Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

Dear [redacted]

FOI 23/056 – RFI

We are writing to you to acknowledge the ICO's decision (IC-244363-G0J0, dated 25 September 2023), and proceed to release the 'Request for Further Information' (RFI) information i.e. part a and b of the request to you.

"a) the document references (inc dates) of those letters
b) how many questions were included in each RFI letter"

The information is as follows:

Moderna mRNA-1273 SARS-CoV-2 vaccine Suspension for injection (PL 53720/0001; Regulation 174 authorisation on 08 January 2021)

Date of RFI letter	MHRA Ref number	Number of RFI questions
16/11/2020	PL 53720/0001 - 0001	16
10/12/2020	PL 53720/0001 - 0001	24 (Q1 includes part a and b)
18/12/2020	PL 53720/0001 - 0001	92 (including 1 unresolved from previous round)
23/12/2020	PL 53720/0001 - 0001	42
24/12/2020	PL 53720/0001 - 0001	5 (Q1 has part a-c, Q2 has part a-d, Q3 has part a-e)
28/12/2020	PL 53720/0001 - 0001	57
29/12/2020	PL 53720/0001 - 0001	12
04/01/2021	PL 53720/0001 - 0001	1

AstraZeneca COVID-19 Vaccine AstraZeneca, solution for injection COVID-19 Vaccine (ChAdOx1-S [recombinant]) (PL 17901/0351; Regulation 174 authorisation on 30 December 2020)

Date of RFI letter	MHRA Ref number	Number of RFI questions
16/10/2020	PL 17901/0351 - 0001	9
26/10/2020	PL 17901/0351 - 0001	11
27/11/2020	PL 17901/0351 - 0001	23
08/12/2020	PL 17901/0351 - 0001	19
14/12/2020	PL 17901/0351 - 0001	17
15/12/2020	PL 17901/0351 - 0001	1 main with 7 specific sub questions.
17/12/2020	PL 17901/0351 - 0001	8 (Q6 has part a-d, Q7 has part a & b)
22/12/2020	PL 17901/0351 - 0001	69 including 3 unresolved from previous round) (Q13 has part a-f, Q14 has part a-e, Q42 has part a-d)

Pfizer/BioNTech BNT162b2 mRNA Covid-19 Vaccine (PL 53632/0001; Regulation 174 authorisation on 02 December 2020)

Date of RFI letter	MHRA Ref number	Number of RFI questions
02/11/2020	PL 53632/0001 - 0001	13
03/11/2020	PL 53632/0001 – 0001	34 (Q18 has 5 parts, Q19 has 3 parts and Q20 has 4 parts)

Please note that the above tables show formal RFI letters that were sent from our case management system and so may not represent the full extent of the questions asked. Additional questions were asked and answered via email/telephone and during meetings with the companies.

The formal RFIs that were sent for Pfizer/BioNTech BNT162b2 mRNA Covid-19 Vaccine (PL 53632/0001) reflect only the clinical and non-clinical aspects. In addition to the modes described above, Quality questions were raised by email and by inclusion in rolling-review assessment reports. The tables above for the other vaccines detail clinical, non-clinical and quality aspects.

Please note, we originally withheld this information due to concerns that the figures, if used without the proper context, could be used to undermine confidence in the assessments of the COVID-19 vaccines. For this reason, should the intention be to host this information elsewhere, we ask that the context provided above is not removed. We would like to reiterate that the number of RFI questions and the dates, are largely meaningless and deductions on the depth of the assessments undertaken, or the quality of medicine's applications, cannot be drawn from these figures.

Yours sincerely,

Senior Scientific Lead
HQ&A FOI Team

info@mhra.gov.uk