IMS Health & Quintiles are now IQVIA™

Quarterly Report: January 2019

GLOBAL TRANSPARENCY UPDATE

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

INTRODUCTION

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

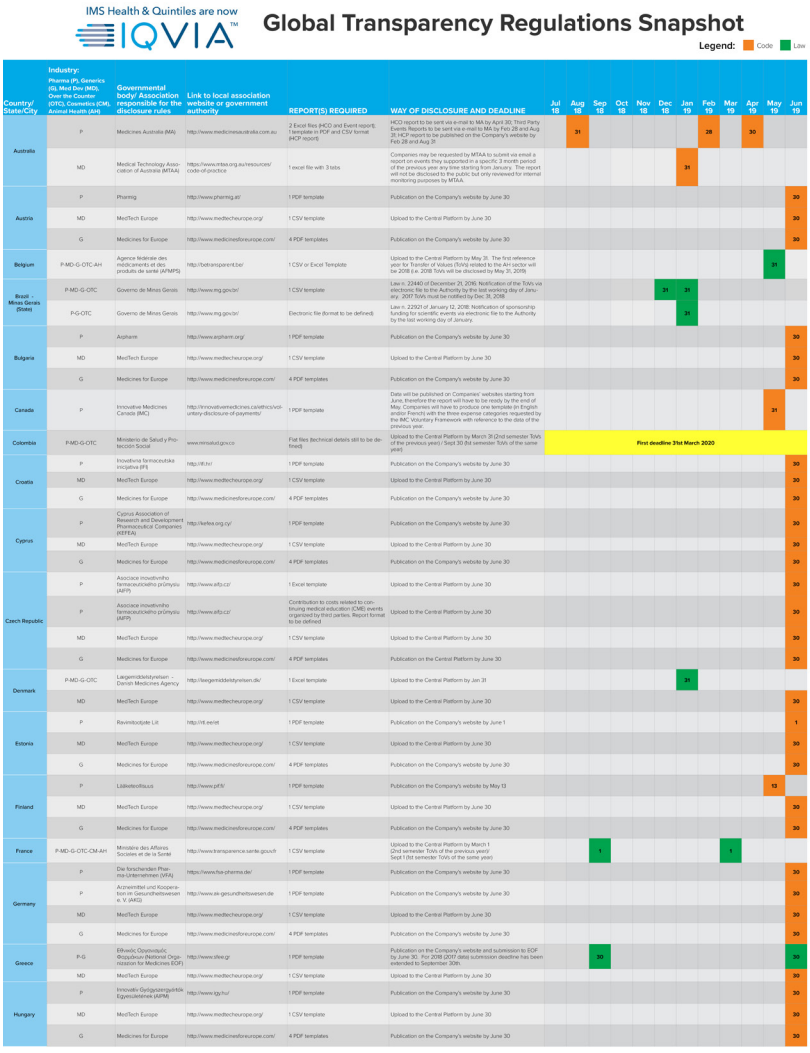
IQVIA's global transparency experts continually monitor transparency changes around the world and regularly update our Regulations Snapshot. We provide the Snapshot and Quarterly Update to our clients as a convenient way for you to stay up-to-date.

In our quarterly Global Transparency Regulations Snapshot, we provide the information you 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.

Click here to view and download the latest Global Transparency Regulations Snapshot.

In this Quarterly Update, our transparency experts take a closer look at 2 specific regulations. We examine 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 your organization, click here.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Global Transparency Regulations Snapshot

Legend: Code Law

Country/ State/City	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 a 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					
Austria	P	Pharmig	http://www.pharmig.at/	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
Belgium	P-MD-G-OTC-AH	Agence fédérale des médicaments et des produits de santé (AFMPS)	http://betransparent.be/	1 CSV or Excel Template	Upload to the Central Platform by May 31. The first reference year for Transfer of Values (ToVs) related to the AH sector will be 2018 (i.e. 2018 ToVs will be disclosed by May 31, 2019)										31		
Brazil – Minas Gerais (State)	P-MD-G-OTC	Governo de Minas Gerais	http://www.mg.gov.br/	1 CSV template	Law n. 22440 of December 21, 2016. Notification of the ToVs via electronic file to the Authority by the last working day of January. 2017 ToVs must be notified by Dec. 31, 2018						31	31					
	P-G-OTC	Governo de Minas Gerais	http://www.mg.gov.br/	Electronic file (format to be defined)	Law n. 22521 of January 12, 2018. Notification of sponsorship funding for scientific events via electronic file to the Authority by the last working day of January.							31					
Bulgaria	P	Aspharm	http://www.aspharm.org/	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
Canada	P	Innovative Medicines Canada (IMC)	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		
Colombia	P-MD-G-OTC	Ministerio de Salud y Protección Social	www.minsalud.gov.co	Flat files (technical details still to be defined)	Upload to the Central Platform by March 31 (2nd semester ToVs of the previous year) / Sept 30 (1st semester ToVs of the same year)	First deadline 31st March 2020											
Croatia	P	Inovativna farmaceutska inicijativa (IFI)	http://ifi.hr/	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
Cyprus	P	Cyprus Association of Research and Development Pharmaceutical Companies (KEFEA)	http://kefea.org.cy/	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
Czech Republic	P	Asociace inovativního farmaceutického průmyslu (AIFP)	http://www.aifp.cz/	1 Excel template	Upload to the Central Platform by June 30												30
	P	Asociace inovativního farmaceutického průmyslu (AIFP)	http://www.aifp.cz/	Contribution to costs related to continuing medical education (CME) events organised by third parties. Report format to be defined	Upload to the Central Platform 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 Central Platform by June 30												30
Denmark	P-MD-G-OTC	Lægemiddelstyrelsen – Danish Medicines Agency	http://laegemiddelstyrelsen.dk/	1 Excel template	Upload to the Central Platform by Jan 31							31					
	MD	MedTech Europe	http://www.medtecheurope.org/	1 CSV template	Upload to the Central Platform by June 30												30
Estonia	P	Ravimitoojate Liit	http://rtl.ee/et	1 PDF template	Publication on the Company's website by June 1												1
	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
Finland	P	Lääketeollisuus	http://www.pfi.fi/	1 PDF template	Publication on the Company's website by May 13											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
Greece	P-G	Εθνικός Οργανισμός Φαρμάκων (National Organization for Medicines (EOF)	http://www.sfee.gr/	1 PDF template	Publication on the Company's website and submission to EOF by June 30. For 2018 (2017 data) submission deadline has been extended to September 30th.			30									30
	MD	MedTech Europe	http://www.medtecheurope.org/	1 CSV template	Upload to the Central Platform by June 30												30
Hungary	P	Innovatív Gyógyszergyártók Egyesületének (AIPM)	http://www.ipy.hu/	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

Click on the image above to view and download the latest Global Transparency Regulations Snapshot

AUSTRALIA

Pharma

OVERVIEW

On November 16th, 2018, Medicines Australia ("MA"), the association representing the discovery-driven pharmaceutical industry in Australia, announced that HCP payment reports will now be published on the new MA Central Reporting System ("CRS"), starting with the August 2019 publication, provided that the HCP was informed in advance by the MA member company of said publication.

CURRENT SCOPE OF HCP PAYMENTS REPORTS

Scope

MA member companies are required to report payments or transfers of value that they make to HCPs twice a year.

Reportable Information (non-exhaustive list)

- Name of recipient and principal practice address
- Type of HCP (i.e. medical practitioner, pharmacist, nurse practitioner)
- Description of the service (i.e. speaker, Advisory Board, Chairperson at educational meeting etc.)
- Amount of payment

Reportable recipients

- Healthcare professionals (HCPs)

Reporting format

PDF and CSV format to be published on the MA member company's website.

Reporting frequency and deadline

Disclosure shall be done twice a year:

- By February 28th covering the period May – October
- By August 31st covering the period November – April

IMPLICATIONS

Review existing HCPs collection notices and verify if they are covering publication of personal data on the CRS platform.

Update, where needed, collection notices to make sure that publication on the CRS platform is legally covered.

MACEDONIA
Pharma

OVERVIEW

On June 25th, 2018, Farmabrend Nova ("FBN"), the Association of innovative companies in Macedonia, adopted a Disclosure Code with transparency reporting obligations ("Code"). With these changes, FBN transparency requirements are now fully aligned with the EFPIA Disclosure Code. FBN recently became an EFPIA member association (November 29th, 2018).

NEW PROVISION(S) OR CHANGE(S)

Scope

The Code requires FBN member companies to disclose their payments and in-kind transfers made to healthcare professionals (HCPs) and healthcare organizations (HCO) on a yearly basis. The first reporting period shall be the 2019 calendar year.

Reportable information

- Name of the recipient
- Categoryof the ToV
- Amount of the ToV

Reportable recipients

- Healthcare professionals (HCPs)
- Healthcare organizations (HCOs)

Reporting format

PDF to be published on the member company's website and/or upload of the information into the FBN central platform.

Reporting frequency and deadline

Disclosure shall be done once a year, by the end of June with reference to the ToVs of the previous year.

First reporting deadline: June 30th, 2020 for the ToVs made in 2019

IMPLICATIONS

Evaluate if you or your local affiliate are currently an FBN member or are planning to become a member in the future.

Start planning internal assessment in order to be ready for collection of data for transparency.

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