

Summary of MHRA’s regulatory position for Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) reported following COVID-19 Vaccines

Background

The MHRA is responsible for regulating vaccines in the UK by ensuring that they work and are acceptably safe. No medicinal product is completely without risk. In the context of medicinal products authorised by the MHRA, acceptably safe means that based on the assessment of the MHRA, the benefits, or expected benefits, associated with a particular product are considered to outweigh any risks associated with that product, at a population level.

Part of the MHRA’s monitoring role includes reviewing reports of suspected side effects – known as suspected Adverse Drug Reactions (“ADRs”) – through the Yellow Card scheme. The MHRA operates the Yellow Card scheme on behalf of the Commission on Human Medicines (CHM). The scheme collects and monitors information on suspected safety concerns or incidents involving vaccines, medicines, medical devices, and e-cigarettes. The scheme relies on voluntary reporting of suspected adverse incidents by healthcare professionals and members of the public (patients, users, or carers). The purpose of the scheme is to provide an early warning that the safety of a product may require further investigation.

Yellow Card reports of ADRs are evaluated, together with additional sources of evidence, by a team of safety experts to identify any new safety issues or side effects. The MHRA apply statistical techniques that can tell us whether we are seeing more events than we would expect to see, based on what is known about background rates of illness in the absence of vaccination, if this information is available. This aims to allow for factors such as coincidental illness. The MHRA also regularly reviews safety information from the COVID-19 vaccine marketing authorisation holders.

The MHRA supplement this form of safety monitoring with other epidemiology studies, including analysis of data on national vaccine usage; anonymised GP-based electronic healthcare records; and other healthcare data. The MHRA also take into account the international experience based on data from other countries using the same vaccines. Further information is available in the COVID-19 vaccine surveillance strategy published on the MHRA’s website¹.

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

CIDP is the most common chronic autoimmune peripheral nervous system disorder. The prevalence of CIDP has been reported to vary widely in different populations, with differences likely relating, in part, to use of different diagnostic criteria. An estimated worldwide prevalence of about 3 per 100,000 has been described. The incidence of CIDP is less than 1 per 100,000 per year. The latest European Academy of Neurology/Peripheral Nerve Society Guidelines published in 2021 have provided up-to-date directives and guidance on diagnosis and treatment of CIDP. Typical CIDP presents with symmetrical motor and sensory dysfunction of proximal and distal regions of the four limbs progressing over more than 8 weeks. CIDP may also present in variant forms, which can be focal, multifocal, distal, pure motor or motor-predominant, pure sensory or sensory-predominant. There are no currently established biomarkers for CIDP. Evidence-based first-line

¹ <https://www.gov.uk/government/publications/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance/report-of-the-commission-on-human-medicines-expert-working-group-on-covid-19-vaccine-safety-surveillance>

treatments for CIDP include immunoglobulins, corticosteroids and plasma exchange. A small number of randomized controlled trials have been performed to evaluate the efficacy of immunosuppressant agents for CIDP, none of which demonstrated benefit. In spite of these results, azathioprine and methotrexate remain in use worldwide. Cyclosporine and mycophenolate mofetil are also used in practice on a frequent basis, despite only limited data coming from case series or case reports. Other agents including interferon- α , alemtuzumab, natalizumab, etanercept, fludarabine and tacrolimus, have been described as occasionally effective, although they are not of common use in clinical practice. Cyclophosphamide is today frequently utilized as first immunosuppressant in severe, refractory CIDP, in many centres. Rituximab has been found to be effective in CIDP as reported by numerous case-series throughout the world, particularly in situations of refractoriness².

While the early presentations of CIDP and Guillain–Barré syndrome (GBS) can be similar, it is important to correctly distinguish the two conditions as treatment approaches may differ.³

GBS is a recognized side effect of Vaxzevria, the AstraZeneca COVID-19 vaccine⁴ and is described in the product information. GBS is not recognized in association with any other COVID-19 vaccine approved in the UK (noting that the licence for Jcovden, the Janssen COVID-19 vaccine, has been withdrawn and this product was never deployed in the UK).

A signal for CIDP has never arisen during MHRA surveillance of adverse event reports for the COVID-19 vaccines. CIDP is not a recognized side effect for any COVID-19 vaccine ever approved in the UK, and it has not been raised as a safety signal by any other international regulator.

MHRA

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Review of regulatory summary: Chronic Inflammatory Demyelinating Polyneuropathy

There has been no change to the regulatory position on this condition.

MHRA

8 August 2024

² [Chronic Inflammatory Demyelinating Polyradiculoneuropathy: Current Therapeutic Approaches and Future Outlooks - PMC \(nih.gov\)](#)

³ [Differentiation Between Guillain–Barré Syndrome and Acute-Onset Chronic Inflammatory Demyelinating Polyradiculoneuritis—a Prospective Follow-up Study Using Ultrasound and Neurophysiological Measurements - PMC \(nih.gov\)](#)

⁴ https://assets.publishing.service.gov.uk/media/655def6d046ed4000d8b9e14/PLGB_17901_0355_AZ_SmPC.pdf