**ABBREVIATED SUBMISSION CHECKLIST**

**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** | |
| * *Check licensed indication compared to parent product.* * *Changes in indication may be subtle e.g. may vary between different formulations of the same medicine.* * *Care is required in situations when the new medicine is associated with a change of indication / licence extension as well as a new formulation. With the exception of licence extensions to paediatric or adolescent patient groups (see separate procedure) SMC requires a full submission to cover extensions of a medicine’s marketing authorisation.* * *If the new formulation is licensed for the same indication(s) as the reference medicine(s) but with one or more additional indications, then it may be possible to accept an abbreviated submission for the original indication and request a full submission for the new indication(s).* * *If a revised indication extends the treatment to a substantially new group of patients (e.g. moving a product from second-line to first-line use), then a full submission is likely to be required. NB; the licence for a new formulation may also include a revised indication.* | |
| **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? 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 [Principal Pharmaceutical Analysts [PPA], Principal Pharmacists, 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*   + *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 whether referral to the principal pharmacists / SMC executive team is required.* * *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 (PPA / principial 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?** | |
|  | |
| **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 principal 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?** | |
| *Data from indirect treatment comparisons are generally not acceptable unless regulatory authority has approved medicine based on these data.* | |
| **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** | |
| * *Consider if the medicine is available at a pro-rata cost to alternative treatment(s).* * *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.* * *When the comparator medicine is an unlicensed ‘special’ ascertaining an accurate cost comparison can be difficult; advice from the service may be required.*   ***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**