acquisition cost of the formulation/product under consideration been compared with:**   * **an appropriate reference product(s)/parent compound with the same indication** * **appropriate routes, doses and treatment periods** | |
| * *Cost comparison will be versus the medicine with the highest volume share within class or, in the absence of a single market leader, a volume-weighted average.* * *If the company offers a PAS for the medicine under review, it must be a simple discount or an indication specific rebate (not a complex scheme).* * *If the key comparator(s) is available under a confidential PAS, the PAS price should be used for the comparison of acquisition cost. This price will not be known to the submitting company and will be requested from PASAG by the assessor.* **Yellow highlighting must be used for all results where there is a comparator PAS.** * *No budget impact threshold is applied.* * *The medicine’s likely impact on budget and resource allocation across NHS Scotland is a key consideration in whether or not an abbreviated submission is appropriate.*    + *If a medicine could potentially have a significant budget impact, a full submission should be made.* * *Check the costs provided by the submitting company and calculate any relevant costs that may have been omitted. Costings should follow the procedure for calculation of costs for the cost table in the DAD (Procedure 04b), and should be calculated as annual costs, cost per course or an alternative as appropriate.* * *If the executive team is not satisfied that the medicine has limited budget impact the company can resubmit (once only) to the abbreviated process with a new/revised PAS.*   ***Differences in costs***  *If the difference in costs between the new medicine and reference medicine(s) or alternative treatment(s) is small and the potential budget impact is limited in some circumstances an abbreviated submission can be accepted. There are no criteria for this; the following information, if readily available, may assist decision-making:*   * *Additional cost per annum, per course or per unit cost compared with the reference product(s) in absolute figures and as a percentage increase.* * *Volume and cost of NHS prescribing within the most recent year for the reference product(s) or alternative treatment(s) if available e.g. from submitting company’s estimates in the submission, from ISD website or from the service.* * *The volume and cost of current prescribing within the most recent year for the relevant therapeutic area e.g. if this can identify that overall prescribing is low whatever the market share of the new product.* * *An estimate of the size of the eligible population e.g. from submitting company’s estimates, from the service, from readily available epidemiological data or from Forward Look/SMC horizon scanning if available.* * *Evidence that the target population for the new formulation is clearly a minority of the overall target population or limited. For example, where solid oral dosage forms are available, a new oral liquid formulation may only be relevant to children and adults unable to swallow solid dose units.* | |
| 3.2.2 With reference to medicine costs only and compared with reference/parent/ components/alternative treatments, is the product/new formulation available at: | |
| **Pro-rata cost?** |  |
| **Less cost?** |  |
| **Cost premium?** |  |
| **3.2.3 If there is an acquisition cost differential/premium compared with the current treatment options in Scottish practice:** | |
| **How significant is the difference e.g. in terms of percentage increase in unit cost?** |  |
| **What is the estimated net budget impact e.g. small impact [<£100,000], medium impact [≥£100,000-<£500,000], large impact [≥£500,000]?** |  |
| **Are there any benefits that can be described in simple terms, e.g. preservative free?** |  |
| **4. ADDITIONAL CONSIDERATIONS** | |
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**REFERENCES**

**APPENDIX 1: RELEVANT SMC ADVICE**