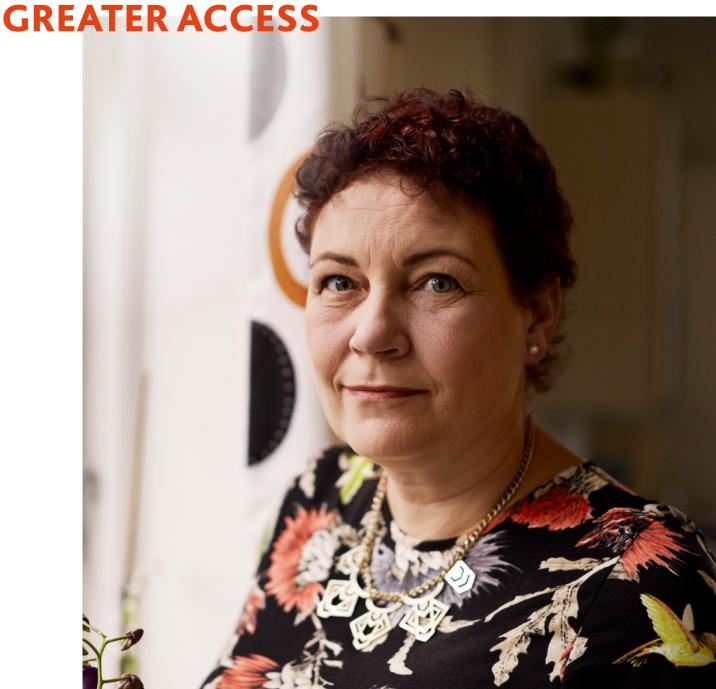


Mental Health for All

GREATER INVESTMENT





ABOUT LUNDBECK

Lundbeck is a global pharmaceutical company specialized in brain diseases

We are tirelessly dedicated to restoring brain health, so every person can be their best. To fulfill this purpose, Lundbeck is engaged in the research, development, manufacturing, and commercialization of pharmaceuticals across the world. For more than 70 years, Lundbeck has been at the forefront of neuroscience research.

With our unique position as specialists in brain disease, we want to raise disease awareness and challenge the international agenda for broader acceptance of patients and increased opportunities for better treatment.



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PART I

A global challenge: Mental Health for All

The global burden of mental health disorders is growing and requires determined action.¹ As a leader in brain health, Lundbeck proactively collaborates with a range of stakeholders and peers to prioritize and improve Mental Health for All by addressing key challenges.

1. THE GLOBAL BURDEN OF MENTAL **HEALTH DISORDERS**

Mental health disorders are serious and can be life-threatening diseases that compromise

people's ability to live and work normally, also having detrimental effects on people and their loved ones.

It is estimated that in 2017 over 790 million people were living with a mental health disorder globally, representing almost 11% of the world population at the time.²

The burden of mental health disorders is significant in terms of their overall impact on society and the global economy.3

Mental health disorders are responsible for €1.75 trillion per year in productivity losses.4

Schizophrenia, anxiety, and depressive disorders account for almost 83 million disabilityadjusted life years (DALY). One DALY equals one lost year of healthy life.⁵

The global cost of mental health disorders is expected to reach \$16 trillion (US) by 2030.6 This is more than the GDPs of countries such as Japan, the UK, Germany, or Russia.

Mental health has profound effects on an individual's quality of life and physical and social wellbeing.7 Alarmingly, the World Health Organization (WHO) estimates that there is a 10-25-year life expectancy reduction in people with severe mental health disorders.8

2. LUNDBECK'S APPROACH TO MENTAL

As a leader in brain health, Lundbeck is committed to improving Mental Health for All. We work with community partners around the world, and we base our efforts in mental health on internationally accepted frameworks and guiding principles, such as the United Nations (UN) Guiding Principles on Business and Human Rights.⁹ In addition, we became a signatory to the UN Global Compact¹⁰ in 2009.

The UN's 2030 agenda for the Sustainable Development Goals (SDG), launched in 2015, are a series of non-binding calls to action to advance peace and prosperity at global level, in true partnership.¹¹ Sustainability is an integral part of Lundbeck's strategy. We have defined shortterm actions and long-term aspirations for the six SDGs we have a significant impact on.12

Based on the UN SDG 3 on Good Health and Wellbeing and mirroring the principles of the

WHO's Right to Health,13 we recently established an Access to Brain Health strategy. We are focusing on these four components:

- Availability we are committed to drawing on our expertise and knowledge and using it to address the growing burden of poor mental health globally. Our aim is to make innovative medicines available. We currently distribute our medicines in more than 100 countries worldwide, improving the lives of millions of people.14
- Accessibility we are committed to continue to promote accessibility to our innovative medicines by addressing physical, economical, discriminatory, and informational barriers. Examples of our work in this field include nonpromotional disease education campaigns and patient safety programs.15
- Acceptability through our Progress in Mind model and collaborations, we seek to fight stigma, increase the recognition of mental health disorders, and improve mental health parity with other physical and chronic diseases
- Good quality we adhere to strict standards and provide high-quality medicinal products, safeguarding patient safety, and combating counterfeit medicines.

We aspire to address these components and acknowledge that further work is needed to define gaps for improvement and best understand the role we play.

undbeck is a proud supporter of World Mental Health Day (WMHD). In 2020, WMHD's theme focuses on Mental Health for All. In this position paper, we have chosen to highlight some of the key challenges we recognize and want to work collaboratively to achieve Mental Health for All. We call on our stakeholders and partners to share their vision on how to improve Mental Health for All and to support WMHD. Mental Health for All can only be achieved in collaboration across all sectors in the community. We seek to work together with our stakeholders who believe in the significant benefits of the WMHD campaign.

THE GLOBAL MENTAL **HEALTH BURDEN IN NUMBERS**



It is estimated that more than 264 million people are affected by depression worldwide.16

According to the WHO, the total estimated number of people living with depression increased by nearly 20% between 2005 and 2015.17

45 million

Bipolar disorders affect about 45 million people worldwide.18



The total estimated number of people living with anxiety disorders in the world has increased by almost 15% since 2005.19

20 million

Schizophrenia is a chronic and severe mental health disorder affecting 20 million people globally.20

PART II The challenges we work to address and our recommendations

To improve Mental Health for All, greater investment in, and greater access to treatment and care are needed.

1. MENTAL HEALTH FOR ALL

We believe that each person's mental wellbeing is important. We strive for a society in which Mental Health for All is the norm, and access to treatment and care is free from stigma and barriers. There is still a lot of progress to be made, and we are looking forward to taking a leadership role in addressing this important goal.

To improve Mental Health for All, several challenges need to be addressed. We have chosen to highlight two societal challenges that pose significant barriers to Mental Health for All. These are not the only challenges, but reflect some of the main issues the mental health community still faces.

KEY CHALLENGES TO ACHIEVING MENTAL HEALTH FOR ALL INCLUDE:



Stigmatization of mental health disorders remains a widespread issue.



Access to diagnosis and mental health care remains challenging.



More investment is needed to better understand and treat psychiatric disorders.



Patients need better access to innovative treatments.



The heterogeneity (individuality) of mental health disorders is often misunderstood and dismissed

For Lundbeck, Mental Health for All goes beyond people who already live with a diagnosis. We want everyone to have access to mental health care services, to safeguard their mental wellbeing, and treat their psychiatric disorders in a timely and effective way.

- Stigma continues to be a significant barrier to mental health. Despite huge advances in increasing awareness, prejudice against people diagnosed with mental health disorders continues to exist in our social, professional, and community networks. Stigma affects the understanding and perception of mental health, which has consequences on access to care and treatment and on the way mental wellbeing is prioritized and invested in. A US study shows that the public has widespread perceptions of individuals with mental disorders as dangerous to themselves and others.21 However, people with mental health disorders are, in fact, 11 times more likely to be victims of a violent crime.22
- The heterogeneity of mental health disorders is often not fully understood, posing a significant barrier to acceptability, appropriate diagnosis, and care. Mental health disorders are heterogeneous, which means that the way a person's disease occurs and how that person reacts to treatment will vary from someone else's.²³ For example, of people receiving treatment for depression, only one in two achieve remission after treatment,24 with only 37% achieving remission after the first line of treatment.25 The complexity of mental health disorders coupled with the existing pressures on healthcare services (budgetary) and shortages in professionals trained in mental healthcare means the system is failing to properly support people seeking professional help. For example, about 45% of people who died by suicide consulted a primary care physician within one month before they passed away.26

At Lundbeck, we advocate that there is no health without mental health. Not only are mental health disorders imposing a major disability burden worldwide, but if untreated, they can negatively affect the way a person manages major co-occurring diseases, such as tuberculosis and HIV, diabetes, hypertension, cardiovascular disease, and cancer.²⁷ We are committed to eliminating the stigma associated with mental disorders. By continuing to collaborate with all

stakeholders, we are working towards achieving parity of care with other chronic and physical

2. GREATER INVESTMENT TO IMPROVE ACCESS TO MENTAL HEALTH FOR ALL

Lundbeck believes mental health stakeholders should focus on the following issues and grow their investments in these areas to improve access to Mental Health for All.

Despite the growing global burden of mental health disorders, the global median mental health expenditure is only \$2.5 (US) per capita.²⁸

According to the WHO, the global median of general government health expenditure per capita in 2015 was \$141 (US), making government expenditure for mental health less than 2%.²⁹

A. STIGMA ERADICATION:

Stigma against mental health disorders is a major cause of discrimination and exclusion.³⁰ Mental wellbeing is an integral part of a healthy life, and we strive for a society in which people are free of stigma, feel comfortable to talk about their mental wellbeing, and can access appropriate care to best manage their disorders. Measures seeking to reduce the stigma of mental health disorders should be a core component of broader strategies that emphasize freedom from discrimination, human rights, and social inclusion.³¹

Lundbeck calls on governments and key community-based stakeholders (local authorities, public bodies, and workplaces) to strengthen their investments to fight the stigma associated with mental health disorders. Public education and disease education together with parity of care campaigns are crucial to creating a stigma-free environment for mental health. We also encourage governmental and public institutions to continue collaborating with advocacy groups representing the needs and interests of those seeking mental health support.

Closing the gap between mental and physical health funding should be a priority to ensure parity of care. Better care will lead to better chances of functional recovery for individuals with mental health disorders, and in turn help families and communities function effectively.

B. STRENGTHENING HEALTHCARE SYSTEMS TO IMPROVE DIAGNOSES IN MENTAL HEALTH:

The stigma associated with mental health, the fragility of primary health care systems, and the lack of specialized psychiatric healthcare professionals³² ultimately lead to severe delays or a lack of diagnosis of mental health disorders, which negatively impacts care plans. The current supply of psychiatrists is not in balance with the growing demand for psychiatric services. There is a shortage of general practitioners (GPs), psychiatric and specialized staff,³³ and psychiatry is often overlooked in physician supply

discussions.³⁴ For example, there are currently approximately 30,400 psychiatrists in active patient care in the US – this represents approximately one psychiatrist per 100,000 people.³⁵ Similarly, in the UK about one in ten consultant psychiatrist posts are unfilled, and the rate of vacancies has doubled in the last six years.³⁶ With a growing mental health disease burden, access to primary and specialized psychiatric care is an urgent priority to improve Mental Health for All.

Across the world, there are shortages of hospital beds for people with mental health disorders needing hospitalization (in-patient setting). High-income countries average at 50 hospital beds per 100,000 people, and low-income countries average at less than two hospital beds per 100,000 people.³⁷

Once a diagnosis has been established, it is crucial that a strong therapeutic alliance between the healthcare professionals, the patient, and their loved ones (provided consent is given) is established. This is based on a patient-centric approach that champions shared decision-making, which is likely to improve treatment adherence and outcomes. ³⁸ Patients want a collaborative relationship with their physicians. To facilitate this approach, patients should have input on their specific treatment objectives, and receive in-depth information about their disorder and the interventions that may be useful in treating it, so they can make informed treatment choices. ³⁹

Mental health care needs greater investment in several key areas. Firstly, more investment is needed to attract medical students and other allied healthcare professions to specialize in psychiatry. Similarly, funding is vital to suitably equip psychiatric healthcare professionals with education, training, and tools that will empower them to work closely with their patients and establish a robust therapeutic alliance. Increased investment is also needed to create and maintain better mental health care services, from emergency medical care to psychosocial support.



Lack of access to primary and specialist care for mental health continues to be a barrier to improving Mental Health for All.

The WHO states that a combined psychosocial and pharmacological approach is likely to yield the best results when treating mental health disorders.⁴⁷



C. INNOVATION AS A KEY DRIVER TO IMPROVING MENTAL HEALTH FOR ALL:

The brain is a very complex organ, and despite incredible advancements in scientific research, we still do not have any biomarkers for predicting, diagnosing, or assessing treatment for psychiatric disorders. 40 Often, current treatments for psychiatric disorders aim to address symptoms and prevent relapse, without appropriate focus on functional recovery and quality of life. Mental health disorders are the outcome of the interaction of biological, environmental, and developmental factors throughout the life course. 41 They are heterogeneous in nature, meaning they affect people in different ways - so a one-size-fits-all approach cannot, and should not, be taken for mental health disorders

Even though we may not know exactly what causes someone to experience a mental health disorder, this does not mean that it is any less serious than any other illness, and any less deserving of recognition and treatment.⁴²

We are committed to continuing our scientific research to best understand how the brain functions and what that means for mental health disorders.

Although mental health disorders make up the largest portion of the global health burden, only 15% of research and development funding is spent on nervous system research.⁴³

We believe there is a need for improved and innovative medicines for psychiatric disorders. While nearly ten of the largest pharmaceutical companies have scaled back their R&D investments or even left the central nervous system (CNS) space in less than a decade,⁴⁴ Lundbeck remains steadfast in our commitment.⁴⁵ We continue to develop innovative treatments for psychiatric and neurological disorders, so every person can be their best. Our R&D costs were 467m USD in 2019.⁴⁶

Our purpose is to help people restore their mental health and wellbeing, so they can be their best selves. There are currently no cures available for mental disorders, so improving a patient's functioning and quality of life are important aspects requiring innovative treatments. Given the heterogeneity of mental health disorders, access to diverse and innovative treatment is crucial to improve disease management and outcomes for everyone, which

will enable people with mental health disorders to be their best

We ask governments and other research funding bodies to grow their investments in basic, translational, and clinical research for mental health disorders. We also call on drug pricing decision-making bodies to strongly consider the added value of innovative medicines, which inherently carry a high R&D cost. It is also crucial that these bodies do not make decisions based on criteria used for somatic (physical) diseases or generic, older treatments when assessing the value innovative treatments provide in terms of functional recovery.

Quality of life, patient functioning, and the side effect profile of medicines should be considered when assessing market access, given the heterogeneity of mental health disorders, the lack of cures available, and the associated socioeconomic costs. In addition, Lundbeck calls for new and tailored regulatory pathways to enable people to access innovative medicines for psychiatric disorders.





PART III

Lundbeck's commitments to Mental Health for All

We are committed to Mental Health for All, and collaborate with medical, governmental and community stakeholders so every person can be their best.

1. A MULTISECTORAL APPROACH FOR MENTAL

As a leader in brain health with a strong commitment to corporate sustainability, we are continuously taking steps to ensure we promote the WHO's Right to Health and to support the UN SDGs. In addition, we are committed to contributing to Mental Health for All, and we are working to make sure every person has the care they need to be their best.

Furthermore, the Lundbeck Foundation is the largest private financial contributor to public brain research in Denmark. The Lundbeck Foundation also works to raise awareness of the brain and brain diseases. Its aim is to promote the careers of the most promising scientists and help fund a strong pipeline of biomedical science researchers, regardless of their field of research. The Foundation awards scientific grants of over 75m USD a year for biomedical research focused on the brain⁴⁸.

In 2014, we launched Progress in Mind (PiM) as our dedicated model summarizing Lundbeck's commitment to working collaboratively to advance brain health. Medical Patient **PROGRESS** IN MIND Community **Family**

10

largest brain single research prize, with a monetary value of around \$1.5 million US.⁴⁹

The Lundbeck Foundation also awards The Brain Prize, the world's

Progress in Mind guides how we collaborate and work with the medical community, patients, their families, and community stakeholders. We do this by listening to their needs and feedback, and empowering them to provide support and education programs to those in need.

Lundbeck's core focus is on the medical sphere. We are tirelessly dedicated to improving treatments for mental health disorders. We do so by continuously researching and developing new medicines, but also by funding independent research through our medical grants and by establishing collaborations. For example, in 2018 Lundbeck entered a collaboration with Vanderbilt University's (Tenn., USA) for a research program aimed at a novel approach to treating schizophrenia. In addition, in 2017 Lundbeck partnered with genetics company, 23andMe Inc., and with the Milken Institute to conduct the first-ever study combining genetic data from 25,000 patients to increase the understanding of the underlying causes of major depressive disorder and bipolar disorders.

Medical education is also a key component of the work we do to improve Mental Health for All. Lundbeck runs the Lundbeck Institute, a medical, non-promotional platform aimed at providing impartial, evidence-based medical education and informative content on brain diseases to healthcare professionals and the medical community. In 2019, the Lundbeck Institute's Campus had 63,200 users, and its Progress in Mind Resource Centre, available in 36 countries, had 570,000 visitors.⁵²

Our ultimate purpose is to ensure people with brain diseases can be their best. We work closely with the patient community and involve them across our value chain, including in our scientific research pipeline. For example, we are members of the pan-European public-private partnership Paradigm, ⁵³ which provides a unique framework enabling effective, meaningful, ethical, innovative, and sustainable patient engagement in medical R&D. We also collaborate with the patient community for our disease awareness campaigns. One example is Rethink Depression, ⁵⁴ a global non-promotional, non-profit website and social media account we run. It provides evidence-based information and support on major depressive disorder for patients, families, and carers.

Every individual should have access to high quality mental health support to be their best selves. We continue to be committed to the development of new medicines, treatments, and programs to improve the quality of lives of people across the world.

Lundbeck proactively works with community stakeholders at global, regional, and local levels. We support the capacity-building of advocacy groups, strengthen their share of voice, and help fight stigma against mental health disorders.



Families and carers play a key role in mental health, given the debilitating and often chronic nature of mental disorders. Carers for those with schizophrenia report a mean of nearly 40 hours per week providing direct care. ⁵⁵ In addition, carers usually do not feel involved in important decisions, with less than four in ten feeling that medical staff are taking them seriously. ⁵⁶ At Lundbeck, we understand and value carers' contributions, and we are working to build awareness of the support they provide.

In 2019, Lundbeck co-supported a survey led by the London School of Economics to better understand the economic value of carers to society.⁵⁷ In addition, we supported the Schizophrenia Carer Academy in 2016, an open educational course providing participants with an opportunity to explore key issues for carers supporting someone with psychosis. The program included an online peer discussion platform where carers could share their experiences.⁵⁸

Stigma and misunderstanding of mental health disorders continue to be huge barriers to achieving Mental Health for All. Broader societal acceptance for mental health is key to overcoming these challenges, and to that end, Lundbeck proactively works with community stakeholders at global, regional, and local levels. We support the capacity-building of advocacy groups, strengthen their share of voice, and help fight stigma against mental health through a series of partnerships. In addition, we support disease awareness campaigns and public advocacy on a range of mental health

disorders, through venues such as World Mental Health Day, which Lundbeck has been supporting and celebrating since 2012

The Progress in Mind model will continue to guide us as we work to improve Mental Health for All. We will also continue to seek partnerships to maximize impact across our sustainability efforts, which includes turning the aspirations in our Access to Brain Health strategy into action.

We encourage our stakeholders to challenge us on where and how we can contribute to improving Mental Health for All.

2. WORKING TOWARDS A BRIGHTER FUTURE FOR MENTAL HEALTH AND WELLBEING

At Lundbeck, we believe that achieving Mental Health for All will contribute to better functioning within families, workplaces, and communities. Every individual should have access to high quality mental health support to be their best selves, and we continue to be committed to the development of new medicines, treatments, and programs to improve the quality of lives of people around the world.

There have already been many exciting advancements in this field, and we are looking forward to continuing our work with patients, collaborative partners, and other stakeholders as we progress towards achieving Mental Health for All.

Language guidelines

Suffering vs. Living with a mental health disorder⁵⁹ – not portrayed as victims or sufferers lacking quality of life.

Someone is not defined by their disease, but rather has a disease – e.g.: Anna is not depressed, Anna has depression⁶⁰ or Anna is experiencing depression.

Glossary

ANXIETY DISORDER: anxiety disorders involve more than temporary worry or fear. For a person with an anxiety disorder, the anxiety does not go away and can get worse over time. The symptoms can interfere with daily activities such as job performance, school work, and relationships. There are several types of anxiety disorders, including generalized anxiety disorder, panic disorder, and various phobia-related disorders. ⁶¹

BIPOLAR DISORDER: characterized by episodes in which the person's mood and activity levels are significantly disturbed. This disturbance consists on some occasions of an elevation of mood and increased energy and activity (mania), and on others of a lowering of mood and decreased energy and activity (depression).⁶²

DEPRESSION: depression is a serious medical condition that is associated with a wide range of emotional, cognitive, and physical symptoms, ⁶³, which have an impact on daily life.

HEALTH TECHNOLOGY ASSESSMENT: the role of Health Technology Assessment (HTA) is to summarize evidence on the value of new technologies to guide decisions regarding their optimal use in routine care. ⁶⁴

INCREMENTAL INNOVATION: the process of expanding therapeutic classes, increasing the number of available dosing options, discovering new physiological interactions of known medicines, and improving other properties of existing medicines ⁶⁵

MENTAL HEALTH DISORDERS: are generally characterized by some combination of abnormal thoughts, emotions, behavior, and relationships with others.⁶⁶

MENTAL HEALTH: mental health is a state of wellbeing in which an individual can realize his or her own potential, cope with the normal stresses of life, work productively, and contribute to society.⁶⁷

PARITY OF CARE: valuing mental health equally with physical health. It is also referred to as parity of esteem.⁵⁸

POST-TRAUMATIC STRESS DISORDER: a delayed or protracted response to a stressful event or situation (of either brief or long duration) of an exceptionally threatening or catastrophic nature. Typical features include episodes of repeated reliving of the trauma in intrusive memories ("flashbacks"), dreams or nightmares, a sense of "numbness" and emotional blunting, detachment from other people, unresponsiveness to surroundings, anhedonia, and avoidance of activities and situations reminiscent of the trauma. Anxiety and depression are commonly associated with the above symptoms and signs, and suicidal ideation is not infrequent.⁶⁹

QUALITY OF LIFE: an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships, and their relationship to salient features of their environment.⁷⁰

SCHIZOPHRENIA: a chronic, psychotic disorder, often long-lasting, which may lead to marked changes in a person's perception of reality.⁷¹ It is characterized by episodes of psychosis (losing touch with reality) in between periods of blunted emotions and withdrawal. Schizophrenia symptoms can be defined by what are known as positive symptoms and negative symptoms, along with cognitive symptoms, mood symptoms, and motor symptoms.

STIGMA: a distinguishing mark establishing a separation between the stigmatized person and others attributing negative characteristics to this person. The stigma attached to mental illness often leads to social exclusion and discrimination and creates an additional burden for the affected individual.⁷²

SUBSTANCE ABUSE: substance abuse refers to the harmful or hazardous use of psychoactive substances, including alcohol and illicit drugs. Psychoactive substance use can lead to dependence syndrome – a cluster of behavioral, cognitive, and physiological phenomena.⁷³

SUICIDAL BEHAVIOR: a range of behaviors that include thinking about suicide (or ideation), planning for suicide, attempting to die by suicide, and suicide itself.⁷⁴

Notes

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- 53 https://imi-paradigm.eu/project-partners/
- 54 https://rethinkdepression.com/
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