Antivirals Taskforce – Recommendations from the Chair

Dear Secretary of State,

As you know, the Antiviral Taskforce (ATF) has recently submitted options for purchase of antivirals over the next two years. In short, the headline recommendation is to purchase 25 million courses from two companies (coded as Arrow and Tyne) at a cost of approximately I&S (not including wider programme costs).

2. In considering this recommendation, it is important to recognise that the ATF was responding to a clear set of objectives as outlined by the Prime Minister: to have at least two effective treatments this year, either in a tablet or capsule form, that the public can take at home following a positive COVID-19 test or exposure to someone with the virus. There are also wider clinical imperatives around having treatment options for vulnerable population cohorts who cannot receive a vaccine or for whom vaccination is relatively less effective and ensuring the UK is fully prepared to tackle future Variants of Concern and potential vaccine evading variant virus. I consider this essential to the UK's pandemic response and protecting the population and NHS in the forthcoming autumn and winter and beyond.

3. I consider that procuring the maximum volume available to the UK at this time is the most complete and appropriate response to this challenge to give the UK the best possible insurance policy against COVID-19. Nonetheless, I also recognise the approach is highly specific and is strongly influenced quantitatively by the assessment of the likelihood of a vaccine evading variant virus in the next 18-24 months. It is my responsibility as Chair, in accordance with the independent clinical advice received, to ensure this risk is clearly stated and understood in the interests of public health, but also the Prime Minister's irreversible roadmap and the Government's stated policy of learning to live with COVID-19. Notwithstanding, the ATF's objectives and remit do not include asking it to consider a wider analysis of opportunity cost in relation to wider public expenditure across government.

4. I have discussed this approach with senior officials across Government, including the Government Chief Scientific Adviser and DCMO Van-Tam, and would summarise the overall reaction as follows:

1) acknowledgment of potential contribution of antivirals;
2) an understanding that the proposal comprehensively addresses the question posed;
3) a concern that the current state of knowledge/data on these products does not offer certainty of full potential value being delivered;
4) the cost is such that it may compromise important spending elsewhere

5. I consider to be an appropriate assessment, as I also recognise that the original scenario may have implicitly assumed aspects of product supply and pricing that have not subsequently materialised. I note that the reality of commercial negotiations has

highlight that the ATF budget of £623m is insufficient to allow procurement of any reasonable volume, given market dynamics (very high demand, very few suppliers, very high pricing and inflexible purchase options) and the international context of constrained global supply until at least 2024. All recommendations must be assessed within this real-world context.

6. Having submitted and supported the recommendation, how do I now view a possible way forward?

7. In regard to process, I have always been conscious that the complexity of the variables in this area are significant, and that the need for strong understanding of virological, clinical and epidemiological factors needed to be allied to an insight into drug development, manufacturing and commercial/pricing. This is an almost impossible ask and does not respond well to repeated iterative review processes that lack the experience or intuitive understanding of the crucial interplay of the factors listed above. The response to the recommendation cited above has quickly generated a proposed review of options by the PM, SoS and Chancellor, supported and advised by DHSC Commercial, and the Offices of the CMO and GCSA. I do believe given the complexity and seriousness of the issues being considered this is the most appropriate way to proceed and I am fully supportive of that approach.

8. In regard to content, I do feel it is important that decisions are not 'reverse engineered' from a financial target - rather, a revised set of clinical/scientific targets more clearly informed by what we now know of the current COVID-19 situation and of what we now know regarding supply considerations. I think the population would expect and respond positively to this clinically led approach that places public health first and emphasises the critical importance of the UK's ongoing pandemic preparedness and a path towards living with SARS-CoV-2 long-term. I accept the changing circumstances and considerations referenced above. A process based on a fresh review and expert advice regarding clinical goals, decided at the most senior levels, is one I can support.

9. In this spirit, I have continued to interrogate whether a more realistic view of scientific goals can garner support amongst those best placed to know, and overlay that with the real-world pragmatism inherent in the commercial deals on offer. I have had further detailed discussions with GCSA and Deputy CMO (who is regularly in contact with CMO) and I think the following can be a positive and worthwhile contribution to public health at this time, whilst also being more affordable.From this perspective, common ground seems to exist around the following factors:

- Treatment of the most vulnerable over the age of 65/70
- Post exposure prophylaxis in specified high-risk environments
- The need to provide cover for the next two winters (rather than just one)

10. Expert advice would suggest there is good overlap between these categories and some of the priority groups referenced in 'Annex H' of the recently prepared submission. Treatment of those over 70 years for two winters, based on the Government's Central

modelling scenario, equates to 2 million courses as per Priority Group 1. Post exposure prophylaxis for high risk individuals over two winters, also based on the Government's Central modelling scenario, equates to 700,000 courses as per Priority Group 5

11. Given the design and size of commercial offers available, there a few options to consider. We should first consider Arrow, who has the most advanced set of data, should reach the market in October and November ,and can deliver the most significant volume for Autumn and Winter 2021/22. Arrow offer 1.8 million doses for this 2021/22 and 4.7 million doses for the 2022/23. If we procure the 1.8 million package, I&S I&S . If we take both, then all doses are discounted at [I&S]

12. Tyne offer only 250,000 this 2021/22 scheduled for late January/early February 2022. They have escalating volumes on offer at increasing I&S discounts up to [I&S] Similar to Arrow, the deal is I&S up to 5 million doses and then a negotiated [I&S] and higher volumes. There is a clinical imperative of having two classes of drug with separate mechanisms in the UK antiviral portfolio and that must be emphasised in line with the clear clinical advice.

13. In summary, the reality therefore of having the required 2.7 million doses, regardless of company, is that it will be at I&S with no additional flexibilities as negotiated.In the event of affordability constraints, I would therefore propose the following be considered.

14. As an absolute minimum, we seek to take the full 1.8 million from Arrow and the full 250,000 from Tyne from this Autumn and Winter 2021/22 giving us a total of 2.05 million doses. In addition, we secure 700,000from Arrow for the following Autumn and Winter 2022/23. It should be noted that shelf life should not be a problem, but should be monitored as a potential risk.

15. It is key to note the offer from Arrow does not currently address whether we can take only a proportion of the 4.7 million doses offer for next year. This requires urgent follow up dialogue and speed of decision-making is vital. If Arrow refuses, then we either stay at 2.05 and accept that the high-risk prophylaxis patients cannot be treated, which would be clinically sub-optimal and potentially have public health consequences, or we secure the 4.7 million on offer and extend treatment age range to 60yrs, which would be my earnest recommendation. These two fallback positions mean totals of 2.05 million doses in the first case or 6.8 million in the second scenario.

16. The cost of the recommended option - assuming Arrow agree terms - is [I&S] Irrelevant & Sensitive The fallback positions Irrelevant & Sensitive [I&S] and Irrelevant & Sensitive .

17. I must stress that this is a very different 'risk acceptance' position than the original scenario, but a potential path forward given affordability constraints. The fallback position of 2.05 million doses is clearly a lot more exposed and crucially depends on the