5th August 2022

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

To Whom It May Concern,

We, the undersigned, are writing to complain about a programme entitled "Unvaccinated" which was broadcast on BBC2 on Wednesday 20th July at 9 PM. We believe that this programme constitutes promotion of medicinal products as defined in the Regulations applying to advertisements relating to medicinal products. We will be quoting from the MHRA document ***"The Blue Guide, Advertising and Promotion of Medicines in the UK (Updated 2020)"*** which will be referred to as the Blue Guide.

Section 3.3 of your Blue Guide identifies that the term, "Advertisement" is defined in regulation 7 of these Regulations as:

"Any thing or any activity which is intended to encourage prescription or supply by healthcare professionals and use of medicines by the general public, generally by means of highlighting qualities of the medicine ("product claims"), sale or consumption of medicinal products".

Section 3.3 also makes it clear that:

"An advertisement is not limited to specific media. It includes articles published in journals, magazines and newspapers, displays on posters and notices, photographs, film, broadcast material, video recording, electronic transmissions and material posted on the internet".

We will demonstrate by reference to both the tone and specific content of this programme that it constitutes promotion of the covid vaccines currently licenced and available in the UK. There are only three such vaccines currently licenced and available in the UK so it is very clear which specific medicinal products are being promoted.

Furthermore, your Blue Guide makes several references to the fact that the legislation is not limited to "*any thing*" or "*any activity*" produced or conducted solely by the marketing authorisation holder of the medicinal product :

- **4.4 Who is responsible?** ***: "Whilst the responsibility for ensuring that all advertising and promotional material for a medicine complies with the Regulations lies predominantly with the licence holder, the Regulations provide that it is an offence for "any person" to breach the Regulations."***

- Section Headed ***"LEGAL REQUIREMENTS FOR MEDICINES ADVERTISING IN THE UK".***

  This section contains the following statement : ***"It [UK legislation] makes it the responsibility of 'any person' who promotes a medicine, including the licence holder, a private individual or any third party such as journalists, publishers or public relations agencies, to ensure compliance with the legislation."***

- **7.2 Independent information sources**: ***"The Regulations apply to 'any person' who promotes a medicine, not just pharmaceutical companies. Journalists and patient organisations can have an important role in informing patients and the public about medicines; the MHRA has issued guidance to help ensure that they can provide information to help people make informed choices, while keeping out of the advertising controls. This can be found at Appendix 5.***

Materials should be balanced and factual, independently authored and designed to inform rather than to promote specific medicines."

- **"Appendix 5, Reporting to the public on medicines: Advice for journalists and patient organisations :**

  Health issues always hit the headlines and access to health information is important in empowering people to make informed decisions about their health care. Articles often draw attention to a prescription only medicine (POM) or results from trials on new products still in research. Yet the advertising legislation prevents these medicines being advertised to the public and the law applies to 'any person' - not just pharmaceutical companies. 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. <u>The bottom line is - keep it factual and balanced to keep out of the advertising controls.</u> [We have underlined this final sentence as it seems particularly relevant to this case]

  Background – what the law says
  There are a number of legal safeguards on advertising medicines intended to protect public health. These apply to materials which fall within the definition of an 'advertisement', which broadly speaking is anything "designed to promote the prescription, supply, sale or consumption" of a medicine. The safeguards include a ban on advertising medicines which have not been granted a marketing authorisation and on advertising prescription only medicines to the public. They also state that advertisements must present medicines objectively, without exaggerating their properties and that advertisements must not be misleading. <u>The key point is that these controls (and the penalties for breaches) apply to any person who promotes a medicine - not just the manufacturer.</u> [Again, our underlining]

  How is the advertising law interpreted
  <u>Any person could be viewed as promoting a medicine and proof of a commercial link to the sale of the product is not required.</u> [Once again, we have added the underlining for emphasis]
  The MHRA will take this into account in taking any action and eventually the national courts are best placed to decide on individual cases, balancing the right to free speech against the potential for damage to public health that the law is designed to protect[1].
  [[1] A judgment from the European Court of Justice would be informative in providing clarification of the advertising law. The Court held that under European law "dissemination by a third party of information about a medicinal product, including its therapeutic or prophylactic properties, may be regarded as advertising …, even though the third party in question is acting on his own initiative and completely independently, de jure and de facto, of the manufacturer and the seller of such a medicinal product". Details of Case C421/07 (Reference for a preliminary ruling from the Vestre Landsret, Denmark: Criminal proceedings against Frede Damgaard) are available at:
  http://curia.europa.eu/jurisp/cgibin/form.pl?lang=en&alljur=alljur&jurcdj=jurcdj&jurtpi=jurtpi&jurtfp=jurtfp&numaff=&nomusuel=
  damgaard&docnodecision=docnodecision&allcommjo=allcommjo&affint=affint&affclose=affclose&alldocrec=alldocrec&docor=docor&docav=docav&docsom=docsom&docinf=docinf&alldocnorec=alldocnorec&docnoor=docnoor&radtypeord=on&newform=newform&docj=docj&docop=docop&docnoj=docnoj&typeord=ALL&domaine=&mots=&resmax=100&Submit=Rechercher 2 Part 14 of the Human Medicines Regulations 2012 (SI 2012/1916 as amended). 3 For further

information see https://www.england.nhs.uk/tis/. ***information see https://www.england.nhs.uk/tis/.]"***

What are the reasons why this BBC programme is promotional in nature?

As stated in your Blue Guide **any** thing or activity would be deemed to be promotional if it intended to encourage sale, consumption, prescription or supply by healthcare professionals, and use of medicines by the general public of medicinal products. The BBC announcement on their website about the airing of this programme initially stated, ***"In this timely, eye-opening investigation commissioned by BBC Factual for BBC 2 and BBC iPlayer, due to air on Weds 20 July at 9PM, Professor Hannah Fry seeks to understand why a portion of the population remain unvaccinated against Covid-19"***. However later in that same release it also says the following:

"At the end of the experiment each contributor will be asked if what they have learned has changed their mind and whether they will now take up the vaccine." Use of the term ***"experiment"*** *clearly* indicates that the intention here was to encourage use of the vaccine by these members of the general public (and by inference, possibly "vaccine hesitant" members of the general public watching the programme) and to assess the success or otherwise of this encouragement. These statements and this behaviour fits exactly within the definition of promotion as set out in the Advertising Regulations and included in your Blue Guide. Furthermore, this BBC announcement on their website goes on to say the following:

"what will it take to convince those who are unvaccinated to get their first Covid-19 vaccination?" Thus further reinforcing the fact that it was an aim of the producers of this programme to change the participant's minds and encourage them to use a Covid-19 vaccine.

This programme aim becomes even clearer on watching the programme itself. Very early in the programme Professor Fry herself says (when referring to the choice of the participants not to be vaccinated) ***"I want to know why, and if anything can change their minds".*** Towards the end of the programme she also says:

"It's a last attempt to see if anyone will change their mind" and…….

"It was always going to be hard to change peoples' minds"

It is further indicative of the promotional nature of this programme that when the producers engaged a doctor to discuss possible side-effects of the vaccines with the participant, the doctor chosen for this role (a GP called Dr Arora) was described by Professor Fry in the following way ***"She works with the BMA to promote the vaccine online."***

The producers' choice of venue for the final reunion of participants was a Covid-19 vaccination clinic. The intention here was clearly a final attempt to further encourage the participants to receive a vaccination by facilitating that vaccination, if they had been encouraged by their participation in the programme to do so.

These statements and editorial decisions, together with the programme's general tone, structure and content could lead no reasonable person to conclude anything other than that the intention of its producers and presenters is to encourage the use of Covid-19 vaccines. Therefore, according to the definition in the UK Regulations relating to the advertising of medicinal products, this is a promotional activity and the programme is an advertisement. As such it is therefore the responsibility of those producing and disseminating it to ensure its compliance with the

requirements of the legislation regarding the Quality Standards expected of such material. Your Blue Guide sets out these Quality standards as follows:

"Section 4.3 Quality standards : By regulation 280 of the Regulations, an advertisement must:

(1) comply with the particulars listed in the summary of product characteristics (SPC);

(2) encourage the rational use of the product by presenting it objectively and without exaggerating its qualities; and

(3) not be misleading.

The provisions are not mutually exclusive and each one must be complied with."

It is Quality Standards 2) and 3) with which we have particular concerns. Your Blue Guide goes on to further expand on these requirements: (sections particularly relevant to the case we will make have been underlined)

"(2) Encouraging rational use

An advertisement must present information which is factually correct and those facts should not be exaggerated in any way by the presentation of the advertisement. The factual accuracy should be independently verifiable. For example, an advertisement for a product offering symptomatic relief should not imply that it cures the underlying condition. An advertisement would not be 'objective' where it relies solely on the feelings or opinions of the advertiser. An advertisement would not be objective if it failed to refer to any significant limitations that were relevant to the claims made for the product. Similarly an advertisement that includes data, trials or studies that are not presented accurately or in context would be considered as exaggerating the properties of a product. Where a relative change is quoted, the absolute values should also be given to enable the reader to fully assess the magnitude of the claimed benefit.

(3) Not misleading

This is a widely drawn prohibition. It will catch any advertisement which leads to an erroneous belief of any nature about the medicine. In particular it will catch advertisements which mislead as to the potential benefits or possible risks of a medicine. Often advertisements which fall foul of this provision will already have breached regulation 280(1) or (2). A factually accurate advertisement may also be misleading due to the overall impression given. Unrealistic or inappropriate images can give rise to misleading expectations about the product or the indicated patient population."

As promotional material it is clear to us that this programme is in breach of your Quality Standards in a number of ways which we will illustrate below. In addition, possibly most importantly, this programme is promoting a prescription-only-medicine to the general public. This is what your Blue Guide has to say about this subject:

"Section 1.3, Regulation of Advertising:

The legislation lays down the requirements and restrictions for advertising, aimed at either prescribers or suppliers of medicines to the public, or at the public as purchasers of over-the-counter medicines. Central to this is the principle that advertising of prescription only medicines to the public is prohibited. The decision to prescribe a certain medicine is taken by a qualified healthcare professional on the basis of informed discussion with the patient."

"Section 5.2 Medicines suitable for advertising to the public

The Regulations prohibit the issue of any advertisement wholly or mainly directed to the general public which is likely to lead to the use of a prescription only medicine (POM)."

We note that section 5.2 also says that ***"Advertisements for a licensed vaccine product that have been approved by Health Ministers as part of a Government controlled vaccination campaign are exempt from this prohibition."*** We think it unlikely that this promotion has actually been approved by any Health Ministers but would be very interested to hear if it has.

Failure to Meet Quality Standards Required of an Advertisement for a medicinal Product

As we have discussed above, Section 4.3 of your Blue Guide lists a set of Quality Standards established by Regulation 280. According to this Regulation an advertisement must:

(1) comply with the particulars listed in the summary of product characteristics (SPC);

(2) encourage the rational use of the product by presenting it objectively and without exaggerating its qualities; and

(3) not be misleading.

This promotional programme fails to meet these standards in numerous ways. Below we list some of the more egregious examples of breaches of Standards 2) and 3):

- **Minute 1**: The programme introduction stated that 4 million adults are unvaccinated, but government data shows the correct figure is 12.4 million. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1088929/Weekly_Flu_and_COVID-19_report_w27.pdf (see table 5, page 65). This error was apparently pointed out to the BBC before the programme was aired. This misrepresentation, and misleading use of data, giving the wrong figure, is clearly intended to make unvaccinated people feel they are in a much smaller minority than they actually are.

- **Minute 17**: GP Dr Arora from the BMA told a participant that ***"all the research studies that have been done have shown there is no impact on fertility in male or female patients***. ***However, research studies and clinical evidence has shown that if you have Covid-19 infection that can temporarily affect sperm quality and count"***. She has omitted to mention animal studies showing the lipid nanoparticles accumulating in ovary and testes of rats 672212000_30300AMX00231_I100_1.pdf (pmda.go.jp) but more importantly, has also omitted a recent report on human sperm donors, showing that sperm count and motility fell 22% after vaccination and this persisted after 5 months. https://onlinelibrary.wiley.com/doi/epdf/10.1111/andr.13209

- **Minute 23**: The jelly bean exercise trivialised vaccine-induced myocarditis, a serious condition which has resulted in deaths and life-altering cardiac damage. Statistics given about myocarditis quoted a rate of 1 in 33,000 people aged 18-29 but with no further breakdown by age or gender or vaccine dose, and so it was seriously misleading for younger males after a second dose. Reports from Hong Kong demonstrated a rate of 1 in 2680 in young men after their second dose of Pfizer https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8767823/ . Hannah Fry then goes on to state that myocarditis risk is higher after Covid-19 infection. This is only true for older age groups eg an Oxford study shows vaccine risk exceeds infection risk for under 40s https://www.nature.com/articles/s41591-021-01630-0 . An Israeli study showed no increase in myocarditis post infection when confining all the data to the first year of the pandemic i.e. before any vaccinations https://www.mdpi.com/2077-0383/11/8/2219/htm . This report to the

CDC gives a very different view of the seriousness of myocarditis https://www.fda.gov/media/153514/download .

Other side effects are mentioned, but again with no overview of the risk of serious adverse events such as shown in the recent analysis of all the randomised trials Serious Adverse Events of Special Interest Following mRNA Vaccination in Randomized Trials by Joseph Fraiman, Juan Erviti, Mark Jones, Sander Greenland, Patrick Whelan, Robert M. Kaplan, Peter Doshi :: SSRN.

- **Minute 27**: Hannah Fry states that VITT deaths were in the '10s' when, in May 2021, the AstraZeneca covid vaccine was withdrawn from use for younger age groups. However, she made no mention of ongoing cases. 443 cases have been reported up to 29th June 2022 in the latest MHRA report "Coronavirus vaccine - summary of Yellow Card reporting" - Coronavirus vaccine - summary of Yellow Card reporting - GOV.UK (www.gov.uk) with an incidence of 15.8 per million. There is also no discussion, or even any mention, of the issue that spontaneous adverse event reporting is a voluntary and often time-consuming system with known underreporting, a world-wide problem https://www.researchgate.net/publication/7090916_Underreporting_of_adverse_drug_reactions_A_systematic_review. An MOH questionnaire to vaccinees in Israel, confirmed massive underreporting in their system https://jackanapes.substack.com/p/the-israeli-ministry-of-health-actually-db7 . Similarly, insurance data from Germany BKK sounds the alarm: Vaccine side effects totally underestimated | Nordkurier.de suggested a major under-reporting in their governmental system. The fact that none of this information, or anything similar, was discussed meant that the benefit/risk discussion about covid vaccines was extremely unbalanced.

- **Minute 31**: Professor Finn stated that covid vaccine is very good at preventing illness but not at preventing transmission. But when asked by one of the participants about the effect of infection, he replied ***"We think that vaccine immunity is more consistent and usually stronger than infection immunity."*** However, this opinion runs contrary to all the recently published data showing that naturally acquired immunity is strong and durable eg. from Qatar Protection of prior natural infection compared to mRNA vaccination against SARS-CoV-2 infection and severe COVID-19 in Qatar (medrxiv.org) , US https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v3 or Switzerland ciab495.pdf (nih.gov). This is especially true for children in Israel. https://www.medrxiv.org/content/10.1101/2022.06.20.22276650v1.full.pdf+html

- **Minute 39**: Hannah Fry explains that participants are meeting Professor Khalil ***"to hear about the latest results from one of the largest trials vaccine and pregnancy trials in the UK".*** This is not correct, as the paper from Professor Khalil and colleagues was an analysis of real world data and included less than 100 women vaccinated within a controlled trial – the trials all specifically excluded pregnant women.

  In general the tone of this entire pregnancy segment of the programme is very disturbing. Professor Khalil and her "volunteer" assistant apparently go to great lengths to reassure the participants about the safety of the vaccine in pregnancy, without at any time even mentioning that there could be any risk at all to either the pregnancy or the foetus from covid vaccination. At the beginning of this segment Professor Khalil states unequivocally that ***"we know for sure that the vaccine does not cause miscarriage and that the vaccine does not increase the chance of stillbirth"***. The potential benefits of vaccination in terms of a positive outcome to a pregnancy are emphasised strongly and exclusively with no mention of potential risks. The vaccine is described as ***"useful"*** in preventing stillbirth. In fact, what Professor Khalil actually says is as follows : ***"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 [the Professor Khalil puts a heavy emphasis on the word ***"could"***] ***reduce the risk of stillbirth by about 15%".*** Hannah Fry then "repeats" the Professor's words as a voiceover. However, the key words ***"potentially"*** and ***"could"*** are omitted and instead Fry says that the risk ***"is"*** reduced by 15%. Her exact words are as follows***: "If you catch covid whilst pregnant, your risk of losing your baby to stillbirth is 15% lower if you are vaccinated"*** (Contrary to the regulations there is also no indication provided to participants or viewers of whether these figures are absolute or relative risk reductions). The pregnant participant specifically asked if all the studies were aligned in terms of the results and she was assured that they were. It is therefore surprising to read Professor Khalil's paper and find (Figure 3) that of 7 studies reporting on stillbirths, three showed a reduction, three showed no difference and one showed an increase. Moreover, in a review of the publication in Nature Communications, there is a reworking of the data by a separate author, questioning the certainty of the claim of a 15% reduction in stillbirths. (https://disqus.com/home/discussion/ncomms/systematic_review_and_meta_analysis_of_the_effectiveness_and_perinatal_outcomes_of_covid_19_vaccinat/) This author concludes that the data do not actually support the statement that vaccination decreases the risk of stillbirth. The author further observes that using the results of this study to predict ***" the effectiveness of vaccination on stillbirth for a new cohort would exceed the threshold of the odds ratio. As a result the findings are too uncertain to be communicated to future patients."*** He goes on in his summary of his review and analysis of this study's methodology to state the following:

"the statement that vaccination protects stillbirth sits on the edge of acceptable certainty following the analytical methods used by the authors but disappears when applying adjustments."

"……it very much remains to be seen if new studies will strengthen the current shaky evidence base." and finally …..

"When boundary findings are susceptible to tipping by choices made, and unable to inform the next patient, it is perhaps best if such findings are purposefully downgraded to prohibit any grand claims on the protective effects of vaccinations. In fact, it gives false hope and that is not what evidence-based medicine should be about."

Furthermore, in the 40th minute Professor Khalil told the pregnant participant that the vaccine will ***"prevent hospitalisation because of covid in the infant for the first 6 months of age",*** but she failed to mention that the mother's own recent covid infection would have exactly the same effect, with antibodies crossing the placenta.

Thus the unwarranted level of certainty and lack of balance exhibited by the producers of this programme when presenting the results of this study to a pregnant participant, and possibly thousands of pregnant viewers, is entirely inappropriate. The overall unbalanced and misleading nature of the segment of the programme dealing with pregnancy is particularly disturbing because one must view it in the context of the additional guidance provided by the MHRA in Appendix 3 of your Blue Guide which deals with the promotion of drugs for use during pregnancy and which states :

"This guidance is intended for advertisers to ensure safe and responsible advertising of medicines which may be promoted for use during pregnancy." In section 4.1 of this Appendix, Advertising to the general public, it states that : " Regulations 282 to 293 of the Human Medicines Regulations 2012 lay down the requirements and restrictions for advertising medicines to the general public. In addition, the following guidance is provided for the advertising of any licensed medicine which is promoted for use during pregnancy:

(a) Advertisements to the general public mentioning the use of the product during pregnancy are only acceptable for medicines where a positive statement in section 4.1 or 4.6 the Summary of Product Characteristics (SPC) supports the use of the product in pregnancy – <u>providing the other principles/guidance are followed (see below).”</u>

We acknowledge that the SPCs for the 3 vaccines licenced and available in the UK do have a statement in section 4.6 indicating that they can be used during pregnancy. However as stated in (a) above promotion is still only permitted if certain additional conditions are met. Amongst those conditions are listed the following:

(b) Advertisements should not convey the message that it is usual for pregnant women to take medicines. Advertisers are encouraged to include advice on non-pharmacological measures where appropriate.

(c) Advertisements should not state or imply that the advertised product, or any other medicine, cannot harm the developing fetus

(f) All advertisements for medicines promoting use in pregnancy directly to pregnant women should include a general warning message appropriate to the medium being used (e.g. print, television, radio). An example of appropriate wording is given below. We would also encourage the inclusion of such a warning in any general advertising for a systemic medicine where the target audience is mainly pregnant women (e.g. in a pregnancy magazine). “Medicines can affect the unborn baby. Always talk to your doctor or pharmacist before taking any medicine in pregnancy”.

At no stage during this programme did any presenter or expert comply with requirements b) c) and f)

It is also worthy of note that section 4.6 of the SPCs for these vaccines states ***that “While data on pregnancy outcomes following vaccination during the first trimester are presently limited, no increased risk for miscarriage has been seen”.*** However, an initial “General Statement” in your Blue Guide Appendix 3 refers the reader to the following boxed warning in the BNF (We have underlined the final line as we believe it to be particularly relevant to this point :

“An important general principle is that caution should always be taken when medicines are prescribed/taken during pregnancy and the risks to both the mother and fetus should always be considered.

The British National Formulary (BNF) states that drugs can have harmful effects on the fetus at any time during pregnancy and that it is important to bear this in mind when prescribing for a woman of childbearing age. The Prescribing in pregnancy section of the BNF includes the following boxed warning:

“Drugs should be prescribed in pregnancy only if the expected benefit to the mother is thought to be greater than the risk to the fetus, and all drugs should be avoided if possible during the first trimester.

Drugs which have been extensively used in pregnancy and appear to be usually safe should be prescribed in preference to new or untried drugs; and the smallest effective dose should be used.

Few drugs have been shown conclusively to be teratogenic in humans but no drug is safe beyond all doubt in early pregnancy. Screening procedures are available where there is a known risk of certain defects.

Absence of information does not imply safety"

The high degree of caution to be exercised by anyone promoting drugs to be used in pregnancy which is required, indeed specified, by Appendix 3 of your Blue Guide is laudable. Unfortunately it is a degree of caution which appears to have been entirely abandoned by the makers of this programme. This segment of the programme dealing with pregnancy completely ignores the guidance set out in Appendix 3 of your Blue Guide and it is clearly and seriously in breach of your Quality Standards 2 and 3.

- **Minute 43:** Hannah Fry implied that the current vaccines are fully approved rather than confirming that they are still only have conditional marketing authorisations (CMAs). There is a significant difference between a CMA and a full marketing authorisation (FMA) and this should have been explained to the participants and the viewers. You will be aware that the MHRA website contains the following statement about when the MHRA will issue a CMA rather than an FMA :

  "The MHRA may grant a CMA where comprehensive clinical data is not yet complete, but it is judged that such data will become available soon."

  To omit such important information from a response to such a specific question is extremely misleading.

- **Minute 49**: Here the covid vaccines are described as ***"safe and effective".*** Section 6.6 of your Blue Guide contains some very specific instructions about use of the word "safe" to describe any medicinal products in promotional material:

  "Advertising which states or implies that a product is "safe" is unacceptable. All medicines have the potential for side-effects and no medicine is completely risk free as individual patients respond differently to treatment……no medicine is completely risk-free"

- **Minute 53:** The consultant at Lewisham Hospital's ICU states that all their deaths were unvaccinated. It was not discussed that those within 21 days following their first dose may be classified as 'unvaccinated'. Nor that there is there any acknowledgement of an increase in cases in the first 9 days post vaccination, as in PHE report here https://www.bmj.com/content/373/bmj.n1088. Similar findings have been reported from Israel after the 4th dose, with data censored until day 8 https://www.nejm.org/doi/suppl/10.1056/NEJMc2202542/suppl_file/nejmc2202542_appendix.pdf

In addition to the illustrative specific points listed above, there were numerous omissions from this programme which contributed to its biased, unbalanced and misleading nature:

- There was no acknowledgement that those participants who had already had covid, would almost certainly have good natural immunity.
- There was no acknowledgement of the waning efficacy of the vaccines especially against the omicron variant.
- There was also no mention of potential conflicts of interest of any of the 'experts'.

- ‘Experts’ included in this programme did not include anyone with a different opinion e.g. doctors treating patients with vaccine injuries or an immunologist talking about immunity post-infection. The implication was that all ‘experts’ are agreed that the vaccine is ‘Safe and Effective’.

Finally we would say that promotional recommendations and endorsements by scientists, clinicians and celebrity academics, as used in this programme, runs contrary to requirements set out in section 5.7 of your Blue Guide which states:

“Recommendations and endorsements

Advertisements to the general public should not contain material which refers to recommendations by scientists or healthcare professionals, or which refers to recommendations by celebrities who, because of their celebrity, could encourage consumption of products…….. Nor should an advertisement state that a product has MHRA or Department of Health and Social Care “approval”.

Summary

Society demands that advertising of any commodity, service or anything that may be of interest to the consumer, should be of a high standard. It should not include anything that could cause serious or widespread offence, create unrealistic expectations in the consumer or be misleading. Furthermore, UK law recognises that medicines should not be treated as an ordinary general commodity by placing specific restrictions on them. There is recognition in this approach that potentially vulnerable, sick people and their carers could be affected or even targeted by such promotional activities.

Therefore, over and above the general legislation and controls on advertising, there is additional specific legislation that applies to the advertising of medicines. All advertising and promotion of medicines, both for self-medication and to healthcare professionals where medical prescription is required, must be responsible and of the highest standard. All means and media used in the promotional marketing of medicines are subject to the legislation controlling advertising. This includes academics, journalists and broadcast media.

The television programme “Unvaccinated” broadcast by the BBC and still available on its iPlayer streaming service meets the definition of an advertisement for a medicinal product as set out in the Advertising Regulations. As such it is therefore in breach of these regulations as it is promoting specific POMs to the general public. It also fails to meet the required quality standards for the advertising of medicinal products as set out in these regulations as, on a number of counts, it fails to encourage the rational use of the products by presenting them objectively and without exaggerating their qualities, it is misleading and it also describes them as “safe”.

We would be grateful if you would take the necessary steps to ensure that these breaches of the UK legislation are dealt with appropriately.

Yours sincerely,

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