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Quarterly Report: April 2019

GLOBAL TRANSPARENCY UPDATE

Stay up-to-date with the latest transparency legislation, regulations and codes around the world.

INTRODUCTION

Global transparency regulations and codes are constantly being introduced, revised or updated. Keeping up with all these changes can be a major challenge.

IQVIA's global transparency experts continually monitor transparency changes around the world and regularly update our Regulations Snapshot. We provide the Snapshot and Quarterly Update to our clients as a convenient way for you to stay up-to-date.

In our quarterly Global Transparency Regulations Snapshot, we provide the information clients need to be compliant with regulations or codes in 47 countries, as well as information for all existing local and state legislation in the United States and Canada.

In this Quarterly Update, we take a closer look at 2 specific regulations, examining what's new and/or changed as well as the possible implications for your business and the industry. To schedule a time to speak with one of our experts about how these regulations will impact you, click here.

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Global Transparency Regulations Snapshot

Legend: Code, Law

Country/ Jurisdiction	Industry: Pharma (P), Generics (G), Med Dev (MD), Over the Counter (OTC), Cosmetics (CM), Animal Health (AH)	Governmental body/ Association responsible for the disclosure rules	Link to local association website or government authority	REPORT(S) REQUIRED	WAY OF DISCLOSURE AND DEADLINE	Jul 18	Aug 18	Sep 18	Oct 18	Nov 18	Dec 18	Jan 19	Feb 19	Mar 19	Apr 19	May 19	Jun 19
Australia	P	Medicines Australia (MA)	http://www.medicinesaustralia.com.au	2 Excel files (HCO and Event report); 1 template in PDF and CSV format (HCP report)	HCO report to be sent via e-mail to MA by April 30; Third Party Events Reports to be sent via e-mail to MA by Feb 28 and Aug 31; HCP report to be published on the Company's website by Feb 28 and Aug 31		31						28		30		
	MD	Medical Technology Association of Australia (MTAA)	https://www.mtaa.org.au/resources/code-of-practice	1 excel file with 3 tabs	Companies may be requested by MTAA to submit via email a report on events they supported in specific 3 month period of the previous year any time starting from January. The report will not be disclosed to the public but only reviewed for internal monitoring purposes by MTAA.							31					
Canada	P	Innovative Medicines Canada	http://innovativemedicines.ca/ethics/voluntary-disclosure-of-payments/	1 PDF template	Data will be published on Companies' websites starting from June, therefore the report will have to be ready by the end of May. Companies will have to produce one template (in English and/or French) with the three expense categories requested by the IMC Voluntary Framework with reference to the data of the previous year.											31	
Finland	P	Lääketeollisuus	http://www.pif.fi/	1 PDF template	Publication on the Company's website by May 31											13	
	MD	MedTech Europe	http://www.medtecheurope.org/	1 CSV template	Upload to the Central Platform by June 30												30
	G	Medicines for Europe	http://www.medicinesforeurope.com/	4 PDF templates	Publication on the Company's website by June 30												30
France	P-MD-G-OTC-CM-AH	Ministère des Affaires Sociales et de la Santé	http://www.transparence.sante.gouv.fr	1 CSV template	Upload to the Central Platform by March 1 (2nd semester ToVs of the previous year)/ Sept 1 (1st semester ToVs of the same year)			1						1			
Germany	P	Die forschenden Pharma-Unternehmen (VFA)	https://www.fsa-pharma.de/	1 PDF template	Publication on the Company's website by June 30												30
	P	Arzneimittel und Kooperation im Gesundheitswesen e. V. (AKG)	http://www.ak-gesundheitswesen.de	1 PDF template	Publication on the Company's website by June 30												30
	MD	MedTech Europe	http://www.medtecheurope.org/	1 CSV template	Upload to the Central Platform by June 30												30
	G	Medicines for Europe	http://www.medicinesforeurope.com/	4 PDF templates	Publication on the Company's website by June 30												30
Indonesia	P-MD-G-OTC	Kementerian Kesehatan Republik Indonesia (Ministry of Health of the Republic of Indonesia)	http://www.depkes.go.id/	1 report in Excel and PDF format	Companies must submit via email to the Corruption Eradication Commission (Komisi Pemberantasan Korupsi - KPK) a report of sponsorships covering 1 (one) month period no later than the 10th of the following month	10	10	10	10	10	10	10	10	10	10	10	10
Japan	P	Japan Pharmaceutical Manufacturers Association (JPMA)	http://www.jpma.or.jp/	5 categories of expenses to be disclosed: 1. Research and development expenses; 2. Academic research support expenses; 3. Manuscript/writing fees; 4. Information provision-related expenses; 5. Other expenses.	Publication on the Company's website by the end of December with the reference to the data of the previous year						31						
	MD	The Japan Federation of Medical Devices Associations (JFMDA)	http://www.jfmda.gr.jp/	5 categories of expenses to be disclosed: 1. Research and development expenses; 2. Academic research support expenses; 3. Manuscript/writing fees; 4. Information provision-related expenses; 5. Other expenses.	Publication on the Company's website by the end of December with the reference to the data of the previous year						31						
United States (National)	P-MD-G	Centers for Medicare & Medicaid Services (CMS)	https://www.cms.gov/openpayments/	3 CSV files	Upload to the Central Platform by the 90th day of each calendar year (i.e., March 31)									31			
US District of Columbia (State)	P-G	Department of Health	https://doh.dc.gov/service/prescription-drug-marketing-costs-access-rx	1 Excel file	Email to government agency by July 1st of each year	1											

The chart above is just a sample of what clients receive. Click on it to download the sample report.

COLOMBIA

Pharma, Medical Device, Animal Health and Cosmetics

OVERVIEW

In March 2019, the Ministry of Health and Social Protection of Colombia ("Ministry"), released an FAQ document which provides further clarity on specific aspects of the Colombian Sunshine Act (Resolution n. 2881 of 2018). Among the various clarifications, it should be noted that the Ministry further specified the definition of "pharmaceutical product", stating that this includes any product intended for the cure of humans and animals, including cosmetic products.

CURRENT SCOPE OF COLOMBIA REPORTING

Companies are required to report any type of payment in cash or in kind, including but not limited to, food and drinks, consulting fees, sponsorship of HCPs to attend an educational event, clinical studies, delivery of medical samples, promotional material, travel and accommodation.

Reportable Information (non-exhaustive list)

- Name of recipient
- Nature of the expense (clinical studies, consulting fees, food and drinks, etc.)
- Amount and date of the expense

Reportable recipients

- Healthcare professionals (HCPs)
- Healthcare organizations (HCOs)
- Patient Organizations (POs)

Reporting format

Two flat files to be uploaded into the Central Platform managed by the Ministry of Health in Colombia (PISIS)

Reporting frequency and deadline

Disclosure shall be done twice a year:

- By September 30th covering the period January - June
- By March 31st covering the period July - December

First reporting deadline: March 31st 2020 (2019 2nd semester ToVs)

IMPLICATIONS

Review the FAQ document released by the Ministry of Health and Social Protection of Colombia and evaluate the impact on your activities.

Start planning for the first reporting session which will start on July 1st, 2019 and make sure that you collect all required data to report it by the end of March 2020.

PHILIPPINES

Pharma and Medical Device

OVERVIEW

On February 20th, 2019, the President of the Philippines signed the Universal Health Care Act ("UHC") which will guarantee universal access to quality and affordable healthcare services for all Filipinos citizens. As far as transparency reporting is concerned, the UHC has introduced a specific provision (art. 35) that will oblige pharma and medical device companies to collect, track and report to the Department of Health ("DOH") all financial relationships with health-care professionals and health care providers. Technical details on how this obligation will be implemented are expected to be outlined in a future decree.

CURRENT SCOPE OF PHILIPPINES REPORTING

Under the current regulation, Administrative Order n. 53 of December 21st, 2015, Pharmaceutical and Medical Devices Companies ("companies") are required to submit through the Philippines Food and drug administration ("FDA") website, information on events/congresses involving local and foreign travel including details of HCP participating in such events.

Reportable information (non-exhaustive list)

- Name of the HCP
- Title of the event attended
- Type of travel (domestic/international)

Reportable recipients

- Healthcare professionals (HCPs)

Reporting format

No specific format. The information must be submitted manually in the FDA website.

Reporting frequency and deadline

Submission of the relevant information shall be done within the year of occurrence of the event.

IMPLICATIONS

Continue to report, for the time being, following the current rules.

Continue monitoring the status of implementation of new reporting rules under the UHC in order to be ready to report once the new rules are defined and effective.

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CONTACT US

Ben Carmel

benjamin.carmel@iqvia.com

Global Head of Business Development

IQVIA Commercial Compliance

+1 908 507 3588

iqvia.com

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