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# **NO LONGER UNDERSERVED: A EUROPEAN CALL TO ACTION ON AUTOIMMUNE DISEASES**

# No longer underserved: a European call to action on autoimmune diseases

**A**utoimmune diseases (ADs) represent one of Europe's most complex and underestimated health challenges. They arise when the immune system mistakenly attacks healthy cells, leading to chronic, often multi-organ conditions that are difficult to diagnose and manage.<sup>1</sup>

With over 80 recognised autoimmune diseases, millions of people worldwide are impacted.<sup>2,3</sup> Approximately 5% of the global population is affected, representing around 22 million people in the European Union (EU) alone.<sup>4,5</sup> Over the past two decades, both incidence and prevalence have steadily increased, turning autoimmune diseases into a growing public health challenge.<sup>6,7</sup>

These conditions often strike individuals during their most productive years,<sup>8,9,10</sup> severely affecting quality of life through fatigue, pain, cognitive impairment, and unpredictable flare-ups.<sup>11,12,13</sup> The impact extends well beyond patients: caregiver burden is substantial,<sup>14,15</sup> often with high stress and depression levels and measurable productivity impacts.<sup>16,17,18</sup> The societal and economic burden is considerable: autoimmune diseases cost European healthcare systems over €50 billion annually,<sup>19</sup> driven by hospitalisations, disability, and productivity loss.

While some autoimmune diseases, such as type 1 diabetes and multiple sclerosis, are widely recognised, other autoimmune diseases remain largely invisible and underserved. These **underserved autoimmune diseases** have faced historical underinvestment in therapeutic innovation, limited awareness, fragmented data, delayed diagnosis, and unequal access to care. Importantly, many disproportionately affect women, revealing a persistent gender imbalance in recognition, research, and response.<sup>20</sup>

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<sup>1</sup> Arango, M.T., et al., "Infection and Autoimmune Diseases," in *Autoimmunity* (NCBI Bookshelf, 2013).

<sup>2</sup> National Institute of Allergy and Infectious Diseases, "Autoimmune Diseases," available at: <https://www.niaid.nih.gov/diseases-conditions/autoimmune-diseases> (accessed September 2025).

<sup>3</sup> "Multifaceted Autoimmunity: New Challenges and New Approaches," *eBioMedicine* 88 (2023): 104474.

<sup>4</sup> Bieber, K., et al., "Autoimmune Pre-Disease," *Autoimmunity Reviews* 22, no. 2 (2023): 103236.

<sup>5</sup> Eurostat, "Population Change – Demographic Balance and Crude Rates," available at: <https://ec.europa.eu/eurostat> (accessed September 2025).

<sup>6</sup> Miller, F.W., "Epidemiology of Autoimmune Diseases," *Current Opinion in Immunology* 80 (2023): 102266.

<sup>7</sup> Mayo Clinic, "New Study Calculates Autoimmune Disease Prevalence in U.S.," available at: <https://newsnetwork.mayoclinic.org> (accessed September 2025).

<sup>8</sup> Mayo Clinic, "Lupus," available at: <https://www.mayoclinic.org> (accessed September 2025).

<sup>9</sup> National Institute of Neurological Disorders and Stroke, "Myasthenia Gravis," available at: <https://www.ninds.nih.gov> (accessed September 2025).

<sup>10</sup> Mayo Clinic, "Multiple Sclerosis," available at: <https://www.mayoclinic.org> (accessed September 2025).

<sup>11</sup> Bunschoten, C., et al., "Progress in Diagnosis and Treatment of Chronic Inflammatory Demyelinating Polyneuropathy," *The Lancet Neurology* 18, no. 8 (2019): 784–794.

<sup>12</sup> Lewis, R.A., et al., "Chronic Inflammatory Demyelinating Polyneuropathy: From Bench to Bedside," *Journal of the Neurological Sciences* 443 (2022): 120478.

<sup>13</sup> Brun, S., et al., "Autoimmunity and Inflammation in Neurological Disorders," *Immuno* 2, no. 1 (2022): 118–131.

<sup>14</sup> Phil, J., et al., "Productivity Losses for Generalized Myasthenia Gravis Patients and Their Caregivers: Association with Disease Severity," poster presented at International Congress on Neuromuscular Disorders, 2022, available at: <https://argenxmedical.com> (accessed September 2025).

<sup>15</sup> Kent, T., et al., "The Impact of Systemic Lupus Erythematosus on Health-Related Quality of Life: A Systematic Review," *Lupus* 26, no. 10 (2017): 1095–1100.

<sup>16</sup> *Ibid.*

<sup>17</sup> Pryce CR & Fontana A, *Depression in Autoimmune Diseases* (2017)

<sup>18</sup> Dewilde S et al, Productivity losses in MG and caregivers (2023)

<sup>19</sup> European Parliament, "Question for Written Answer E-001203/2025," available at: [https://www.europarl.europa.eu/doceo/document/E-10-2025-001203\\_EN.html](https://www.europarl.europa.eu/doceo/document/E-10-2025-001203_EN.html) (accessed September 2025).

<sup>20</sup> SWHR, How increased investments can improve health and QoL outcomes for women (2023)

While autoimmune diseases span a wide clinical spectrum, this paper focuses primarily on chronic and underserved autoimmune conditions where unmet need is persistent, and system impacts are most visible.

Building on insights from an expert advisory board (November 2025) and discussions held at the European Parliament (April 2025) and the European Health Summit (December 2025), this paper provides a snapshot of the current state of autoimmune diseases in Europe. It outlines their scale and impact across patient, societal, and economic dimensions, highlights key systemic gaps, and points to policy-relevant opportunities for more coordinated EU-level action. This paper also provides a synthesis of published evidence and stakeholder discussions. Supporters of this work did not influence the selection of evidence, interpretation, or conclusions.

## Scale and Rising Incidence

Many autoimmune diseases emerge in early adulthood<sup>21,22,23</sup> and persist for life.<sup>24</sup> Diagnosis is often concentrated in young to mid-adulthood-years typically associated with peak productivity,<sup>25</sup> resulting in significant economic implications.<sup>26</sup>

- Between 5-10% of the global population is affected by at least one autoimmune disease.<sup>27,28</sup>
- Approximately 5% of the global population is affected, corresponding to around 22 million people in the EU.<sup>29,30</sup>
- There are approximately 80-150 recognised autoimmune diseases.<sup>31,32</sup>
- Autoimmune disease frequently does not occur in isolation: around 25% of patients are at risk of developing a second autoimmune condition.<sup>33</sup>
- Global incidence has increased by 20% between 1990 and 2019.<sup>34</sup>

## Diagnostic pathway burden

Evidence cited in the autoimmune value materials indicates that patients visit an average of 4.8 physicians over 4.6 years before receiving an autoimmune diagnosis, illustrating prolonged diagnostic “odysseys” and missed opportunities for early intervention.<sup>35</sup>

## The Burden of Autoimmune Diseases

### Patient Impact

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<sup>21</sup>Mayo Clinic, “Lupus” (see n. 8).

<sup>22</sup>National Institute of Neurological Disorders and Stroke, “Myasthenia Gravis” (see n. 9).

<sup>23</sup>Mayo Clinic, “Multiple Sclerosis” (see n. 10).

<sup>24</sup>National Academies of Sciences, Engineering, and Medicine (see n. 16).

<sup>25</sup>National Academies of Sciences, Engineering, and Medicine, Health and Medicine Division, Board on Population Health and Public Health Practice, Committee for the Assessment of NIH Research on Autoimmune Diseases, *Enhancing NIH Research on Autoimmune Disease* (Washington, DC: National Academies Press, 2022), PMID: 35593778.

<sup>26</sup>Miller, “Epidemiology of Autoimmune Diseases” (see n. 6).

<sup>27</sup>Bieber, et al., “Autoimmune Pre-Disease” (see n. 4).

<sup>28</sup>Conrad, N., et al., “Incidence, Prevalence, and Co-Occurrence of Autoimmune Disorders over Time and by Age, Sex, and Socioeconomic Status,” *The Lancet* 401, no. 10391 (2023).

<sup>29</sup>Bieber, et al., “Autoimmune Pre-Disease” (see n. 4).

<sup>30</sup>Eurostat (see n. 5).

<sup>31</sup>“Multifaceted Autoimmunity” (see n. 3).

<sup>32</sup>Mayo Clinic, “Autoimmune Disease Prevalence Study” (see n. 7).

<sup>33</sup>Global Autoimmune Institute, “Comorbidities in Autoimmune Disease” available at: <https://www.autoimmuneinstitute.org/articles/comorbidities-in-autoimmune-disease-multiple-autoimmune-syndrome/> (accessed September 2025).

<sup>34</sup>GBD 2019 IMID Collaborators, “Global, Regional, and National Incidence of Six Major Immune-Mediated Inflammatory Diseases: Findings from the Global Burden of Disease Study 2019,” *EClinicalMedicine* 64 (2023): 102193.

<sup>35</sup>AMN Healthcare, *The Most Difficult Autoimmune Diseases to Diagnose*, 2024.

Autoimmune diseases are associated with a wide range of symptoms, including pain, inflammation, fatigue, and potentially fatal organ damage.<sup>36</sup> Their clinical complexity often contributes to delayed or incorrect diagnosis, with early signs frequently missed by non-specialists.<sup>37 38 39</sup>

For patients with underserved autoimmune diseases, these diagnostic delays can be particularly harmful, compounding clinical deterioration, psychological distress, and long-term disability.<sup>40</sup> Beyond the physical toll, cognitive impairment and unpredictable flare-ups<sup>41</sup> also disrupt daily life, employment, education, and relationships, often translating into significant mental strain. Around 25% of patients go on to develop a second autoimmune condition, compounding this burden further.<sup>42</sup>

Furthermore, misdiagnosis can be substantial in autoimmune neurology: in a retrospective study of patients referred with a diagnosis of Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP), 47% failed to meet minimal European Federation of Neurological Societies/Peripheral Nerve Society (EFNS/PNS) diagnostic requirements, highlighting key diagnostic pitfalls.<sup>43</sup>

### Impact on healthcare systems

Autoimmune diseases place sustained and substantial demands on health systems through hospitalisations, specialist referrals, and long-term disease management.<sup>44,45</sup> Increasing demand for treatments such as IVIg, driven by a growing patient population and expanding indications, has raised concerns about supply security and system resilience.<sup>46,47,48,49</sup>

In addition, European coordination mechanisms such as European Reference Networks (ERNs) remain underused and insufficiently integrated into national systems, limiting their potential to improve care delivery and patient outcomes.<sup>50</sup>

Taken together, delayed diagnosis, multi-morbidity and long-term treatment dependence position underserved autoimmune diseases as a growing challenge for health system resilience and sustainability.

### Economic Impact: Patient and Caregiver Productivity

The economic consequences of autoimmune diseases extend beyond healthcare systems accounting for over €50 billion annually.<sup>51</sup> The consequences extend well beyond the individual: a global survey on the burden of CIDP found that 44% of employed patients

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<sup>36</sup> Arango, M.T., et al. (see n. 1).

<sup>37</sup> Forrest, I.S., et al., "A Machine Learning Model Identifies Patients in Need of Autoimmune Disease Testing Using Electronic Health Records," *Nature Communications* 14, no. 1 (2023): 2385.

<sup>38</sup> National Academies of Sciences, Engineering, and Medicine (see n. 16).

<sup>39</sup> Mitchell, J.L., "Understanding the Impact of Delayed Diagnosis and Misdiagnosis of Systemic Lupus Erythematosus (SLE)," *Journal of Family Medicine and Primary Care* 13, no. 11 (2024): 4819–4823.

<sup>40</sup> Highmark Health, "Autoimmune Disorders and Invisible Illnesses: A Behavioral Health Perspective," available at: <https://www.highmarkhealth.org> (accessed September 2025).

<sup>41</sup> Global Autoimmune Institute, "Outbursts in Autoimmunity: Disease Flare-Ups," available at: <https://www.autoimmuneinstitute.org> (accessed September 2025).

<sup>42</sup> Global Autoimmune Institute, "Comorbidities in Autoimmune Disease" (see n. 33).

<sup>43</sup> Allen JA & Lewis RA, CIDP diagnostic pitfalls and perception of treatment benefit, 2015.

<sup>44</sup> Divino, V., et al., "The Economic Burden of CIDP in the United States: A Case-Control Study," *PLoS One* 13, no. 10 (2018): e0206205.

<sup>45</sup> Dewilde, S., et al., "Myasthenia Gravis Patients Have a Higher Productivity Loss and Lower Utility Values than a Matched Sample of the General Population," paper presented at ISPOR Europe, 6–9 November 2022.

<sup>46</sup> Danieli, M.G., et al., "Intravenous Immunoglobulin as a Therapy for Autoimmune Conditions," *Autoimmunity Reviews* 24, no. 1 (2025): 103710.

<sup>47</sup> So-Osman, C., et al., "Plasma-Derived Medicinal Products and Transfusion Demand," *Transfusion* 64, no. 5 (2024): 775–783.

<sup>48</sup> Belmonte, M., et al., "Understanding Supply Sustainability of Plasma-Derived Medicinal Products: Drivers and Consequences of Shortages," *Vox Sanguinis* 120, no. 8 (2025): 754–764.

<sup>49</sup> Covington, M.L., et al., "Shortage of Plasma-Derived Products: A Looming Crisis?" *Blood* 139, no. 21 (2022): 3222–3225.

<sup>50</sup> European Parliament, Autoimmune Diseases — Modern Diseases (2017)

<sup>51</sup> European Parliament, "Question for Written Answer E-001203/2025," available at: [https://www.europarl.europa.eu/doceo/document/E-10-2025-001203\\_EN.html](https://www.europarl.europa.eu/doceo/document/E-10-2025-001203_EN.html) (accessed September 2025).

stopped working due to their symptoms, 27% reported missing work within the previous seven days due to CIDP, and 13% retired prematurely.<sup>52</sup>

### Social and Societal Impact

The burden of autoimmune diseases is also deeply social. Caregivers face substantial emotional, social, and financial challenges, with elevated levels of stress and depression and a measurable negative impact on their own productivity.<sup>53 54</sup> In a study of productivity losses associated with Myasthenia gravis severity, **15.6%** of caregivers had to cut down working hours, by an average of **14.4 hours** of work time.<sup>55</sup>

Autoimmune diseases also disproportionately affect women, who are two to ten times more likely than men to develop an autoimmune disease,<sup>56</sup> and represent around 80% of diagnosed patients.<sup>57</sup> This makes autoimmunity not only a public health issue but also a gender-equality issues, requiring greater recognition in research funding, clinical trial design, and policy response.

### **Data Fragmentation and Research Gaps**

A comprehensive understanding of autoimmune diseases remains limited by fragmented data and infrastructure. Biobanks and patient registries are often scattered and insufficiently connected, and there is no centralised system to capture the full scope of disease burden across Europe.<sup>58 59 60</sup>

Funding has historically lagged other fields such as oncology,<sup>61</sup> leaving many disease mechanisms insufficiently understood and lesser-known conditions chronically underrepresented. The lack of agreed definitions and classification frameworks further limits research, delays diagnosis, and undermines coordinated care.<sup>62,63,64,65,66</sup>

Autoimmune research activity is also concentrated: autoimmune value-deck mapping indicates that 60% of autoimmune trials in Europe (May 2004–January 2025) focused on five prevalent conditions (type 1 diabetes, multiple sclerosis, psoriasis, rheumatoid arthritis and chronic urticaria), leaving over 100 autoimmune diseases within the remaining 40% of trials.<sup>67</sup>

### Innovation Gaps

Despite their scale, autoimmune disease treatments account for only a limited share of available medicinal products and innovation remains uneven across conditions.<sup>68</sup>

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<sup>52</sup> Allen, J.A., et al., "A Global Survey of Disease Burden in Patients Who Carry a Diagnosis of Chronic Inflammatory Demyelinating Polyneuropathy," *Advances in Therapy* 38 (2021): 316–328.

<sup>53</sup> Phil, J., et al. (see n. 14).

<sup>54</sup> Kent, T., et al. (see n. 15).

<sup>55</sup> Dewilde S et al., Productivity losses for MG patients and their caregivers: association with disease severity, *BMJ Open* (2023)

<sup>56</sup> National Jewish Health, "Trigger for Autoimmune Disease Identified: Newly Identified Cells Help Explain Why Women Suffer Autoimmune Disease More Often," available at: <https://www.nationaljewish.org> (accessed September 2025).

<sup>57</sup> Society for Women's Health Research, *How Increased Investments Can Improve Health and Quality of Life Outcomes for Women*, available at: <https://swhr.org> (accessed September 2025).

<sup>58</sup> Miller, F.W. (see n. 6).

<sup>59</sup> GBD 2019 IMID Collaborators (see n. 6).

<sup>60</sup> Mayo Clinic (see n. 7).

<sup>61</sup> Fugger, L., et al., "Challenges, Progress, and Prospects of Developing Therapies to Treat Autoimmune Diseases," *Cell* 181, no. 1 (2020): 63–80.

<sup>62</sup> Miller, F.W. (see n. 6).

<sup>63</sup> "Multifaceted Autoimmunity: New Challenges and New Approaches" (see n. 3).

<sup>64</sup> Autoimmune Association, "Rare Autoimmune Disease: Anthony's Journey with Vasculitis," available at: <https://autoimmune.org> (accessed September 2025).

<sup>65</sup> HDR UK, "Using Health Data Science and Large-Scale Data to Improve the Lives of People with Rare Diseases," available at: <https://www.hdrak.ac.uk> (accessed September 2025).

<sup>66</sup> AMN Healthcare, "The Most Difficult Autoimmune Diseases to Diagnose," available at: <https://www.amnhealthcare.com> (accessed September 2025).

<sup>67</sup> European Union Drug Regulating Authorities Clinical Trials Database (EUDRACT).

<sup>68</sup> Fugger L, Jensen LT, Rossjohn J. Challenges, progress, and prospects of developing therapies to treat autoimmune diseases (2020)

Research efforts tend to focus on a small number of prevalent conditions.<sup>69,70</sup> As a result, standard of care in many cases remains non-disease-specific and largely symptomatic, offering limited efficacy and significant side effect burdens.

Regulatory patterns also reveal a clear imbalance in innovation, as reflected in European Medicines Agency (EMA) authorisations. An analysis of EMA medicine data shows that, among approximately 1,122 authorised innovator medicines (excluding generics, hybrids, and biosimilars), only around 56 (~5%) were indicated for autoimmune diseases, compared with roughly 251 (~22%) for cancer.

Across an estimated 140 autoimmune and immune-mediated conditions, just about 12% (17/140) had at least one EMA-authorised innovator medicine. Moreover, approvals are highly concentrated: of the ~56 autoimmune innovator medicines, around 30% (17) target multiple sclerosis and 29% (16) target rheumatoid arthritis. Approximately half of these autoimmune authorisations pre-date 2014.<sup>71,72</sup>

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<sup>69</sup> European Union Drug Regulating Authorities Clinical Trials Database (EUDRACT).

<sup>70</sup> Wikipedia, "List of Autoimmune Diseases," available at: <https://en.wikipedia.org> (accessed September 2025).

<sup>71</sup> European Medicines Agency, medicine data / EPAR database (accessed Aug–Sep 2025)

<sup>72</sup> Global Autoimmune Institute, A–Z Autoimmune Disease List (2025).

## EU Policy Landscape: Opportunities for Action

Although not absent from the European policy landscape, autoimmune diseases remain insufficiently prioritised and inconsistently reflected across existing frameworks despite their scale and impact.

As the EU implements recent reforms and advances new legislative files, there is a timely opportunity to ensure that underserved autoimmune diseases are explicitly recognised as a healthcare priority.

### Building on existing commitments

The 2017 European Parliament report "**Autoimmune Diseases — Modern Diseases**"<sup>73</sup> acknowledged the growing burden of these conditions, yet coordinated follow-up has remained limited. An updated EU-wide assessment of prevalence, burden, and socioeconomic impact would strengthen the evidence base to guide policy prioritisation going forward.

### Strengthening data and evidence infrastructures (EHDS)

The implementation of the **European Health Data Space (EHDS)** provides a concrete opportunity to address long-standing data fragmentation in autoimmune diseases. Given documented diagnostic delays and heterogeneous disease trajectories, autoimmune diseases are well-suited as a priority use case for EHDS secondary data use. Policy considerations include prioritising autoimmune registry interoperability and enabling secondary data use to support real-world evidence generation for diagnosis, outcomes, and long-term system impact.

### Ensuring fit-for-purpose assessment of autoimmune innovation (EU HTA/JCA)

The rollout of **Joint Clinical Assessments (JCAs)** under the EU HTA Regulation (Regulation (EU) 2021/2282 on Health Technology Assessment) creates an important opportunity to ensure that autoimmune complexity - heterogeneity, relapsing courses, multi-indication therapies, and patient-reported outcomes - is appropriately reflected in assessment frameworks, supporting more consistent patient access across Member States.

### Operationalising unmet need in pharmaceutical legislation

Ongoing EU pharmaceutical legislation reform and its implementation offer an opportunity to clarify how **unmet medical need** is defined and applied. The evidence in this paper supports interpreting unmet need in a way that captures diagnostic delay, disease complexity, and limited disease-specific innovation in underserved autoimmune diseases - without relying solely on prevalence-based thresholds.

### Improving research-to-patient translation (EU Biotech Act)

The evidence base demonstrates that autoimmune innovation remains concentrated in a limited number of conditions and that many authorised therapies are older. The EU Biotech Act offers a platform to strengthen translation from immunology research into patient-relevant innovation, particularly for underserved disease areas. Policy considerations include prioritising immunology/autoimmunity as translation-critical domains and strengthening connections between research funding, regulatory science, and patient-centred outcomes.

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<sup>73</sup> European Parliament, *Biotechnology and Autoimmune Diseases Study*, available at: <https://www.europarl.europa.eu>.

### Embedding autoimmune diseases in women's health priorities

Autoimmune diseases disproportionately affect women, often during early and mid-adulthood, with long-term implications for health and socioeconomic participation. Embedding autoimmune diseases more explicitly within EU women's health and gender equality initiatives could improve visibility, data reporting by sex, and alignment of research priorities with disease burden.

### A coordinated opportunity for action

Taken together, these policy considerations point to a clear conclusion: the challenge in autoimmune diseases is not the absence of EU-level tools, but their fragmented application. Through more coherent use of existing instruments—EHDS, HTA, pharmaceutical legislation, biotech policy, and women's health initiatives—the EU can materially improve recognition, evidence generation, and patient outcomes for underserved autoimmune diseases.

## Conclusion

Autoimmune diseases affect millions of Europeans, place growing burdens on patients, caregivers, and health systems, and disproportionately impact women. Yet many remain underserved, under-researched, and unevenly addressed across Member States. The evidence is clear and so is the cost of inaction.

Addressing these challenges does not necessarily require new EU frameworks, but more effective prioritisation and implementation of existing instruments. Concretely, this means:

- **Recognising** underserved autoimmune diseases as a European public health priority, with explicit integration across EU health, research, and innovation frameworks.
- **Strengthening** data infrastructure to enable consistent, interoperable registries that reflect the true prevalence and burden of autoimmune diseases across Member States.
- **Advancing** research and innovation in immunology, ensuring that scientific progress translates into timely and equitable access to therapies.
- **Calibrating** regulatory, HTA, and reimbursement frameworks to reflect the full complexity and value of autoimmune disease innovation.
- **Embedding** sustained and meaningful patient involvement in research, policy development, and implementation.

Europe has an opportunity to lead for the millions living with these conditions today, and for the many more who will be diagnosed in the years ahead.

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