

# OTSUKA EUROPEAN CODE OF CONDUCT



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## Message from our leader

## Dear Colleagues,

Otsuka is a business founded on a core aspiration, to create new products for better health in Europe and around the world. The health and wellbeing of our patients is our main focus, and everything we do as a company is geared around trying to make a real difference to their lives, and those of their families and carers. By working with passion, perseverance and integrity, we strive to discover and develop the healthcare solutions of tomorrow.



Andy Hodge
President & CEO,
Otsuka Pharmaceutical
Europe Ltd.

For sustained success, and to ensure we can continue to tackle some of the world's most unresolved health challenges, trust is essential. The usage of our medicines across Europe is a testament to the high quality that our customers have come to expect from Otsuka, and the trust that they place in our products.

Across the globe, the pharmaceutical industry is highly regulated; laws, regulations and national codes are aimed at a single objective—to protect the health and safety of patients.

Otsuka's European Code of Conduct establishes our corporate standards of ethical behaviour and expectations for all Otsuka employees in Europe. It represents our commitment to each other, our patients and our alliances, ensuring we operate with integrity at all times. It is the written expression of our core value of 'Integrity'. Behaving ethically is the foundation of any healthy and successful business. If there are weaknesses in these foundations, we simply will not be able to build lasting success.

By following the principles described in our European Code of Conduct, you enable Otsuka to achieve its commitment to the highest ethical standards while at the same time building trust with those we aim to help. This document provides an overview of these ethical principles and business standards applicable to our day-to-day operations.

Our actions, words and behaviours matter. In whatever role we have, acting with integrity and "doing the right things, right" will show how we care for the people we serve and the respect we have for our colleagues and partners.

We expect all employees and third parties working on behalf of Otsuka in Europe to read, fully understand and abide by the spirit of our European Code of Conduct, ensuring that business is conducted with integrity at all times. This should be our daily guide. We live in a complex world, so use this document to navigate it and ensure that our words and actions reflect the right behaviour.

Should you have any questions or require further information in relation to this document, please contact your line manager or the Ethics & Compliance department.

Thank you for your support in helping us make a genuine difference to people's lives across Europe.

## One Otsuka

Our global philosophy defines Otsuka. No matter where we work or for which legal entity, we are one Otsuka, with local roots.

When you see "Otsuka" or "Company" or "we" or "our" in this European Code of Conduct, it means all employees and non-employees (e.g. contract staff) working for or on behalf of the following Otsuka entities:

- Otsuka Pharmaceutical Europe Ltd. (OPEL)
- Otsuka Pharmaceutical Development & Commercialisation Europe GmbH (ODCE)
- Otsuka Pharma Scandinavia AB (OPSAB)
- Otsuka Pharmaceutical France SAS (OPFS)
- Otsuka Pharmaceuticals (U.K.) Ltd. (OPUK)
- DACH Region, composed of Otsuka Pharma GmbH (OPG) and Otsuka Pharmaceutical (Switzerland) GmbH (OPCH)
- Otsuka Pharmaceutical Italy S.r.l. (OPIT)
- Otsuka Pharmaceutical S.A. (OPSA)
- Otsuka Pharmaceutical Netherlands B.V. (OPNL)

Our corporate values are the essence of our identity and are fully aligned with the group philosophy:

'Otsuka-people creating new products for better health worldwide'



#### **RYUKAN-GODO**

## 'By sweat we recognise the way'

Passion and hard work are important in helping to bring an idea to reality

#### **JISSHO**

#### 'Actualisation'

Proof through execution or actualisation; persevering until success is achieved and the idea becomes reality

## **SOZOSEI**

## 'Creativity'

Creativity is the most essential element for any business that depends on research and development Underpinning these corporate values are our European core values and behaviours. Take the time to understand the values, talk to your peers, teams, line managers and direct reports to help shape successful ways of working.



#### INTEGRITY

We are guided by a foundation of trust, ethics and honesty

We will:

Do the right thing

Act with positive intent

Hold ourselves and each other accountable

Show authenticity and humility

Always be open and transparent



### **COMPASSION**

We consistently demonstrate genuine empathy and respect

We will:

Take the time to listen and understand

Embrace diversity

Welcome and encourage feedback

Support each other proactively

Be caring towards people



### **COLLABORATION**

We work together to deliver the best outcomes

We will:

Communicate with purpose

Recognise individual strengths

Learn and grow together

Make valuable contributions

Aim to be respected partners



## **EXCELLENCE**

We always give it our best

We will:

Focus on what matters

Learn from our mistakes

Be disciplined in our execution

Celebrate when things go right

Aim to simplify



### **CREATIVITY**

We embrace unconventional thinking and welcome innovative solutions

We will:

Find the best way forward

Seek out different perspectives

Build on each other's ideas

Take on challenge and evolve

our thinking

Make time and space to innovate

We are all responsible for owning those values and making sure they are at the forefront of every business decision we make on behalf of Otsuka.

## 1 How to Use the European Code of Conduct

While all Otsuka employees are expected to exercise good judgement, we understand that it is not always easy to determine what the 'right' decision to make is. We face many complex situations every day. The principles set out in the European Code of Conduct are intended to help you come to the right decision, and help you understand where to go or who you should contact for further guidance.



## When you are unsure what to do, ask yourself

- Does it align with Otsuka's values?
- Is my conduct consistent with Otsuka's policies and procedures?
- Does it meet laws and regulations?
- Would my colleagues, family and friends think my conduct is ethical?
- Am I being fair and honest? Would I be comfortable if someone treated me in the same way?
- Would I feel comfortable if my conduct became widely known or was publicised?
- Will my conduct allow us to maintain the trust of all our patients, healthcare providers, suppliers and other stakeholders?

If you answer 'no' or 'I'm not sure' to any of these questions, then you should seek support. You can speak to your line manager, another colleague you trust or the Ethics & Compliance, Legal or Human Resources departments. They may be able to give you the guidance and advice you need. You can also use the **Otsuka 'Speak Up' line**. For more information, please refer to the section **"Reporting Concerns"**.

Where requirements of local laws, regulations, guidelines, industry codes of practice or Otsuka procedures are more specific or stricter than those contained in this European Code of Conduct, the stricter provisions must be applied.

If you are a line manager, you have an important role in ensuring our European Code of Conduct is understood and applied by your team. In particular, we expect you to:

- Be a role model for doing what is right, even when it is difficult
- Ensure your team members are familiar with our European Code of Conduct and that they understand it
- Help your team members use our European Code of Conduct in daily work by showing them how you refer to it when uncertain or unsure

## 1.1 Consequences of Non-compliance with our European Code of Conduct

## O1 For patients, Healthcare Professionals (HCPs) and other stakeholders:

compromised product safety or efficacy, environmental risk, higher cost of medicines, loss of good faith and trust in dealings with Otsuka.

## 02 For our company:

damage to Otsuka's reputation, prosecution or fines, disclosure to regulatory authorities, loss of business.

## 03 For our colleagues:

prosecution, fines and/or possibly imprisonment, disciplinary actions, damage to personal reputation.

## 04 For our investors:

loss of confidence in Otsuka and its products, loss of investment value, damage to Otsuka's reputation for good corporate governance.

## 1.2 Addressing Potential Violations of the European Code of Conduct

If you learn of or suspect a legal or ethical violation, we encourage you to seek advice from your line manager, the Ethics & Compliance, Legal or Human Resources departments. You can also report any concern through our **Otsuka 'Speak Up' line**.

Otsuka will investigate all allegations of misconduct, including violations of this European Code of Conduct, applicable industry codes, and laws and regulations. Failure to comply with them may result in disciplinary action, up to and including dismissal.

Otsuka adheres to a strict policy of non-retaliation to protect anyone who, in good faith, raises issues, concerns, or allegations of compliance violations or unethical conduct. For more information, please refer to the section "Reporting Concerns".

# 2 Otsuka's Commitment to Integrity

Our business activities should be conducted in compliance with all applicable laws and regulations of each country where we operate. Otsuka believes in self-regulation, not just within Europe but around the world. We adhere to self-regulatory organisations' guidelines and codes of practice because we believe they improve our industry and our support to patients.

On a global level, Otsuka is a member of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). In IFPMA's Code, trust is recognised as the core on which our Otsuka actions are based. It states that we pledge to:

"Act with integrity and honesty to improve patient care and build trust with those we serve and to respect the independence of patients, healthcare providers and other stakeholders."

In Europe, we are a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA), which itself is also a member of IFPMA. EFPIA, too, recognises the importance of trust, stating that the Code:

"...aims to foster an environment where the general public can be confident that choices regarding their medicines are being made on the basis of the merits of each product and the healthcare needs of patients."

EFPIA's member associations have their own codes, which incorporate the principles established by IFPMA and EFPIA, including but not limited to:

- The Association of the British Pharmaceutical Industry (ABPI) in the United Kingdom
- The Irish Pharmaceutical Healthcare Association (IPHA) in Ireland

- The Code for Pharmaceutical Advertising (CGR) in the Netherlands
- Farmaindustria in Spain
- Farmindustria in Italy
- The Freiwillige Selbstkontrolle für die Arzneimittelindustrie (FSA) in Germany
- Les Entreprises du Médicament (LEEM) in France
- Läkemedelsindustriföreningen (LiF) in Sweden
- Legemiddelindustrien (LMI) in Norway
- Pharma Industry Finland (PIF) in Finland
- Verband der pharmazeutischen Industrie Österreichs (Pharmig) in Austria
- Etisk Nævn For Lægemiddelindustrien (ENLI) in Denmark
- Mdeon in Belgium
- Association Pharmaceutique Luxembourgeoise (APL) in Luxemburg
- ScienceIndustries in Switzerland

No matter under which local industry code we operate, we understand our risks and strive to design processes that control or mitigate those risks. We also train our employees to follow these processes, speak up when they see something unusual or have a concern, investigate these concerns and evaluate the effectiveness of our processes.

By following these principles and local laws, regulations and industry codes of practice, we ensure our actions build and maintain the trust of patients, healthcare providers, regulators, other stakeholders and our peers.

# 3 Maintaining an Ethical and Respectful Workplace

At Otsuka, we recognise that our employees are one of our key strengths and we pride ourselves on looking after their wellbeing and fostering a diverse and inclusive culture.

We aim to create an ethical working culture, where trust and honesty supports our employees to perform their jobs with integrity.

## 3.1 Equal Opportunities

Otsuka is committed to ensuring equal opportunities in the workplace for all of our employees from recruitment to departure. One of the key aims of our equal opportunity strategy is to provide a working environment where our people feel comfortable and assured that they are treated with respect and dignity.

We treat our employees, contractors, customers

and suppliers equally and fairly, irrespective of race, gender, colour, nationality, ethnic origin, religion, sex, marital status, age, sexual orientation or disability.

Such a rich culture of diversity and inclusion of individuals, viewpoints, talents and experiences directly supports our mission to help our employees to excel.

## 3.2 Harassment

At Otsuka we place great value in maintaining a professional environment free of verbal or physical harassment. Therefore, we promote a culture in which all individuals are valued, treated with mutual respect, openness and integrity.

Workplace harassment is any action that inappropriately or unreasonably creates an intimidating, hostile, offensive or uncomfortable work environment or unreasonably interferes with an individual's ability to perform the duties or responsibilities of their employment.

Physical, sexual, racial, religious, psychological, verbal or any other form of harassment at any level is prohibited and will not be tolerated. Harassment includes any behaviour, action or conduct including words, jokes or comments (whether verbal, written or in any electronic

medium) that denigrates or shows hostility or aversion towards any individual. This standard applies while working at the office, from your home office, in the field, on business trips or any situations where individuals are representing Otsuka.

We expect our leaders to set the tone for ethical and professional behaviour. Complaints of harassment and/or bullying will be taken very seriously and dealt with promptly and in confidentiality. If you observe any inappropriate behaviour, such as unprofessional conduct or comments please contact the Ethics & Compliance or Human Resources departments. You can also raise this situation through the Otsuka 'Speak Up' line. For more information, please refer to the section "Reporting Concerns".

## 3.3 Health & Safety

We have a duty of care to protect the health, safety and welfare of our colleagues, contractors, customers and suppliers. We must do whatever is reasonably practicable to achieve this.

This means making sure we protect them from anything that may cause harm by effectively controlling any potential risks to injury or health that could arise in the workplace.

You must take an active role in ensuring your own safety by complying with all workplace safety rules and procedures. Health and safety concerns, near misses and injuries should be reported immediately in accordance with our standards.

If you have any specific questions or concerns relating to health and safety in your workplace, we encourage you to talk to your line manager.

# 4 Industry Laws & Regulations

We recognise the duty we have to follow all laws, industry codes and regulations governing areas related to research, development, transparency, manufacturing, promotion, sales and distribution of our products in the countries where we operate. Ensuring product quality and safety is paramount.

Your understanding of, and compliance with, these requirements helps us maintain the reputation for trust we have built within the marketplace. It is therefore important that you are aware of those that apply to the work you do.

Your commitment to an ethical culture not only helps us to comply with these requirements, it also helps to promote an ethical workplace, and sustain the kind of success, we all want.

Remember: where stricter local laws, regulations or industry codes of practice apply, these always take precedence and must be adhered to in all circumstances.

If you have any questions about which of these apply to your local activities, please contact the Ethics & Compliance or Legal departments for guidance.

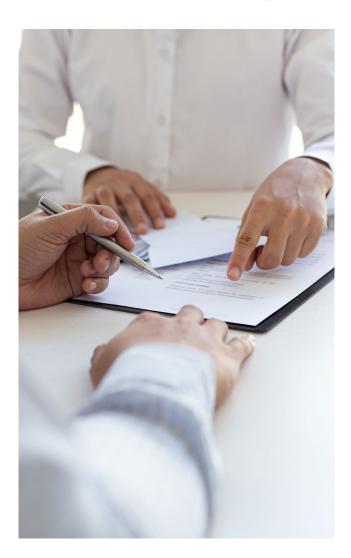


## 5 | Ethical Business Practices

Otsuka requires the highest ethical standards in the process of conducting business. Interactions with external parties including patients, HCPs, Healthcare Organisations, other relevant decision makers, third parties (such as suppliers or distributors) or government officials, must always be legal, transparent and ethical.

Whatever the situation you face, you should always apply good judgement, make decisions that are consistent with our values and ask for support or guidance from the Ethics & Compliance or Legal departments if the right course of action is unclear to you. You can also raise a concern through the **Otsuka 'Speak Up' line**. For further information, please refer to the section **"Reporting Concerns"**.

## 5.1 Antibribery and Anticorruption



Otsuka has zero tolerance towards bribery or any other form of corrupt conduct. We are committed to comply with the national antibribery and anticorruption laws applicable to our daily activities.

Some of the national laws of European countries are **far-reaching** (i.e. apply outside of a country's border, such as the United Kingdom Bribery Act 2010).

This means any wrongdoing by act or omission by an individual or company working for Otsuka, or acting on behalf of Otsuka anywhere in the world, would make Otsuka potentially liable for their actions.

We never give or accept, directly or indirectly through a third party, "anything of value" (e.g. bribes, kickbacks, improper gifts or hospitality, etc.) that may influence, or be perceived to influence, the judgement, conduct or decision of a third party (e.g. governmental agents, HCPs, Healthcare Organisations, patient organisations, suppliers, etc.) or to obtain or retain a financial, business or other advantage. No matter where we operate, our commitment to integrity and transparency remains vital to our company.

By striving to build on this commitment, we maintain the trust and confidence of our patients, healthcare providers, other stakeholders and the wider community around the world.

## 5.2 Gifts, Entertainment and Hospitality

Operating in diverse legal and cultural environments, the provision of business gifts and hospitality varies between countries and regions. Any gifts or hospitality should be reasonable, proportionate, unsolicited and made in good faith. They must also comply with any monetary limits or other restrictions specified by relevant local laws, regulations or local codes of practice. We should never accept or give a gift or hospitality that might influence, or be perceived to influence, any business decisions.

As defined in our internal policies and procedures, the term "gifts" includes tendering to a recipient products, services, cash or cash equivalents (e.g. cheques, travellers' cheques, gift cards, gift certificates, vouchers, loans and shares) and all business courtesies, gratuities, discounts not authorised, favours and other things of value that can be perceived as a benefit for the recipient.

It is the company's responsibility to comply with all applicable laws and regulations prohibiting the offering or giving of gifts, offer or promise of any benefit or bonus, whether in money or in kind as inducement for any HCP to prescribe, supply, administer, recommend, buy or sell any of Otsuka's medicinal products or medical devices. Offering a gift to/receiving a gift from an HCP, Healthcare Organisation, other relevant decision makers, governmental or any other kind of public official is not permitted.

The term "hospitality" may include meals, drinks, entertainment, recreation (e.g. tickets or invitations to sporting or cultural events), travel, accommodation (e.g. hotel stays) and other forms of hospitality that are of value.

Hospitality offered to HCPs should always be legitimate, secondary to the meeting or event, reasonable, proportionate, related to a business activity (e.g. scientific event sponsored by Otsuka or an Healthcare Organisation, etc.) and made in good faith. Where hospitality is provided, it should be disclosed in accordance with local applicable laws, regulations and codes of practice. In case of any doubt, please seek advice from your line manager or contact the Ethics & Compliance department.

## 5.3 Interactions with Healthcare Professionals and Government Officials

As a global company operating in different countries, we interact with different kinds of public officials, such as HCPs and Government Officials.

**HCPs** include members of the medical, dental, pharmacy and nursing professions and any other person, who in the course of their professional activities may administer, prescribe, purchase, recommend or supply a medicine.

Otsuka may engage HCPs to render genuine services such as lectures, presentations or scientific expert report. Interactions between Otsuka and HCPs must always be ethical, adhere to applicable local laws and regulations, be professional, commercially legitimate

and never be used as an inducement or reward to an HCP to prescribe, supply, administer, recommend, purchase or sell any product of Otsuka.

The definition of a **Government Official** varies from one country to another but includes anyone holding public office, employed by the state or who has political influence, such as employees of governmental institutions, HCPs, employees of public companies and/or public hospitals, etc.

We want our continued success to be based on the merits of the products and services we bring to the marketplace, but never on unethical or illegal business practices.

## 5.4 Interactions with Healthcare Organisations

To continue being a successful global company we need to develop new innovative drugs and improve our existing medicines. We must be transparent when we interact with Healthcare Organisations (HCOs). HCOs can offer invaluable and expert knowledge to help us continue to improve patient care and outcomes.

**HCOs** can be defined as a healthcare, medical or scientific association or organisation such as a hospital, clinic, foundation, university or other teaching institution or learned society whose business address, place of incorporation or primary place of operation is in Europe.

When we interact with HCOs, we must ensure that we are transparent and comply with the code of practice issued by the EFPIA

and respective local laws, regulations and applicable codes of practices.

To meet these requirements we must, but not be limited to:

- Have written agreements in place when we provide financial support to HCOs
- Publicly disclose all interactions involving transfer of value with HCOs on our affiliate websites
- Ensure that all events sponsored or organised by or on behalf of Otsuka including scientific, business or professional meetings, are held in appropriate locations and venues that are conducive to the main purpose of the event

## 5.5 Interactions with Patient Organisations

Working with patients and Patient Organisations (POs) can bring significant benefits to public health. Our ultimate goal of becoming an indispensable contributor to people's health worldwide means that, when we interact with POs we must:

- Respect and guarantee the independence of the PO
- Not seek to influence the text of POs' materials or activities, however we can contribute to the drafting of text from a fair and balanced scientific perspective

- Not promote prescription only medicines to the public
- Not require that Otsuka is the sole funder of a PO
- Have written agreements in place when we provide financial support to POs
- Be transparent about interactions with POs, including respect of disclosure requirements in compliance with local laws and regulations

## **5.6 Promotional Activities**

The promotion of our products must be in accordance with the terms of the marketing authorisations and must be consistent with the particulars listed in their Summary of Product Characteristics, (SmPC) e.g.:

- Be accurate, truthful and not misleading
- Provide fair and balanced information
- Only make claims that are properly substantiated

- Not promoted prior to the grant of the marketing authorisation
- Never promote off-label use

Promotional activities must comply with the EFPIA requirements and applicable local laws, regulations and codes of practice.

# Bringing Transparency to the Public in Disclosing Interactions with HCPs, HCOs & POs and Other Covered Recipients

As an affiliate member of EFPIA, local trade associations across Europe through relevant affiliates and by abiding by applicable local laws, we uphold ethical standards in disclosing and publishing direct or indirect transfer of values made to HCPs, HCOs and POs, which we have interacted with, and Other Covered Recipients when it is required by local laws and regulations.

We publish these reports on our public websites, central disclosure platforms or local governmental portals as required. All Otsuka employees are obliged to accurately report their transfer of value relevant interactions with HCPs, HCOs and POs.

Such submissions are to be made to the relevant teams within Otsuka according to strict timelines.

For submissions and reporting of disclosable data according to strict timelines, HCP/HCO disclosure, PO disclosure and any inquiries related to engagement of Other Covered Recipients, please contact the Ethics & Compliance department for guidance.

## 7 | Third Party Due Diligence

We want what is best for our patients and customers. Our business success depends on us conducting business according to legal, ethical and professional standards.

To ensure that third parties performing services for or on behalf of Otsuka apply the same ethical standards. We perform different due diligence reviews, which may include a risk assessment before entering into a contract, in accordance with our policies and standard operating procedures (SOPs). Depending on the results, additional due diligence controls may have to be performed.

Third party selection is based on objective factors including, but not limited to, quality, service, price, delivery, financial standing of an organisation and overall reputation. We also ensure that the supplier selection process is ethical, transparent and fair.

Therefore, only third parties that are suitable for the interest of Otsuka and, most importantly, for Otsuka's patients and customers, are to be selected.

Remember: Otsuka entities are liable for any acts of wrongdoing or omission undertaken by a third party acting on Otsuka's behalf, anywhere in the world.

## 8 International Trade



Otsuka conducts its business in many countries and regions, engaging in cross-border transactions for products. The trade-related laws go beyond the borders of Europe.

Employees whose job functions involve international trade need to be knowledgeable of and compliant with the trade-related laws, requirements and restrictions, such as trade embargoes, boycotts, import and export restrictions, local importation customs practices, and taxation laws and regulations.

If applicable laws and regulations are violated relating to international trade control, material penalties could be imposed on both the company and the individual employee.

If there are any questions concerning trade-related laws and regulations, please consult the Legal department.

## 9 Insider Trading

We are committed to the fair functioning of the world's financial markets. We prohibit employees and third parties acting on behalf of Otsuka from sharing inside information relating to Otsuka and its alliances or sharing 'tips' that could unfairly influence investment decisions.

**Insider trading** can be defined as buying or selling securities (e.g. stocks, bonds, options, derivatives, etc.) of any public company, using non-public material information (i.e. information that may have an influence on an investment decision of a person) about the company or third parties, and it is illegal. An individual taking advantage of such information gains an unfair advantage over the rest of the market.

**Example:** If you hear of a potential 'tip' and disclose that information for personal financial benefit or provide it to others who may go on to use that confidential information to make an investment decision, this will be considered as insider trading.

Insider trading can trigger serious consequences. If you are facing such a situation, if you have questions or concerns about potential insider trading, please seek advice from the Legal department.



# 10 Anticompetitive Practices and Fair Dealing

To compete fairly and strategically in the marketplace we must understand and be aware of the antitrust and fair competition laws.

We must ensure to build business relationships that comply with the letter and spirit of the laws designed to foster fair competition in the country (or countries) where we do business.

To compete fairly (and to comply with anticompetition laws or antitrust laws), we do not, but are not limited to:

- Discuss prices we are going to charge customers with our competitors
- Participate in any kind of collusion with competitors

- and/or our suppliers (wholesalers, pharmacy, etc.) on pricing, market shares, public tenders, etc.
- Illegitimately prevent another company from entering the market
- Raise, set or hold (i.e. "fix") prices on our products that are not authorised by laws or regulations
- "Tie" products and/or services together—in order to purchase one product, a customer will have to purchase other products associated with it
- Attempt to extend an existing tender agreement to avoid a new one

For more guidance, please contact the Legal department.

## 11 Intellectual Property

With our business model of innovation, Otsuka relies on intellectual property rights and their protection. The company's valuable assets are protected by a variety of intellectual property rights, including but not limited to patents, trademarks, copyrights, trade secrets, domain names, regulatory data and related rights. In the event of a violation of our intellectual property rights, the company will defend its rights.

Otsuka respects any legitimate intellectual property of third parties and expects its employees to consider such rights in its daily work.

If you become aware of a violation of our intellectual property rights by a third party, please contact the Legal department. You can also raise a concern through the **Otsuka 'Speak Up' line**. For further information, please refer to the section **"Reporting Concerns"**.

## 12 | Confidential Information

**Confidential information** includes, but is not limited to, business strategy plans, designs, databases, records, salary information and any unpublished clinical/financial data and reports. To protect these valued assets and those of our third parties, we store and transfer confidential information only by secure, company-approved methods. We should:

- O1 Share information only with those colleagues who have a legitimate business need to know
- Share information only with third parties who are authorised to receive it (e.g. under appropriate non-disclosure/confidentiality agreements)
- Never discuss business-sensitive information in public
- Not use social media as a platform to discuss or endorse any business-related information (see **Digital Social Media** section for further information)

We have a duty to protect confidential information against unauthorised disclosure or use, which could threaten our ability to compete and thrive in our industry.

If you suspect an incident of misuse or theft of confidential information or require a clearer interpretation of what is appropriate, legitimate or considered as an

ethical business behaviour, you can discuss this with your line manager or seek advice from the Legal department.

You can also raise a concern through the **Otsuka 'Speak Up' line**. For further information, please refer to the section "**Reporting Concerns**".

## 13 | Conflicts of Interest

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We are all responsible for a wide range of business decisions daily. In every case, it is essential that we consider all the relevant information and our good judgement to make the 'right' decision.

A **conflict of interest** arises when we place our personal interest before the interest of Otsuka and where such personal interest unduly influences our business judgements, decisions or actions. While it is not possible to list every situation where a potential conflict can arise, common examples of conflict of interest are listed below:



## 01 | Personal relationships:

potential conflicts may arise if you employ, manage or conduct business with a relative, a friend or a person with whom employees have a close personal relationship, including negotiating, engaging or hiring, or being involved in decisions to engage or hire them.

## 02 Outside activities:

board directorship or trustees with HCOs or POs may pose a conflict if they interfere with your job at Otsuka, as well as any kind of paid or unpaid engagement with an Otsuka business associate or competitor.

## **Secondary employment:**

if you undertake work for another employer or a secondary job, you must proactively report it, in order to avoid conflict of interest, especially if it directly competes with the work you do for Otsuka or interferes with the time, talent or energy you bring to your job.

## Personal gain/financial interest:

investing in a company that does business with Otsuka or is a competitor, acting as an advisor or consultant to any government agency with regulatory or supervisory power over Otsuka, or accepting any form of compensation, cash, gifts or invitations from a supplier, customer, competitor or distributor.

National laws and European directives or regulations criminalise conflicts of interest in the public sector (Government Officials) and can result in prosecution for you and our company.

In case of any questions concerning a potential and/or existing conflict of interest, please refer to the Human Resources or Ethics & Compliance departments for specific guidance.

## 14 Research & Development/ Clinical Data Transparency



Research and development plays an essential role in our philosophy: 'Otsuka-people creating new products for better health worldwide'.

We are committed to innovative, high-quality research, conducted with the highest ethical standards in accordance with all applicable regulations and standards. Such regulations include Good Practice Guidelines in each country and The World Medical Association Declaration of Helsinki (Ethical Principles for Medical Research Involving Human Subjects), protection of patient rights in clinical trials, and protection of data privacy of research subjects.

We recognise that access to clinical study data is valuable for the advancement of public health and science. This includes data from interventional and non-interventional clinical studies. Our obligation is to protect the privacy, safety and wellbeing of all clinical study participants.

Otsuka entities in Europe and Otsuka globally are committed to registering Otsuka-sponsored clinical trial/study information on public websites, such as www.clinicaltrials.gov and https://eudract.ema.europa.eu.

Otsuka is committed to providing clinical study results, whether interventional or non-interventional through, among other methods, publication at scientific congresses and/or in peer-reviewed journals, regardless of the outcome of the trials/studies within the required timeframes.

In line with our global policies and procedures, we disclose this information in a manner that is consistent with the EFPIA and IFPMA Principles for Responsible Clinical Trial Data Sharing, and local laws, regulations and codes of practice.

## 15 | Safety and Quality

We are committed to ensuring that our pharmaceutical products and medical devices meet and conform to internationally accepted standards of quality, strength, purity, efficacy and safety.

As described in our internal pharmacovigilance policies and procedures, it is the responsibility of all Otsuka employees to report immediately any adverse drug effects/events and reactions or quality product complaints associated with an Otsuka product or medical device.

An **adverse event** (AE) can be considered as any untoward medicinal occurrence in a patient or clinical study subject administered a medicinal product and that does not necessarily have a causal relationship with this treatment.

A **product quality complaint** (PQC) is any written, electronic or oral communication provided by an HCP, consumer, medical representative, regulatory agency, partner or other third party that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a medical device or medicinal product, or a falsified, tampered or diverted product after it is released for distribution.

They must be reported to the Local Safety Manager (LSM), Pharmacovigilance department, Quality representative or the Global Pharmacovigilance team within 24 hours of when Otsuka personnel and those working on behalf of Otsuka are first notified or become aware of safety information, regardless of whether received in person, or via telephone, email, fax, etc.



## **Examples of adverse events/safety information** (non-exhaustive list):

- Lack of therapeutic efficacy
- Overdose/incorrect dosage (accidental or intentional)
- Medication errors (e.g. patient took wrong dose)
- Exposure to drug during pregnancy
- Suspected counterfeit product
- Off-label use
- Accidental exposure
- Ftc.

Remember: reporting a safety or quality concern could help save someone's life.

## **16** | Falsified Medicines

Be alert to falsification or tampering of our products, this can pose a serious risk to patients and harm our reputation. In the event where you become aware of a suspected falsified or tampered Otsuka product or device, report it immediately to your Quality representative, and if applicable, to local competent authorities.

Do your part to protect the safety of patients and promptly report any safety or quality issues within 24 hours of the first receipt of being notified of the report.

## 17 | Respect for Data Privacy

**Personal data** means any information relating to an identified or identifiable natural person. Otsuka recognises the importance of personal data throughout its activities, from healthcare research and safety reporting to sales and marketing initiatives. In the course of these activities, Otsuka processes personal data related (but not limited) to patients, Healthcare Professionals and employees. We are committed to respecting the privacy of those individuals and ensuring their personal data is protected at all times.

In particular, Otsuka shall comply with all applicable legal requirements and ensure that personal data is processed in a manner that is consistent with the following principles:



- Lawful use, with fairness and transparency
- Purpose limitation
- Data minimisation
- Retention of personal data
- Accuracy of personal data
- Security of personal data
- Third party provision
- Data subject rights

If you need to seek guidance on how to use personal data appropriately, what to do in the event that an individual wishes to exercise their rights or need to report a data breach, contact the Regional Privacy Lead.

# 18 Respect for Information Security

Maintaining the highest level of vigilance over the protection of information and data is essential to preserving the trust of our partners, clients and their customers. We have the responsibility to adhere to all internal procedures, policies and training related to the protection of data such as clean desk policy, visitor access policy, information security policy acceptable use policy, etc.

Otsuka provides its employees with the tools and equipment needed to perform daily activities effectively. Unless authorised as part of daily role and duties, employees have to respect all the security features and software Otsuka uses in its systems and networks.

If you have been authorised to use a corporate device for a business activity, you are expected to follow safeguards and security standards described in our internal documentation. Otsuka provides employees with internet access and email for acceptable business use.

Be mindful of how you use the company's assets and appropriately safeguard them against theft, loss, waste or abuse. Should you have any questions regarding information protection, please contact the organisation's IT department.

## 19 Accurate Record Keeping

It is crucial to create and maintain accurate company records that document our business operations. We follow all applicable laws as well as internal accounting standards; our data integrity is vital to our continued success as a business.

We are all individually responsible for understanding and practising the reporting and documentation requirements applicable to our role.

Falsifying records and accounts, misrepresenting or omitting facts or information constitute fraud. This may carry severe penalties for you and our company and may lead to disciplinary action up to and including termination of employment.

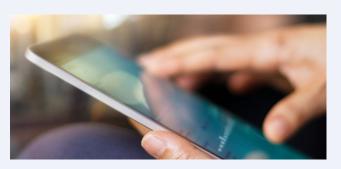
## **Examples of business records** include but are not limited to:

- Invoices
- Contracts
- Proposals, quotes including any negotiations in writing
- Expense claims
- Regulatory documents
- Quality and safety records
- Financial ledgers
- Transparency reporting information
- Sales calls records
- Etc.

## 20 | Digital Social Media

Having a digital social media presence has many benefits for Otsuka although we have to be mindful of the potential risks associated with using any digital social media channel, both for personal and business purposes.

Employees are responsible for any content they publish or engage with when using their own personal digital social media accounts, irrespective of whether using Otsuka equipment or personal equipment and regardless of role. Others may



see you as a representative of Otsuka, therefore anything you publish or engage with on digital social media channels should be considered carefully before posting to ensure posts are appropriate and compliant.

Employees must familiarise themselves with how to conduct digital social media projects or activities compliantly and in line with applicable local laws, regulations, codes of practice, and company policies and procedures.

Where local laws, regulations or requirements of local codes of practice are more specific or stricter than those contained in internal procedures or policies dedicated to digital social media, the stricter provisions should be applied.

For more information, please contact the Communications department.

## 21 | Human Rights

We have a zero-tolerance approach to violations of human rights, such as modern slavery, human trafficking, child labour, or compulsory or forced labour, etc.

We are committed to identifying and minimising the risk of modern slavery and human trafficking occurring in our operations and supply chains in all the locations where we or third parties conduct business on Otsuka's behalf. As part of our due diligence processes, specific obligations are included in our terms and conditions. We expect third parties to hold their own suppliers to the same high standards.

To endorse our commitment, we publish online an annual Slavery and Human Trafficking Statement in adherence with the United Kingdom Modern Slavery Act 2015. For more information, please contact the Legal or Ethics & Compliance departments.

## **22 Environment and Animal Welfare**



We are committed to minimising the environmental impact of our operations and promoting the sustainable use of natural resources. It is our responsibility to comply with the intent and spirit of all environmental laws and regulations, respecting the environment, in which we operate.

Under the corporate philosophy of 'Otsuka-people creating new products for better health worldwide' Otsuka adheres to the *Act on Welfare and Management of Animal*, the *Fundamental Guidelines for Proper Conduct of Animal Experiment and Related Activities in Implementing Institutions Under the Jurisdiction of the Ministry of Health, Labour and Welfare in Japan*, the *Guidelines for Proper Conduct of Animal Experiments* and related laws, regulations and guidelines.

At the global level, Otsuka has created the Otsuka Group Global Environmental Council, comprising a director of Otsuka Holdings, executive officers from each group company, and a secretariat, to identify and develop initiatives across the organisation on environmental topics such as climate change, resource circulation and water conservation. The objective is to define a long-term environmental vision that is consistent with the principles of the United Nations Global Compact, information disclosure under global standards and the setting of medium-term environmental targets with specific action plans.

## 23 | Reporting Concerns

Otsuka in Europe shares a deep commitment to adhering to the highest standards of ethics, compliance and integrity in every activity, interaction and decision. We have a responsibility to our patients, customers, business associates, employees and the world at large to adhere to all laws, regulations, and policies and simply always choose to do 'the right thing', in line with our values.

Otsuka in Europe aims to encourage openness and we encourage employees to ask questions or report any concerns that they believe put our patients, our people or our business at risk. These concerns may be about actual or suspected fraudulent, unethical or unlawful conduct employees have witnessed at work, which may damage the legitimate interests of the company.

If you are in any doubt about the legality or appropriateness of a situation, or require a clearer interpretation of what is appropriate, legitimate or ethical business behaviour, you can contact your line manager, the Ethics & Compliance, Legal and/or Human Resources departments.



If you feel uncomfortable discussing the concern with your line manager or you feel your concern has not been appropriately addressed, you can submit confidential and/or anonymous reports either by telephone or online using the **Otsuka 'Speak Up' line**.

'Speak Up' is a confidential reporting platform operated by an independent third party. All reports are anonymous, unless you choose to be identified.



Please access the online site 24 hours a day, 7 days a week or refer to the posters in your local office to access your local number for the telephone hotline. Your concern will be handled in a confidential manner in accordance with our internal procedures and applicable legal and regulatory requirements.

Speaking up may not be easy, but it is always the right thing to do and Otsuka adheres to a strict non-retaliation policy for reports made in good faith. Speaking up creates a healthy environment for Otsuka in Europe. It allows us to see if our policies or processes in place can be improved, if a training on policies is not effective or if control systems are not adequate.

Otsuka has zero tolerance for retaliation against anyone who raises a genuine concern in good faith. If you feel you have suffered any such treatment you should immediately inform the Ethics & Compliance department. Anyone who engages in retaliation behaviour or reports a concern not in good faith will face disciplinary action up to dismissal.





