

Quality

The supply of batch EJ0553 is authorised providing that:

- Pfizer/BioNTech ensure that Good Laboratory Practice studies are performed to standards in UK national regulations, relevant guidelines and the OECD Principles of Good Laboratory Practice.
- Pfizer/BioNTech ensure that clinical trials are performed to national regulations and relevant guidelines including ICH GCP E6R2
- Pfizer/BioNTech submit to MHRA GCP inspections to assess the compliance any of the clinical trials and applicable data attached to the authorisation by virtue of regulation 174A. The powers of inspection will be the same as those outlined in regulations 325, 326 and 327
- Pfizer/BioNTech ensure that all drug substance and drug product manufacture outside the UK is in accordance with EU GMP and the Human Medicines Regulations 2012 (as amended) in facilities with current EU GMP certificates or other acceptable and suitable authorisation to MHRA.
- QP certification is provided for the final dosage form and applying the approach and standards in EU GMP Annex 16.
- Any importation or manufacturing facilities located within the UK must be authorised by the MHRA to handle Regulation 174 products. All drug substance and drug product manufacture must be in accordance with EU GMP and the Human Medicines Regulations 2012 (as amended) in facilities with current EU GMP certificates or other acceptable and suitable authorisation to MHRA.
- Compliance with GMP requirements is documented in the QP check sheets and Pfizer/BioNTech provide these to the MHRA for each batch along with the QP certificates of conformance. QP certification must take into NIBSC certification process, as this in itself does not imply release to market.
- QP certification declares: (i) compliance with all stages of EU GMP (where non-compliant, a gap analysis must be performed, and captured on the QP checksheet), and (ii) that the batch has been manufactured as per the dossier supplied (currently

BATCH	ADRs	DEATHS	DISABILITIES	LIFE THREATENING ILLNESSES
EM0477	1962	235	118	97
EJ6788	1137	148	26	56
EJ6795	1041	147	46	76
EK9788	2641	140	142	112
EJ6796	1033	120	38	64
EP9598	1133	97	83	59
EP2166	1086	97	101	85
EJ6134	1300	95	169	59
EJ6789	1076	94	101	45
ET3620	1109	86	65	74
ET1831	1122	84	56	68
ER7812	695	77	50	43
EJ6797	1972	76	134	49
EW2239	1315	70	70	72
EP2163	1219	68	73	65
ET7205	932	67	68	61
EX3617	477	66	9	23
EW2246	1077	64	46	63
Notknown	2874	58	328	117