

4th September 2022

Advertising Standards and Outreach Unit
Medicines and Healthcare products Regulatory Agency
10 South Colonnade
LONDON E14 4PU

Dear Ms Tilstone

Re. A Complaint about the BBC Programme : “Unvaccinated”

Thank you very much for your response dated 12th August 2022 to our complaint regarding the BBC programme “Unvaccinated”.

I am writing on behalf of all the co-signatories to our original complaint letter dated 5th August 2022. You will not be surprised to hear that we were very disappointed to receive your response and would like to explain why we strongly disagree with your decision.

Firstly, let me say that we are pleased that you agree with us that this programme actually seeks to **change** the attitudes and behaviours of the participants (and by extension the viewers) by encouraging vaccination.

“I consider that any perceived encouragement by the presenter or guests who feature in the documentary to participate in the UK covid-19 vaccination programme....”.

We therefore are in agreement that the programme is not merely a vehicle for investigation and reporting (despite what you say in your somewhat contradictory following paragraph) but that it also seeks to change attitudes and behaviours by encouraging the participants to receive a covid vaccine. Your use of the word “perceived” may be an attempt to soften the effect of the promotion which is taking place here, but the promotional messages being transmitted by this programme, perceived or otherwise, remain clear. In broadcast material of this nature perception is often reality.

We also note that the 4th paragraph of your response begins *“It is our **initial** view that the broadcast falls outside the definition of an advertisement of a specific medicine or medicines.”* (Our emboldening). We hope that this indicates that you are willing to reconsider your decision.

In our detailed complaint letter we explained that the number of vaccines available in the UK was limited (three in total) at the time of the programme was broadcast, so it is clear which specific medicines were being promoted. In addition you have correctly identified that the programme also refers to specific individual vaccines. Despite these considerations however, you still go on to assert that this programme does not constitute promotion because you consider that reference to the vaccines *“is done in a factual and informative way throughout without highlighting particular qualities of a medicine (ie, without use of any product claims).”* We find it difficult to understand how one could make such a statement when, in our complaint letter, we have listed a number of

instances in which such product claims are made. Product claims illustrated within our original complaint are as follows (the timings are approximate):

- Minute 31
 - Professor Finn states that the vaccine is very good at preventing illness
 - Professor Finn states that *“We think that vaccine immunity is more consistent and usually stronger than infection immunity.”*
- Minute 39
 - Professor Khalil states *“What is new is that actually, potentially, the vaccine is actually useful for you and for the baby. The most recent data tells us that the vaccine could reduce the risk of stillbirth by about 15%”.*
 - This product claim is then repeated by Hannah Fry but paraphrased as *“If you catch covid whilst pregnant, your risk of losing your baby to stillbirth is 15% lower if you are vaccinated”*
 - Professor Khalil claims that the vaccine will *“prevent hospitalisation because of covid in the infant for the first 6 months of age”*

Minute 49

- The claim is made that the vaccines are *“safe and effective”*

The above is a list of product claims which we highlighted in our complaint letter. These examples are illustrative but not exhaustive. There are others contained within the programme. Here are some more examples :

- Minute 32
 - After having explained the beneficial role of antibodies in the immune response to covid, Professor Finn goes on to say *“What we see consistently with people who get vaccine is that you go from having no antibodies, unless you have had the infection before, and you go to having a lot of antibodies.”*
- Minute 33
 - Professor Finn says *“What we are finding though is that people who have had vaccine and then get the infection, they get a very strong immune response”*
- Minute 34/35
 - Hannah Fry says *“Put simply, the mRNA vaccine enables your body to make its own copies of the spike protein which in turn kick-starts the immune system into creating the antibodies you need to fight the virus.”*
- Minute 51/52
 - Hannah Fry says *“I want to remind everyone just how critical the vaccines have been in allowing us to go back to normal.”*

If you continue to assert that this programme was not promotional because there were no product claims made then in order for this line of reasoning to have any credibility it is surely incumbent on you to explain why all of the above do not constitute product claims. We would also remind you that you have used the lack of product claims as a rationale for deciding that this programme is not promotional. Therefore, it would not now be reasonable for you to say that these are not product claims because this programme is not promotional. That is a circular argument and would simply not be credible

Furthermore, you appear to be saying that the discussion of the vaccines within the programme is not promotional because it is *“done in a factual and informative way throughout”*. However, for broadcast material of this nature to be factual and informative it must also be balanced. Indeed, as we pointed out to you in our complaint letter, Appendix 5 of your own Blue Guide (Reporting to the public on medicines: Advice for journalists and patient organisations) makes clear the essential nature of balance in this type of broadcast material.

*“So what do journalists and patient organisations need to do to ensure they stay within the law when writing about medicines? Reporting information fairly and accurately while ensuring a balanced view is represented is paramount. Paying attention to these will help ensure the ban on advertising prescription medicines does not become an issue. **The bottom line is - keep it factual and balanced to keep out of the advertising controls.**”*

We explained, in great detail, in our original complaint why much of the information contained within the programme was neither balanced nor factually accurate. However, in your response letter you do not address any of these points you merely assert that you believe the content to be factual, informative and devoid of any product claims. We have demonstrated that the programme contains many product claims and that it is in many ways inaccurate and unbalanced. If you are to continue to deny our complaint on these grounds then in order for your rationale to maintain any credibility then we must insist that you explain in detail why you disagree with our points relating to product claims, accuracy and balance.

In addition, you also claim that this is not promotional material because it *“cannot be considered to have been designed to lead a member of the public to request a specific prescription-only medicine (as defined in regulation 284)”* However, regulation 284 makes no reference to a “specific” prescription-only medicine. This is what regulation 284 actually says :

“284.—(1) A person may not publish an advertisement that is likely to lead to the use of a prescription only medicine.”

However, as was pointed out above, specific vaccines were indeed named in this programme and as only 3 vaccines were licenced and available in the UK at the time of broadcast it is very clear which specific vaccines are being promoted here.

With regard to your suggestion that we refer our complaint to the ASA : We are aware that the ASA has some responsibilities for dealing with broadcast advertisements for some medicinal products. However, it is difficult to believe that when Ofcom delegated these responsibilities to the ASA they envisaged them dealing with complex cases such as this, involving as it does the misleading advertising of POMs to the general public with potentially serious public health consequences. It is also difficult to believe that the MHRA, as the UK's major medicines regulatory agency, responsible on behalf of the Health Ministers for protecting public health, should try, or even wish, to abrogate its responsibility in this respect. The Memorandum of understanding between the MHRA and the PMCPA states that the MHRA "*reserves the right to take action if serious public health concerns are raised*". We are not aware of any similar memorandum of understanding between the MHRA and the ASA but if there were we would be surprised if a similar clause were not included regarding the public health responsibilities of the MHRA. We strongly believe that it is the responsibility of the MHRA itself to deal with this serious complaint, to investigate it properly and thoroughly, and to provide both the complainants, and the wider general public, with a comprehensive, coherent and credible response.

In summary we, and we are sure many others, found your initial response to our detailed complaint to be superficial, internally inconsistent and unconvincing for the reasons we have set out above. We ask you to reconsider this initial decision.

Yours sincerely

Dr A.S.Black