Regulation and key laws

Tobacco business

The tobacco regulatory environment has been becoming increasingly stringent since the WHO Framework Convention on Tobacco Control (FCTC) took effect in February 2005.

The FCTC's objective is to "reduce continually and substantially the prevalence of tobacco use and exposure to tobacco smoke." The FCTC covers price and tax measures to reduce tobacco demand, non-price measures to reduce tobacco demand (e.g., protection from exposure to secondhand smoke, regulation of tobacco products' contents and emissions, regulation of tobacco product disclosures, regulation of tobacco products' packaging and labeling, regulation of tobacco advertising, promotion and sponsorship) and measures to reduce the supply of tobacco products (e.g., measures to prevent illicit trade in tobacco products and sales of tobacco products to minors).

While the FCTC requires its signatory countries to develop, implement, periodically update and review national tobacco control strategies, plans and programs, it leaves to the discretion of each country the specifics of national regulations' content, scope and methods. The FCTC's governing body, the Conference of the Parties (COP), has been meeting regularly since the FCTC first took effect. The COP is a forum for ongoing discussions among FCTC-signatory countries on issues such as formulating FCTC Article-specific guidelines and protocols (which must be separately ratified or otherwise agreed to by the parties).

Among FCTC-signatory countries, Russia, one of our key markets, enacted a comprehensive tobacco control law in February 2013 and phased it in from June 2013. The law restricts retail sales locations and point-of-sale displays of tobacco products; prohibits advertising, sales promotions and sponsorship; sets minimum retail prices; bans smoking in public; and combats illicit trade in tobacco products.

The EU revised its July 2001 Tobacco Products Directive (TPD) effective May 2014. The revised TPD tightened restrictions on tobacco product packaging and labeling, added new regulations on tobacco product additives, tobacco product flavor and E-Vapor products, and also included measures to address illicit trade. EU-member countries have implemented regulations associated with the revised EU TPD.

Australia mandates generic packaging of tobacco products under its Tobacco Plain Packaging Act, which took effect in December 2012. The law prohibits tobacco packaging from bearing logos, brand images, promotional text or anything else except the product name printed in a standardized font and color. Plain packaging regulations have since been adopted elsewhere, including in France and the U.K. A number of other countries are exploring the possibility of following suit or have already decided to follow.

In Japan, the Tobacco Business Act (TBA) prescribes that we are obligated to purchase a grower's entire tobacco crop excluding any portion not suitable for manufacturing tobacco products and that our own tobacco products as well as tobacco products imported by a designated distributor may be sold by retailers only at prices approved by the Minister of Finance. Tobacco product sales and promotional activities in Japan are regulated under the TBA, related laws/regulations and voluntary industry standards. One regulatory requirement is that advertisements and product packaging must carry a cautionary statement about the health implications of consuming tobacco products. In accordance with the Tobacco Institute of Japan (TIOJ)'s voluntary standards, which were revised in 2020, the cautionary statement on tobacco product packaging was changed to be consistent with the latest scientific knowledge, and the area it occupied on the packaging was enlarged. Revisions to the TIOJ's advertising voluntary standard included measures to more effectively shield those under 20 years of age from tobacco product ads, including online, and new restrictions on point-of-sale ad size and display methods.

In July 2018, the Health Promotion Act (HPA) was amended to better prevent unwanted exposure to secondhand smoke in facilities frequented by the public. We recognize public places that allow smoking are going to decrease in number under the amended HPA, which fully took effect from April 1, 2020. While it is difficult to predict smoking environment changes in detail, we expect our financial results to be affected to some extent.

In relation to RRP (Reduced-Risk Products), the U.S. and European countries are starting to establish new guidelines and frameworks for scientifically assessing the reduction in health risks associated with smoking. Tobacco makers have been stepping up activities to obtain official certification of risk-reduction benefits. Some countries have applied existing tobacco product regulations to RRP while others have newly adopted separate regulations. In the E.U. for example, it was decided in November 2022 that a flavor ban regulation previously applied only to certain tobacco products would also be applied to HTP (heated tobacco products). Also, in the U.S., sales of certain flavored E-Vapor cartridges were banned from February 2020. With a global regulatory consensus yet to take shape, regulatory treatment of RRP varies widely among markets/countries.

Regulatory impacts on our operating performance

While the future content of laws, regulations and industry guidelines on smoking, tobacco products and tobacco product marketing, sales promotions, packaging and labeling is impossible to accurately predict, we expect the regulations discussed above to expand in scope and/or new regulations (including municipal regulations) to be imposed in Japan and overseas markets in which we sell products.

We are supportive of reasonable and appropriate regulation of tobacco, but if tobacco regulations like those described above are tightened or if we are not afforded enough time to adequately adapt to such regulatory tightening, our financial results may be adversely affected by contraction in tobacco product demand, loss of market share and/or increased regulatory compliance expenses.

Self-regulation of marketing

In addition to complying with the regulations of every country and region in which we operate, we also operate in accord with our own Global Marketing Principles (GMPs), the principles based on our recognition of the importance of responsibly marketing tobacco products. Our GMPs are based on the recognition of the importance of conducting responsible marketing activities for tobacco products, and describe the principles for advertising, promotion, and others activities conducted by the Group. This includes ensuring that marketing activities are targeted at people of 18 years of age or older, and of legal smoking age. These marketing activities are not aimed at encouraging anyone to start smoking or discoursing them from quitting, even if they are of legal smoking age. We also recognize that the prevention of smoking by minors (those who have not reached legal smoking age) is an issue that needs to be addressed by society as a whole. We are pursuing various initiatives to address this issue in coordination with governments and concerned organizations in addition to appropriately operating in accord with our GMPs.

Please visit JTI.com for more details.

Pharmaceutical business

Pharmaceutical R&D, manufacturing, sales and marketing are stringently regulated in Japan and major overseas markets. Additionally, regulatory authorities globally have been reviewing new drug applications (NDA) increasingly rigorously in recent years in response to a growing imperative to ensure drug safety. Given the need to demonstrate safety in larger sample sizes over sufficiently long timeframes, clinical trials are growing in both scale and duration. Meanwhile, with required NDA documentation being internationally standardized both qualitatively and quantitatively, drug companies now commonly use a single set of data available in multiple countries for drug development, a practice that increases development efficiency and reduces costs.

In Japan, pharmaceutical manufacturing and sales are regulated by the Ministry of Health, Labour and Welfare (MHLW) and/or prefectural authorities under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the "Pharmaceutical and Medical Device (PMD) Act"). The PMD Act requires companies that manufacture and sell pharmaceuticals to be licensed in every prefecture in which they operate and to renew those licenses every five years. Additionally, every pharmaceutical manufactured or sold in Japan must be approved by the MHLW. Japan's National Health Insurance (NHI) program maintains a drug formulary and sets official drug prices. The NHI is planning to radically reform drug pricing. The planned reforms include annual drug price revisions, paring-down of the list of drugs qualifying for premium pricing intended to incentivize drug discovery and reduce off-label drug use, and tiered reductions in long-listed drug prices based on generic substitution rates.

Processed food business

Our processed food business is regulated as a food product manufacturer and distributor, mainly under the Food Safety Basic Act, Food Sanitation Act and Food Labeling Act.

The Food Safety Basic Act, enacted and effective from 2003 with the purpose to ensure food safety and protect consumers, charges food companies with a responsibility to implement safeguards necessary to ensure food safety from a scientific standpoint through risk control, assessment and communication at each stage of their entire supply chains. The Food Sanitation Act aims to keep food and beverages free of hygienic hazards and protect the health of consumers. It requires food companies to acquire knowledge and technology, verify ingredient safety, inspect their facilities, and otherwise act diligently to fulfill their responsibilities to ensure the safety of their food products, additives, utensils, containers and/or packaging. As part of the revision in 2018, additional requirements such as hygiene management in line with the HACCP (Hazard Analysis and Critical Control Point) are in place. The Food Labeling Act, aiming to uphold consumer interests and contribute to making food production support the protection and/or promotion of consumer health, sets labeling standards for food products offered for sale, including with respect to allergen content, shelf life, ingredients, and place of origin. Food companies are required to label their products in compliance with these standards.

In addition to meticulously complying with these and other applicable laws and regulations, our processed food business is committed to the highest standards of food safety management from the four perspectives—food safety, food defense, food quality and food communication—in order to provide consumers with safe, high-quality food products that they can enjoy with peace of mind.

Japan Tobacco Inc. Act

JT was established pursuant to the Japan Tobacco Inc. Act (the "JT Act") to manufacture, sell and import tobacco products. Under the JT Act, the Japanese government must always own at least one-third of our total issued shares (excluding any non-voting share classes*1). The Minister of Finance must approve any offerings of newly issued stock or subscription rights to shares, as well as any issuance of stock, subscription rights to shares or bonds cum subscription rights to shares in conjunction with a stock swap. In addition to manufacturing, selling and importing tobacco products and operating businesses incidental thereto, we are permitted by the JT Act to engage in other businesses as required to fulfill our purpose and subject to the Minister of Finance's approval. Other matters requiring the Minister of Finance's approval include appointment/dismissal of Directors, Executive Officers and Audit & Supervisory Board Members, amendments to our Articles of Incorporation, appropriations of capital surplus (excluding appropriations to rectify an accumulated deficit), mergers, split-ups and dissolution. We are also required to submit a statement of financial position, statement of income and business report to the Minister of Finance within three months of every fiscal year-end.

The Reconstruction Financing Act*2, which took effect on December 2, 2011, directed the government to reassess state involvement in the tobacco industry under the Tobacco Business Act by March 31, 2023, and to explore the possibility of divesting its JT shareholdings.

*1 Defined as classes of shares with no right to vote on any resolutions at general meetings of shareholders

*2 The Act on Special Measures for Securing Financial Resources Necessary for Reconstruction from the Great East Japan Earthquake

Litigation

Some of JT's subsidiaries are defendants in lawsuits filed by plaintiffs seeking damages for harm allegedly caused by smoking or vaping, the marketing of tobacco or E-Vapor products or exposure to tobacco smoke. There are lawsuits involving smoking/vaping and health-related cases pending in which some of JT's subsidiaries are named as defendants or for which JT may have certain indemnity obligations pursuant to the agreement for JT's acquisition of RJR Nabisco Inc.'s non-U.S. tobacco business. In addition, JT and/or some of its subsidiaries are also defendants in lawsuits other than the smoking/vaping and health-related cases.

There are 10 ongoing health care cost recovery cases in Canada pending against JTI-Macdonald Corp. (hereinafter referred to as JTI-Mac), our Canadian subsidiary and JT's indemnitees (RJR Nabisco Inc.'s affiliates), brought by Canadian provinces. In addition, there are 8 pending class actions in Canada where plaintiffs are seeking damages for harm allegedly caused by smoking of cigarettes. Damages claimed in some of these cases reach sums in the multi-billion-dollar range. We will continue to take all appropriate actions to defend such claims vigorously and believe there are a number of valid defenses.

On March 8, 2019, JTI-Mac filed for protection from its creditors under Canada's Companies' Creditors Arrangement Act (CCAA). The Ontario Superior Court granted the CCAA application on the same date and extended the protection in favor of JTI-Mac. All the Canadian matters against JTI-Mac referred to herein have been stayed by the court order. JTI-Mac carries on business in the ordinary course under the CCAA.

In recent decades, numerous, large-scale smoking and health-related cases have been brought against tobacco product manufacturers in the U.S. and some of the cases initially resulted in verdicts with massive damage awards. We are not defendants in any of these lawsuits, nor are we subject to any indemnity claims with respect to them. The JT Group's U.S. tobacco business does not include the business that it acquired from RJR Nabisco Inc. in 1999, as well as the Natural American Spirit's non-U.S. business that it acquired from Reynolds American Inc. group in January 2016.

There is ongoing litigation in the U.S. alleging health effects associated with E-Vapor use and harm caused to consumers by misleading representations and advertising for which plaintiffs are seeking damages and/or demanding health warnings against E-Vapor manufacturers in the U.S. One such case has been brought against a number of E-Vapor manufacturers including JT subsidiaries. This case has been stayed by a court order. We believe that we have valid grounds to defend this claim and intend to do so vigorously.

Even now, the scale of the JT Group's U.S. tobacco business remains small. Hence, we believe that litigation in the U.S. will not materially affect its businesses in the near future.

Please see "Contingent Liabilities" in our Consolidated Financial Statements' "Contingencies" note for major lawsuits to which some of JT's subsidiaries or indemnitees are named as defendants.

To date, the JT Group has never lost a case or paid any settlement award in connection with smoking/vaping and health-related litigation. However, the Group is unable to predict the outcome of currently pending or future lawsuits. A decision unfavorable to the JT Group and payment of a substantial amount of monetary compensation could materially affect its financial performance. Moreover, regardless of the results of these lawsuits, critical media coverage may reduce social tolerance of smoking, strengthen public regulations and prompt the filing of a number of similar lawsuits against the JT Group, forcing it to bear litigation costs and materially affecting its business performance. Apart from smoking/vaping and health-related ones, the JT Group also may become the defendant in further litigation. Should any problems arise on the Group's product quality, this may lead to claims seeking product liability. Such litigation cases may negatively affect the Group's business performance or the manufacture, sale and import and export of its products, should the outcome of any such claims prove unfavorable.