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Research Article

Medical Affairs Support of Medical Information Requests during COVID-19 Pandemic

James G[1], Veta O[1], Holly G[1], Brad B[2], Jennifer C[3] and Leonie R[1]*

[1]*Ethicon Medical Affairs Johnson and Johnson, USA*

[2]*DePuy Syntheses, Medical Affairs Johnson and Johnson, USA*

[3]*Cardiovascular Specialty Services, Medical Affairs Johnson and Johnson, USA*

Abstract

Introduction: Medical Affairs teams within Medical Device Companies receive Medical Information Requests (MIR) from Healthcare Professionals (HCP) seeking answers to medical, scientific, or technical information because they cannot be answered based on the individual product's current prescribing information, indications, Instructions for Use (IFU), as cleared or approved by the appropriate competent regulatory authority (e.g., Food and Drug Administration (FDA), Notified Body in the European Union, or other regional governmental authority). In 2018, Johnson & Johnson MedTech launched a Cloud-based platform to harmonize Medical Affairs' global management and processing of MIRs from HCPs, seeking scientific or medical information about our portfolio of products. The aim of this comparative retrospective analysis was to critically examine the 2020 MIR volumes in 2020 *versus* 2019 and assess the impact of COVID-19 on Medical Affairs support of patients and Health Care Providers (HCPs).

Methods: The authors conducted a retrospective analysis of Johnson & Johnson MedTech MIR data, across quarters from January 2019 through the December 2020, to evaluate the potential impact of the COVID-19 pandemic on MIR intake volume and key metrics.

Results: The Total Global (US, EMEA, and ASPAC) year over year analysis of Total Johnson & Johnson MedTech MIR volume totaled, 2018-656*, 2019-1155 and 2020-1153. When stratifying Global year over year analysis of Regional (US, EMEA, and ASPAC) MIR data: US MedTech MIR volume for quarterly periods, including initial COVID-19 pandemic, Q2 2020 resulted in a 48% decrease in MIR volume across US MedTech MIR submissions, compared to Q2 2019. Q3 2020 resulted in a 43% increase in MIR volume across US MedTech MIR submissions, compared to Q3 2019. EMEA MedTech MIR volume for the quarterly periods, including initial COVID-19 pandemic, Q2 2020 resulted in a 23% decrease in MIR volume across EMEA MedTech MIR submissions, compared to Q2 2019. Q3 2020 resulted in a 22% increase in MIR volume across EMEA MedTech MIR submissions, compared to Q3 2019. ASPAC MIR volume for the quarterly periods, including initial COVID-19 pandemic, Q2 2020 resulted in an 11% increase in MIR volume across ASPAC MedTech MIR submissions, compared to Q2 2019. Q3 2020 resulted in a 90% increase in MIR volume across ASPAC MedTech MIR submissions, compared to Q3 2019. Analysis of Quarterly MIR volume by Region (US, EMEA, and ASPAC) compared to Quarterly MIR volume from Prior Year (2019-2020): US Q1-18%, Q2 -48%, Q3+39%, and Q4+7%, EMEA Q1-29%, Q2-30%, Q3+25%, and Q4+15%, and ASPAC Q1-16%, Q2+11%, Q3+90%, and Q4+256%.

Conclusion: Total MIR submissions and responses continued with only small variance from the previous year when compared to annual periods, including the impact from the COVID-19 pandemic (2019 vs. 2020). Across Johnson & Johnson MedTech, Healthcare professionals and the commercial sales teams increased their use of the MIR submission website during the COVID-19 pandemic, while face to face interactions were either prohibited or restricted, due to social distancing guidelines. Despite the COVID-19 pandemic, global customers benefited from the wealth of data and information available from MedTech Medical Affairs, through utilization of our interactive MIR submission website and MIRO digital platform. MIRO allowed for the continuous, timely processing of global MIRs, related to both essential hospital activities as well as elective procedures around the world, while limited face to face interactions were enforced, around the world.

Keywords: Cloud-platform; Medical; Device; Compliant communication; Sales force; Johnson & Johnson MedTech

Introduction

Medical Affairs has long served as a peer-to-peer liaison for our medical professionals with scientific communications supporting Johnson & Johnson MedTech's extensive portfolio of medical products and clinical data. Large international companies have a central department of Medical Affairs which has the task to streamline and coordinate worldwide activities, including one of the most important functions of a Medical Affairs department; providing information on the company's portfolio of products to customers, health care providers, patients, and the public at large [1]. Medical engagement across providers, patients, and across a range of touch points will become increasingly digital, and designed to provide tailored information focused on improving outcomes [2]. The emergence of digital ways of working, expedited by the COVID-19 pandemic, means that healthcare relationships are evolving to operate in an increasingly virtual world [3].

Within Johnson & Johnson MedTech a Medical Information Request (MIR) is an unsolicited inquiry from a Healthcare Professional (HCP) for medical, scientific, or technical information which gets routed to Medical Affairs because it cannot be answered based on the individual product's current prescribing information, indications, Instructions for Use (IFU), as cleared or approved by the appropriate competent regulatory authority (e.g., Food and Drug

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***Corresponding author:** James W Galloway, Ethicon Medical Affairs, Raritan NJ, USA, E-mail: jgallowa@its.jnj.com

Administration (FDA), Notified Body in the European Union, or other regional governmental authority). Unsolicited requests are those initiated by persons or entities that are completely independent of the relevant firm. (This may include many health care professionals, health care organizations, members of the academic community, and value analysis committees, as well as consumers such as patients and caregivers) [4]. Medical Affairs groups are entrusted to provide unbiased, up to date, non-promotional medical and scientific information in response to these MIRs providing HCPs with accurate and reliable knowledge of the products' safe and effective uses.

Distinct from MIRs are adverse events and product complaints. An adverse event is any undesirable or potentially undesirable health consequence associated with the use of a product in or on a patient, whether or not considered product related (e.g., Adverse Events, Medical Device Reportable Events, Medical Device Vigilance, or medical occurrences). A complaint or any product complaint includes any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution. Adverse events and product complaints are handled outside of the MIR process. MIRs are not representative of in market adverse events or product complaints.

Johnson & Johnson MedTech developed and launched MIRO (Medical Information Response) to expedite Medical Affairs' global management and processing of MIRs from Health Care Professionals (HCPs) seeking scientific or medical information about our portfolio of products, as part of a Johnson and Johnson digital transformation initiative, in January of 2018. MIRO was designed on a robust cloud-based software platform, which delivers an efficient and compliant system for all Johnson & Johnson MedTech platforms and products. Multiple MIR submission intake channels were harmonized into one simplified process, using a globally accessible website to accept all requests, which represents an industry first for medical device companies. The MIRO system was built to adhere to regional variations in data collection and data privacy regulations. Following its launch, the cloud-based software platform enhanced the MIR experience for HCPs, providing medical insight and guidance more quickly, while concurrently improving Johnson & Johnson MedTech compliance.

MIRO leverages Johnson & Johnson MedTech global talent base in responding to MIRs, enhancing Medical Affairs' support of global and regional product launches with peer-to-peer product related content, while highlighting relevant and up-to-date clinical evidence. The cross-functional collaboration to develop MIRO resulted in a process which is more efficient with improved compliance; allowing us to better serve our customers with critical data, even during unprecedented times.

During the COVID-19's preliminary lockdowns and restrictions on elective surgical procedures in hospitals, healthcare systems and integrated delivery networks around the world, our Medical Affairs group prepared for disruptions in how we supported our customers, which rely on our group to respond to unsolicited requests for information on our devices and their use. Due to COVID 19quarantine directives, the ability to interact face to face with customers was impacted by social distancing mandates. Commercial sales groups and related groups were not able to physically access hospitals and clinics. However, using our digital platform, MIRs continued to be submitted, including questions related to the COVID-19 Virus, new product launches, and medical device related topics, even while Johnson & Johnson MedTech was limited in its ability to interact in person with external HCPs and customers. Despite the COVID-19 pandemic, global customers benefited from direct access to Medical Affairs subject matter experts that serve patients from within the walls of industry through our globally accessible MIR submission website. While elective procedures were limited, MIRO allowed for continued, timely processing of a large volume of MIRs from HCPs and healthcare systems/integrated delivery networks that were continuing to perform essential surgeries worldwide.

The combination of a cloud based platform with a digitally connected externally facing website has enabled our Johnson & Johnson MedTech Medical Affairs teams to directly support HCP' sin treating their patients, by leveraging technology for improved quality and connectivity. Currently, to our knowledge there are no publications demonstrating how medical device companies adapted during the COVID-19 pandemic, to maintain support of HCP's while elective surgeries were placed on hold and face to face interactions in hospitals were restricted. The aim of the study was to analyze the MIR volume in comparison to prior periods and assessed the impact of COVID-19 on our support of customers.

Methods

This retrospective review of Johnson & Johnson MedTech MIR data includes analysis of MIR data from the January of 2018 through December of 2020, to evaluate the impact of the COVID-19 pandemic on MedTech MIR volume, intake channel utilization, and key COVID-19 related MIR metrics, which inform the use of this process for continued support of our HCPs and customers, during this challenging period.

The baseline MIR data extracted from MIRO for review, included Location of the Request, Product Name, Business Unit, Submission data, Type of Submission channel utilized (website, pdf form, phone, etc.), and the Question, for each platform. Global data was deidentified and only the data related to the MedTech business unit, volume, geographic location, and product were analyzed for this report. Data was collated into a single data source which allowed for the utilization of data visualization tools for categorization of key data points across each Business Unit and device platform.

Statistical Analysis included collecting total global aggregate MIR volumes for each region of MedTech, over the periods from 2018 through 2020. The annual data were further broken down into quarterly volumes for more accurate analysis, during the two year period of 2019-2020. MIR data from 2018 has an asterisk (*), to denote data migration from 2017 into the new system, following the launch of MIRO. Data from 2019 was used as a guide to assess the impact from COVID-19, on the submission of MIRs, compared to the same periods of 2020. Quantitative data were further assessed to generate metrics on MIR volume, including regions around the world to evaluate any region specific COVID-19 related impacts, present in the data.

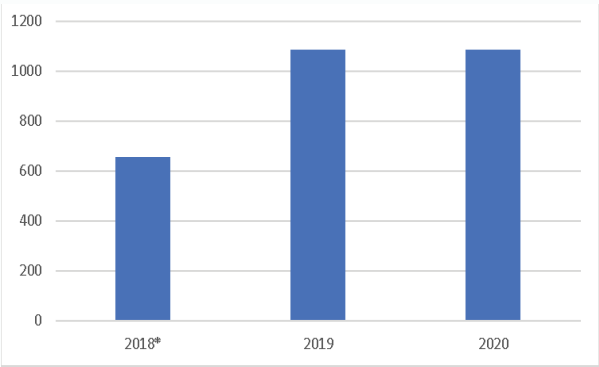
MIR volume data was further analyzed to assess percent increases during annual and quarterly periods (2019-2020). Changes in MIR volumes within these periods were examined and evaluated in the context of the COVID-19 pandemic: including the mandatory closures and timing of halting of elective surgeries. Statistical analysis was performed on selected MIRO data to evaluate the significance of changes in MIR volumes, in comparison to previous periods.

Results

The Total Global (US, EMEA, LATAM, and ASPAC) year over year analysis of Total Johnson & Johnson MedTech MIR volume totaled, 2018*-656, 2019-1155 and 2020-1153. When stratifying Global year over year analysis of Regional (US, EMEA, and ASPAC) MIR data: US MedTech MIR volume for quarterly periods, including initial COVID-19 pandemic, Q2 2020 resulted in a 48% decrease in MIR volume across US MedTech MIR submissions, compared to Q2 2019.Q3 2020 resulted in a 43% increase in MIR volume across US MedTech MIR submissions, compared to Q3 2019. EMEA MedTech MIR volume for the quarterly periods, including initial COVID-19 pandemic, Q2 2020 resulted in a 23% decrease in MIR volume across EMEA MedTech MIR submissions, compared to Q2 2019. Q3 2020 resulted in a 22% increase in MIR volume across EMEA MedTech MIR submissions, compared to Q3 2019. ASPAC MIR volume for the quarterly periods, including initial COVID-19 pandemic, Q2 2020 resulted in an 11% increase in MIR volume across ASPAC MedTech MIR submissions, compared to Q2 2019. Q3 2020 resulted in a 90% increase in MIR volume across ASPAC MedTech MIR submissions, compared to Q3 2019. Analysis of Quarterly MIR volume by Region (US, EMEA, and ASPAC) compared to Quarterly MIR volume from Prior Year (2019-2020): US Q1-18%, Q2-48%, Q3+39%, and Q4+7%, EMEAQ1-29%, Q2-30%, Q3+25%, and Q4+15%, and ASPAC Q1-16%, Q2+11%, Q3+90%, and Q4+256%. Key MIR volume and regional information are summarized in (Table 1) (Graphs 1-6), respectively.

Table 1: Key MIR volume and regional information.

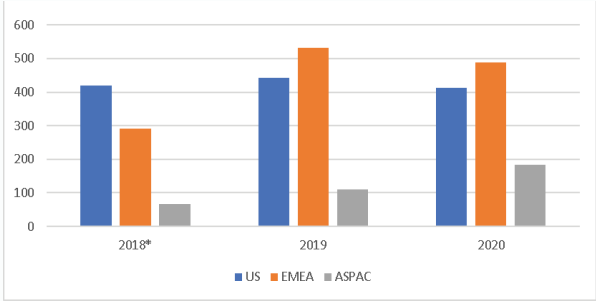
2019-2020								
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
US		-30%	-11%	30%	3%	-56%	139%	0%
EMEA		-5%	-25%	10%	-10%	-6%	33%	1%
ASPAC		44%	-14%	-42%	17%	90%	48%	8%



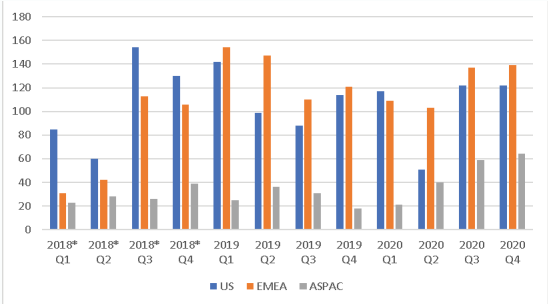
Graph 1: Total year over year MIR volume 2018*-2020.

Conclusion

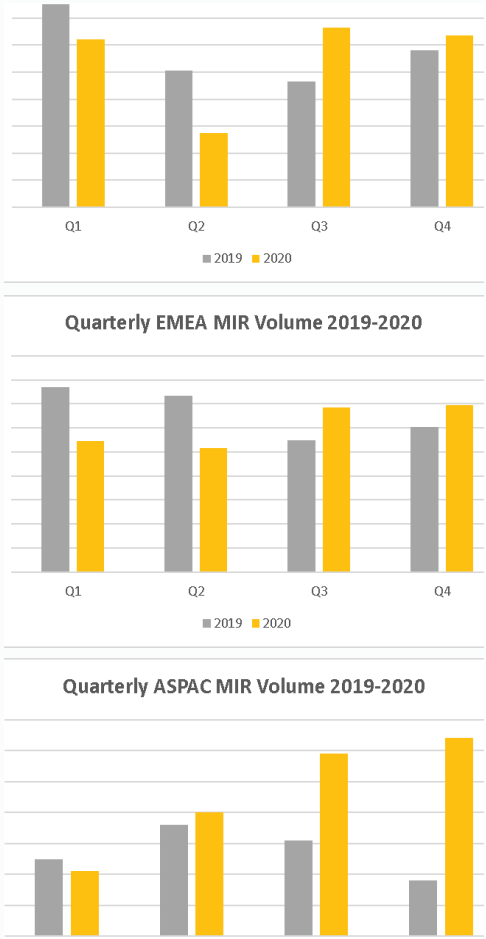
The function of Global Medical Affairs is one of the most important and versatile parts of the organization of a Medical Device company and serves as the ultimate peer to peer interface between the internal departments of a company and the customers, HCPs, authorities, and the public. The development of MIRO was a combined effort across Johnson & Johnson MedTech, demonstrating the synergies between our internal partners, global Medical Affairs teams towards the unified goal of putting patients first. The success in the development of the MIRO platform and its deployment is evident with the global adoption of the MIRO system. MedTech



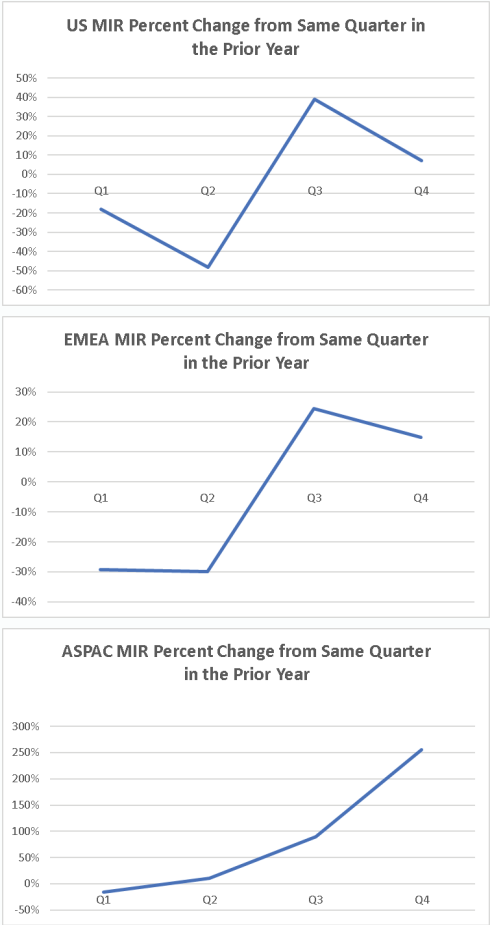
Graph 2: Regional MIR volume 2018*-2020 US, EMEA and ASPAC.



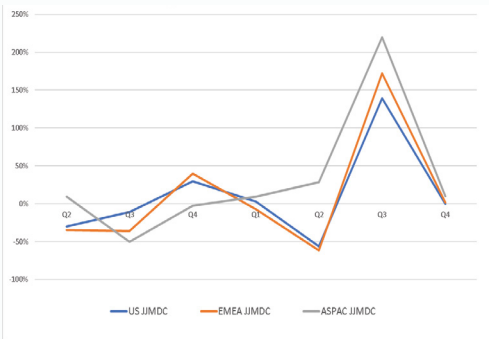
Graph 3: Quarterly MIR volume 2018*-2020 US, EMEA and ASPAC.



Graph 4: US, EMEA, and ASPAC quarterly MIR volumes from year 2019-2020.



Graph 5: MIR percent change from same quarter in the prior year 2019-2020 across regions.



Graph 6: MIR percent change from prior quarter in same year 2019-2020.

companies maintain cross functional collaboration in support of the MIRO platform, with ongoing refinement of the system, through the MedTech MIRO Governance Committee.

Not only is the Medical Affairs function evolving in the way it interacts with HCPs, but it is also creating other channels for digital engagement, expanding the traditional customer base, and defining new digital stakeholders, collaborating with partners who have digital capabilities, in turn transforming the way information and insights are collected and analyzed [3]. Continued adoption of digital tools will eventually replace many face-to-face interactions meaning strong medical and scientific content will become ever more critical for engagement, while collaboration with independent professional education platforms will become the new norm of professional education [2]. The medical leader of the future will need to learn how to work with data scientists who will build and drive medical insights, generate data using advanced digital methodologies, and provide the healthcare community as a whole with impactful medical insights [5].

The US MedTech MIR analysis closely tracks the trends in surgical cases during the beginning of the COVID-19 pandemic, in 2020. Pirracchio et al. [6] observed a nadir in US Surgical case volumes the week of April 6. During the week of April 6, they observed a 71% reduction compared with the same week in 2019. Additionally, between March 16 and May 31, the median per-week reduction in case volume relative to the same weeks in 2019 was 57% (inter-quartile range: 39%-67%) (Figure 1) [6]. According to Pirracchio et al. [6] analysis, an early rapid decrease in US surgical case volumes beginning mid-March 2020 was followed by a similarly rapid increase towards baseline beginning by mid-April while the pandemic was active, and the numbers of COVID-19 cases were rising quickly. During the periods analyzed by Pirracchio et al. [6], Johnson & Johnson MedTech observed a drop in MIR submissions, of approximately 56% in the US. Thus, indicating a correlation between the surgical activity of our customers and the submission of MIRs. Similarly to the Pirracchio et al. [6] analysis, we also noted a, "Rapid increase" in our MIR volume (139%) while the pandemic was active and COVID-19 cases were rising, through Q3 (Figure 2). This relationship between US weekly surgical case volume and Johnson & Johnson MedTech US MIR submission volume highlights an important role Medical Affairs plays in supporting surgical cases, across the US, even during the COVID-19 pandemic while many elective cases were postponed.

There are several potential limitations of this study. MIR data contained in the Johnson & Johnson MedTech MIRO system reflects MIRs that were successfully submitted into our system, limiting our MIR volume only to HCPs that were aware of how to submit an MIR through our digital channel. Earlier data sets for volume analysis are limited due to the system launch data in January 2018. Thus, data analyzed over this two year period is limited and could reflect quarterly anomalies that were not related to the global shut down related to the COVID-19 pandemic. Additionally, there could have been an increase in MIR volume with queries related to COVID-19, which disproportionally skewed our MIR intake volume higher than would have been observed without the Global shutdown related to a highly communicable virus.

MIR submissions, on an annual basis, were continued with low variance from the previous year, during the COVID-19 pandemic, when looking at total MIR volumes from 2019 through 2020. Johnson & Johnson MedTech MIR volumes reflect Medical Affairs preparedness to provide medical and scientific support and scientific engagement, related to essential surgeries and the support of the limited critical elective procedures, throughout the COVID-19 pandemic. Undoubtedly, healthcare providers, customers, hospitals, and integrated delivery networks increased use of MIR submission during the COVID-19 pandemic, as a direct and proximate result of limited face to face interactions were because of social distancing guidelines. Leverage of technological innovations to connect with external HCPs, such as use of QR code (Figure 3) for increased accessibility of the MIR website, proved to be valuable in connecting with our customers. Despite the COVID-19 pandemic, global customers benefited from the peer-to-peer engagement and the provision of relevant medical

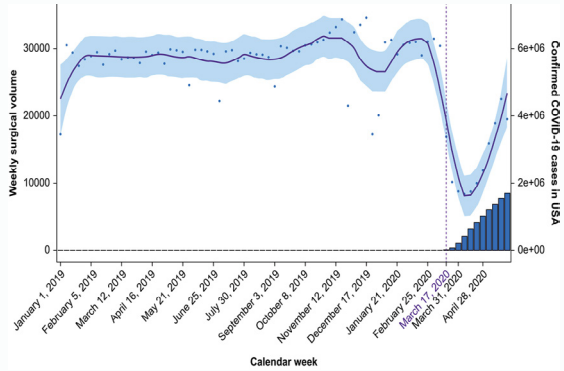


Figure 1: Weekly surgical volume at 33 US hospitals and cumulative number of COVID-19 cases in the USA from January 1, 2019 to May 31, 2020.

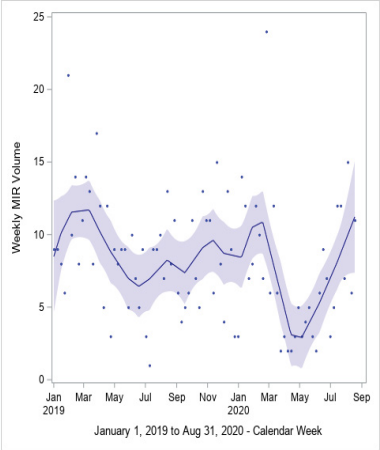


Figure 2: MIR volume Johnson & Johnson MedTechin the USA from January 1, 2019 to September 31, 2020.

Figure 3: Medical Information Request QR Code.

and scientific information through our MIR website and MIRO cloud platform. In the end, MIRO allowed for the continued, timely processing of an increasing volume of MIRs, even as there was limited activity in hospital systems, worldwide.

References

1. Nell GKH. Medical affairs. Pharmaceutical medicine and translational clinical research. 2018:393-9.
2. Evers M, Ghatak A, Holt E, Ostojic I, Pradel C, Suresh B, et al. A vision for medical affairs in 2025. Insights into Pharmaceuticals and medical Products. 2019.
3. Bedenkov A, Moreno C, Agustin L, Jain N, Newman A, Feng L, et al. Customer centricity in medical affairs needs human-centric artificial intelligence. Pharmaceut Med. 2021;35(1):21-9.
4. FDA guidance document on responding to unsolicited requests for off-label information about prescription drugs and medical devices. Food and Drug Administration. 2021.
5. Bedenkov A, Rajadhyaksha V, Beekman M, Moreno C, Fong P, Agustin L, et al. Developing medical affairs leaders who create the future. Pharmaceut Med. 2020;34(5):301-7.
6. Pirracchio R, Mavrothalassitis O, Mathis M, Kheterpal S, Legrand M. Response of US hospitals to elective surgical cases in the COVID-19 pandemic. Br J Anesth. 2021;126(1):e46-e48.