

BENCHMARK STUDY ON MEDICAL AFFAIRS IN THE CANADIAN PHARMACEUTICAL INDUSTRY

October
2019



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CONTENTS

Foreword from LegitiMed Inc.	3
Online Survey Results.....	4
Roundtable Discussion Output by Focused Communications Inc.	11
Introduction	11
Current Trends in Medical Affairs	11
Pain Points.....	12
Future State (Aspirations/Recommendations)	15
The Insider View by Medius International Inc.	17
The evolving role of Medical Affairs in Canada's Pharma Industry	17
Introduction	17
Methodology	19
Foundation Perceptions	20
Major Themes & Key Issues	22
Gap Analysis	26
Summary & Conclusions	27
Afterword from LegitiMed Inc.	28

FOREWORD FROM LEGITIMED INC.

As Canadian Pharma transitions largely from a general practice focus to a specialty focus with increasingly complex product offerings, key stakeholder demands are rising. So too is medical data, including real-world evidence (RWE) and its untapped insights for corporate positioning/strategy. As such, **Medical Affairs (MA)** is emerging as a critical function of Pharma. In order to ensure sustainability of this vital corporate function, an awareness of the current state, pain points and aspirational/future state for Medical Affairs would benefit the industry. To this end, the Council for Continuing Pharmaceutical Education (**CCPE**) commissioned Legitimed Inc. to conduct an independent, benchmark study in Medical Affairs as part of the **BenchSmart Series** (www.benchsmart.ca).

Medical Affairs personnel from across Canadian Pharma were invited to participate in a triangulated research methodology including an Online survey, RoundTable discussion and Key informant (1:1) interviews. A wide cross-section of both positions and companies were represented. The response rate to the survey was 54% (7/13). In addition, a RoundTable discussion facilitated by Focused Communications was held with 4 participants. As well, seven (7) MA professionals participated in Psychmentation™ interviews, a proprietary, key-informant interview method conducted by Medius International. Each method of this study is identified and results reviewed within this report.

There was congruence between feedback received from each of the three methods with, of course, group dynamics eliciting deeper, richer insights via face-to-face interactions. This study identified common challenges & potential solutions that serve the MA mandate within industry & improved outcomes for the patients served. I hope you find this study helpful in your understanding of Medical Affairs in Canadian Pharma.



Paul Abbass
Principal,
LEGITIMED INC.

ONLINE SURVEY RESULTS

Thirteen (13) MA professionals were emailed a link to an online survey, of which 7 (54%) participated. The results are described below in italics.

- 1) What is your role and job function(s)? How is Medical Affairs aligned in your corporate structure? Do you anticipate an increase in the number of employees and/or budget next year?

The roles held by respondents were varied with most describing their MA department as reporting directly to the CEO/General Manager in Canada. Most declined to answer the final portion of this question while one described an increase and another flat/no growth.

- 2) Over the last decade, which of the following roles within Medical Affairs has seen the most evolution? Rank where 1 has seen the most.

The role identified as having seen the most evolution over the last decade was "Providing strategic and tactical leadership in product success" followed closely by "Assisting with routine regulatory requirements", "Pharmacovigilance" and "Medical Information".

- 3) Have Canadian regulations and compliance rules effected the way in which Canadian Medical Affairs interacts with the IMC Code, The PAAB and/or CME Accreditation rules? If so, have any of these regulations and compliance rules altered your interactions with internal and/or external stakeholders? Explain.

Half of the respondents cited no effect on how MA interacts with HCPs while the other half identified a few regulatory changes that have had profound effects on how MA conducts itself. Namely, Sunshine/sponsorship rules; IMC rules on Adboard attendees (no Sales personnel), CFPC accreditation & National Standards (the need to work with 3rd party physician groups), have significantly changed the way MA works with HCPs.

- 4) How have, and how will, US compliance rules and restrictions on commercial interactions with healthcare professionals effect the Canadian Medical Affairs landscape?

Many felt that they were unable to comment on this question, while some stated that changes would be reflected in Global SOPs and therefore compliance across the world would mean that Canada would be aligned. Some stated that the challenge is greater when dealing with HCPs attending US conferences.

- 5) Can Medical Affairs provide solutions to the ever-increasing price pressure on new drugs and the need to demonstrate value? If so, what skills do Medical Affairs professionals need to develop in order to effectively contribute to success in this area?

Many see the role of MA as essential in the price discussions, specifically, a) the work done to “generate data [including real word evidence (RWE)] on functional patient outcomes that support the value of new drugs” and b) to drive “dissemination of this information so it receives the scrutiny and feedback from external stakeholders required to advise future strategies.” The skills needed were identified as follows: i) business acumen; ii) understanding both the Practice and business of medicine & iii) articulating the interconnectedness of the entire healthcare system; iv) translating HEOR study design and evidence into real-world implications.

6) Which of the following would assist Medical Affairs to demonstrate value to INTERNAL stakeholders ? Rank where 1 is most important.

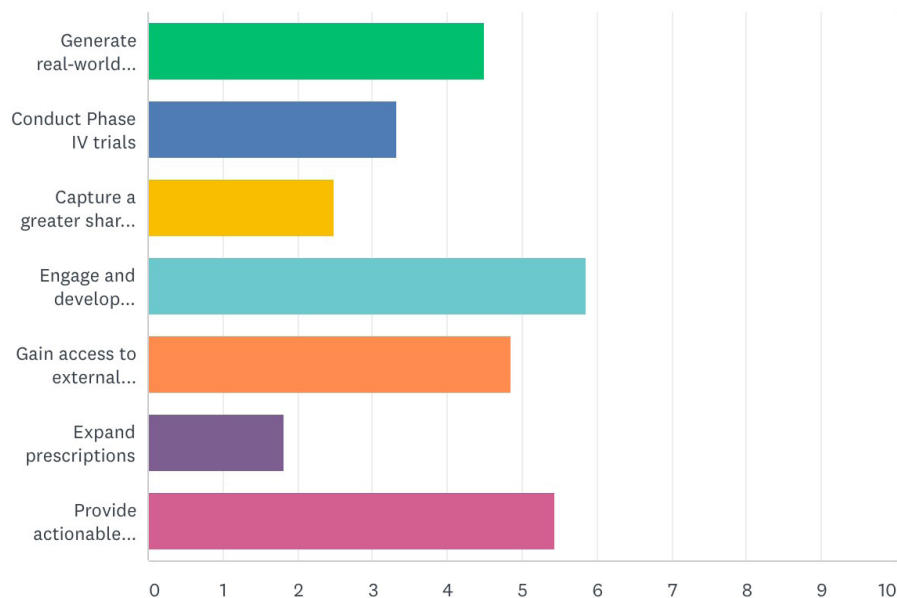
The following were identified in order of importance: i) Engage and develop external experts (KOLs); ii) Provide actionable clinical insights to commercial teams; iii) Gain access to external experts and institutions that limit access to sales reps; iv) Generate real-world evidence; v) conduct Phase IV trials; v) Capture a greater share of voice and vi) Expand prescriptions.

Q6



Which of the following would assist Medical Affairs to demonstrate value to INTERNAL stakeholders? Rank where 1 is most important.

Answered: 7 Skipped: 0



7) Which of the following would assist Medical Affairs to demonstrate value to EXTERNAL stakeholders ? Rank where 1 is most important.

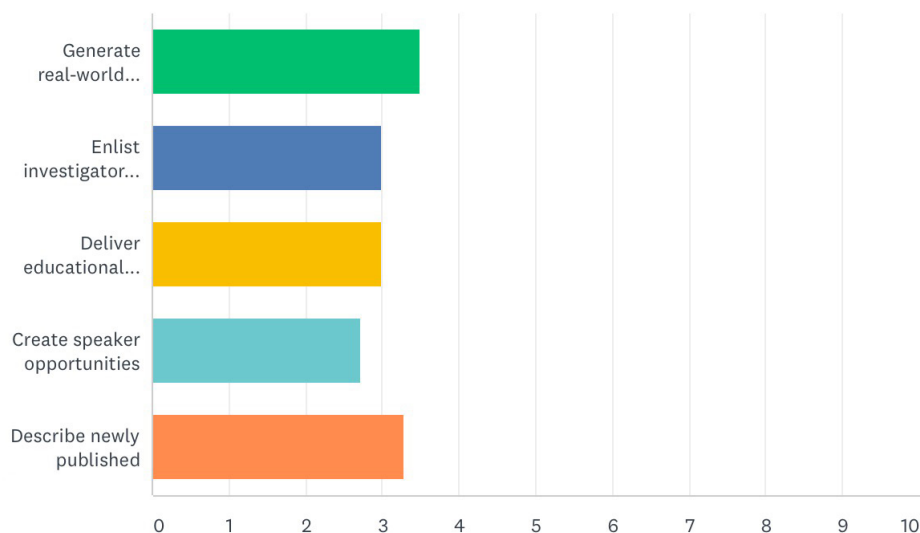
The following were identified in order of importance: i) Generate RWE; ii) Describe newly published data; iii) Enlist investigators in Phase IV trials; iv) Deliver educational programs and v) Create speaker opportunities.

Q7



Which of the following would assist Medical Affairs to demonstrate value to EXTERNAL stakeholders? Rank where 1 is most important.

Answered: 7 Skipped: 0



- 8) Given that the role of Medical Affairs is so highly integrated within the business, what industry-specific knowledge and skills do entry-level Medical Affairs professionals need to acquire quickly and early in their careers? Rate where 1 is most important.

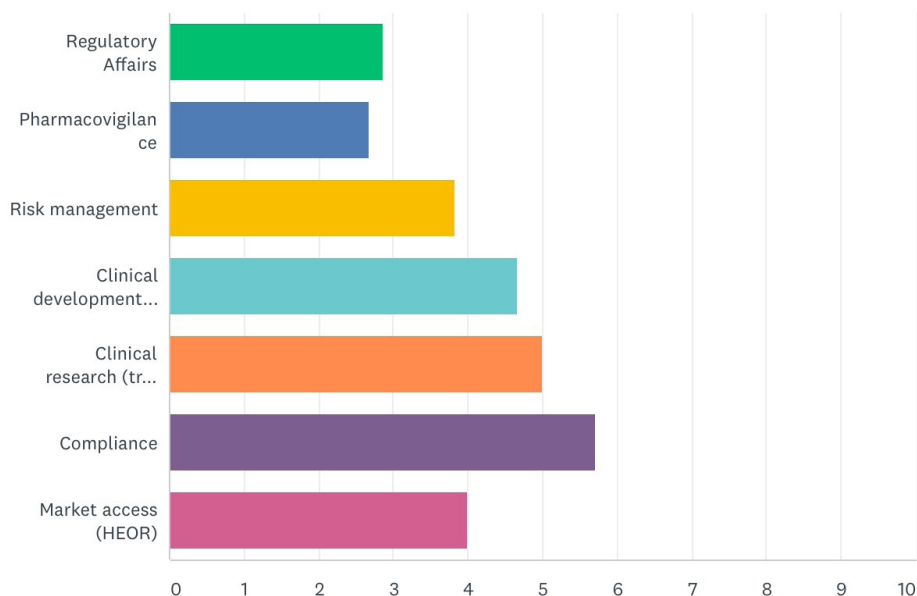
Participants identified the following in order of importance: i) Compliance; ii) Clinical Research (trial conduct); iii) Clinical Development (Phase I-III trials); iv) Market Access (HEOR) v) Risk Management; vi) Regulatory Affairs and vii) Pharmacovigilance.

Q8



Given that the role of Medical Affairs is so highly integrated within the business, what industry-specific knowledge and skills do entry-level Medical Affairs professionals need to acquire quickly and early in their careers? Rate where 1 is most important.

Answered: 7 Skipped: 0



- 9) What knowledge would more experienced Medical Affairs professionals need to continue to develop?

Respondents stated that all skills listed must be continuously developed/improved. Some identified specific skills requiring constant attention, notably Market Access (HEOR) and Risk Management. In addition to those skills listed, participants recommended the following for continuous improvement:

HARD skills such as i) business strategy; ii) statistics & data analysis; iii) clinical trial design

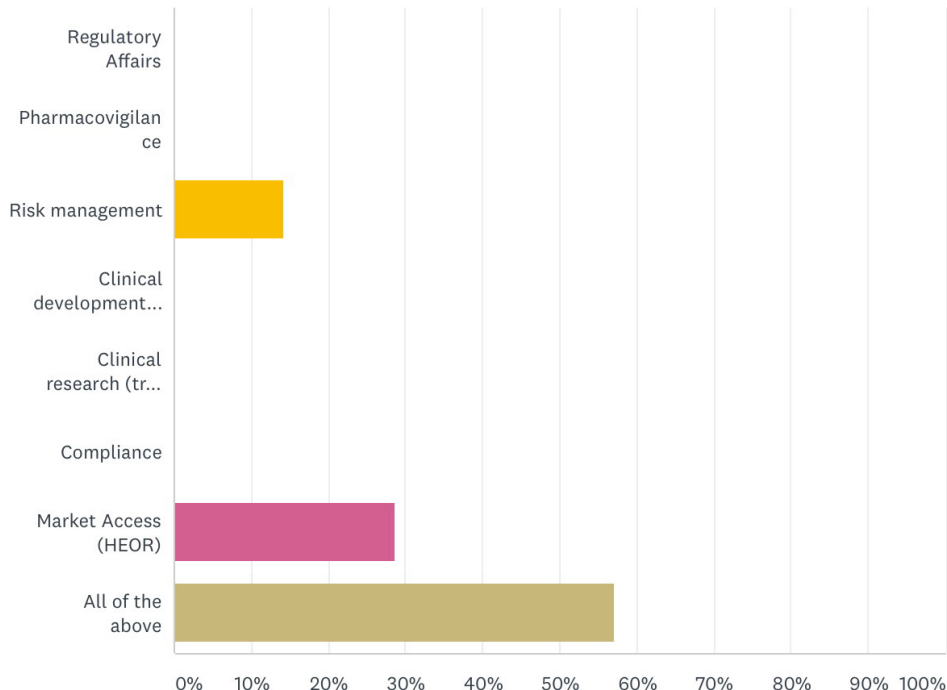
SOFT skills such as a) influence; b) negotiation; c) facilitation; d) leadership; e) coaching & mentoring.

Q9



What knowledge would more experienced Medical Affairs professionals need to continue to develop?

Answered: 7 Skipped: 0



- 10) What do you envision as the future state (3-5 years) of Medical Affairs in Canadian Pharma? What barriers could you identify to reaching that further state?

The following were cited as the most important to the future success of Medical Affairs: Capabilities in the area of Patient Access; Evidence generation; Value-based healthcare; Efficacy and Safety data from RWE, Registries etc.

Threat or barrier: Health Canada and CADTH merging; low investment in soft-skills training; Declining access to HCPs; barriers to collaborative research within academic centres; "limited reach & frequency as there is little appetite to increase resources accordingly."

Predicting an Increasing reliance on Medical Affairs and less on Commercial teams over time. Expect to see "the role of MA to increase with an influx of new medicines for new indications. Further, 'me-too' products need to be supported more by commercial and new innovations require a strong MA team to help create and shape the landscape quickly and could be crucial to clinical and commercial success." More demand for generating and educating physicians and payors on RWE throughout the drug lifecycle.



ROUNDTABLE DISCUSSION OUTPUT BY FOCUSED COMMUNICATIONS INC.

INTRODUCTION

Key insights were gathered from Medical Affairs (MA) personnel in Canadian Pharma representing a wide spectrum of industry including a variety of roles within the discipline. The insights were gathered using three formats (triangulated); 1) survey, 2) key informant interviews (KII) and 3) facilitated roundtable discussions. The overall goal of the study was to assess the current state of Medical Affairs (what they do, know and believe), gain perceptions of changes in the future (vision and impact) and identify obstacles or pain points that impact effectiveness. This section provides output from the RoundTable discussion portion of the study.

CURRENT TRENDS IN MEDICAL AFFAIRS

During the facilitated discussion, Medical affairs personnel were asked about trends they have observed, their roles within the department, their knowledge and skills required to make them most effective and the needs they can identify as they look to the future state of MA.

The participants were fairly homogeneous in their responses. They described the Medical Affairs Department as the leaders in medical, scientific and pipeline knowledge for the organization with a composition of medical advisors, medical science managers and medical science liaisons. Some indicated that the Continuing Health Education (CHE) function is now part of the department structure.

The responsibilities of the department that were cited include:

- New product to market
- Speaker development
- Thought-leader development
- Clinical trial support
- Scientific exchange
- Market Access Support (increasing trend)
- Internal support for sales meetings or training on products/therapeutic areas
- Insights gathering
- Pipeline expertise
- Thought leaders in medical information

It is interesting to note that MA personnel reported that the average time during meetings with thought leaders was 45 minutes to one 1 hour. They all remarked that this was substantial, especially given declining access and time availability for other functions including Sales.

PAIN POINTS

All participants identified that misperceptions and misunderstandings about the role of Medical Affairs and its employees was a common angst. That is, if the company Leadership is from a commercial background, the perception is that there is less understanding or focus of importance on the MA department. Alternatively, if the leadership is from medical, there is a greater understanding of the scope of the role and its value. Perceived value of the department and the role of the MSL varies. Most agreed that external stakeholders would describe the role of MA in very different ways compared to internal and would place a much higher value on the interaction. Part of the challenge expressed by MA personnel is that the commercial side of the business measures impact by revenue generated (\$) compared to MA which does not. There was a shared perception amongst participants that other departments do not understand the importance of Medical Affairs and consequentially MA frequently has to justify and re-justify itself. All felt that when other departments see the MSL in action or observe their impact with KOLs at medical meetings, their minds are quickly changed (this is important to note if the reader of this report is interested in providing an educational intervention that helps increase internal stakeholder value).

Other challenges include:

- Increasing role (due to external factors) but not increasing budget accordingly
- Culture and especially changes in company leadership
- Top down approach in leadership
- Battle to win internal support (selling MA's role and capabilities internally)
- Compliance becoming a bigger challenge – internal stakeholders unaware of roadblocks
- Products have greater complexity and breadth of treatment
- Reimbursement getting more challenging

Perceived training needs were discussed in relation to existing roles and vision of future change and demands. As such, the following training categories and needs were identified with some being addressed currently while others requiring further development:

Scientific and Company:

- Company structure and systems
- Product and disease/therapeutic area knowledge
- How to read a clinical paper
- Know the criteria for clinical trials
- Study Design
- Change management
- Pre-call planning
- Strategy to access KOLs
- Basics of internal systems
- Communication skills – general skills regarding what to communicate
- Scientific development
- MA pipelines
- Business planning responsiveness
- KOL mapping
- Drug development
- Logistics
- Organizational structure
- Statistics

Soft skills:

- Emotional intelligence was stated as a training need including connecting and facilitating trust and adapting to audience(s) for optimal engagement
- Effective story-telling
- Assessing needs
- Contextualizing communication to appropriate audience (example: what does Market Access need vs other departments)
- Optimize relationship and be likeable
- Service-oriented
- Responsive and timely in relation to follow-up
- Coaching
- Leadership
- Presentation and audience engagement skills
- How to sell internally – ensure others know what MA function/role is and its impact

Other training needs:

- Business Acumen: Scope and context of how departments are all connected within the overall company vision and strategy
- Market Access process and needs of/from internal & external stakeholders
- How to measure the impact of MSLs (metrics/ROI)
- Commercial functions excluding sales (perhaps included in Business Acumen)
- Foundation skills certification (how to convey and receive information)
- Certification as basic entry criteria for MA positions
- Improve knowledge in Health Economics, Market Access & Regulatory
- Etiquette training
- How to sell your 'why' to internal & external stakeholders

FUTURE STATE (ASPIRATIONS/ RECOMMENDATIONS)

Participants were asked to provide feedback on their vision of the future as it relates to factors that may impact their role, how it will impact them and what needs they will have in which to become most effective. The results are as follows:

- Big Data strategies including critical paths & publication strategies
- Real World Data (RWD) – knowing the right criteria & aligning on Global meaning
- Payors' info – understanding the deeper context as to what payors need
- Perfect/refine the stories – foundational communication skills
- Manage constant change in submissions and regulatory
- Reimbursement strategies increasing in importance
- Patient Support Group engagement – risk because groups are under Commercial
- Market Access requires more and more support from MA
- Patient Advocacy groups – Highly-informed patient advocates are driving change
- Gathering insights (Therapeutic Area, Brand(s) and Competition)
- Measuring impact/value of MSL – no real, consistent measure
- Artificial Intelligence and its impact on Medical Sciences
- Social Media Listening – How to interpret and integrate insights
- Internet use – increasing
- Patient journey mapping – Real-world impact
- ALL co-morbidities (patient health)
- Personalized medicine – Understand and interpret impact
- Complexity of diseases/indications – rare disease, tumours etc.
- MSL/Medical Advisor hybrid role – trending and problematic due to scale/scope
- Transparency on KOL engagement – Negative impact on access & collaboration?
- Patients – Overall, patients are becoming more and more educated
- Change Management – Adaptability will be an important skill set
- Industry perception – Pharma collaboration discouraged in most Medical schools (Trust?)

MA personnel identified two stages for MSLs: 1) Under 2 years and requiring on-boarding and education related to policies and procedures & 2) More than 2 years of experience where proficiency is optimized but career advancement expectations require greater and nuanced management. Stage 2 MSLs are looking for promotion and there are limited options. Millennials, particularly, are seen as more impulsive, having unrealistic expectations for their careers.

Participants identified MA as having critical value to the business and this is being born out in the growing trend for more MSLs in the Field. There is concern, however, that such advancement will place greater pressure on MD time.

The drug approval process in Canada is being seen as more and more strict with frequent criteria changes and there is a need for MA to collaborate more with Access and other internal groups to be responsive to change. Another challenge cited by participants were the new rules restricting/forbidding interaction between Guideline Committee Members and industry personnel for a protracted period of time post-guideline publication.

All participants see great merit in ongoing industry forums and summits for Medical Affairs' personnel to share common challenges and collaborate on solutions for the common good.



THE INSIDER VIEW BY MEDIUS INTERNATIONAL INC.

THE EVOLVING ROLE OF MEDICAL AFFAIRS IN CANADA'S PHARMA INDUSTRY

INTRODUCTION

A number of published reports have highlighted the growing role of Medical Affairs in helping healthcare providers (HCPs) navigate the new data-driven, patient-centric, evidence-based information landscape. HCPs are not the only stakeholders in this effort. Effectively communicating data and scientific insights to the growing array of parties involved in the purchasing decision “scaffold” is a major challenge for Pharma companies. This is made more complex by the shifting communication channels enabled by digital technology. And as a result of Pharma’s ongoing commitment to balanced scientific communication free of commercial objectives, sales representatives, traditionally relied upon to communicate new information, play a diminishing role in this regard. This gap requires a Medical Affairs function with strong scientific credentials, outstanding communication skills and the facility to operate cross-functionally both within Pharma companies and across external stakeholder groups.

“The most competitive Pharma companies in the coming decade ... will generate and analyze vast volumes of real-world data and excel at communicating scientific evidence. Above all, they will help physicians navigate in a far more complex healthcare universe”¹

¹ Plantevin, L., Schlegel, C., and Gordian, M. (2017). Reinventing the Role of Medical Affairs. Bain & Company. Retrieved June 10, 2019 from: <https://www.bain.com/insights/reinventing-the-role-of-medical-affair>

The present study looks at the evolution of Medical Affairs from two perspectives:

1. The focus is on the Canadian Pharmaceutical industry
2. It taps directly into the perceptions, beliefs, attitudes, and challenges faced by senior Medical Affairs managers tasked with the responsibility of meeting the challenges of a shifting external and internal scientific information landscape.

Objectives for the study included answering the following questions:

1. How is Medical Affairs (MA) changing with respect to its focus, activities, and expectations from various internal and external stakeholders?
2. What is the level of recognition within Pharma companies of the critical role and growing importance of MA? Have the resources followed suit?
3. How is the Pharma industry itself changing in ways that are impacting MA?
4. What are some of the major initiatives being taken to become better prepared for this evolution?
5. What are the challenges in navigating the channel between Science and Commercial?
6. What are the qualifications valued in a Medical Scientific Liaison (MSL)? How are MSLs trained? What value would a standardized MSL training program and third-party certification bring to the industry at large?
7. What needs to happen to become better prepared not to just meet, but to anticipate change, i.e., to get ahead of the curve? What latitude is available (local vs. Global)?

This section of the report is organized in six parts:

- Introduction
- Methodology
- Foundation Perceptions
- Major Themes & Key Issues
- Gap Analysis
- Summary & Conclusions

METHODOLOGY

PSYCHMENTATION™

The methodology consisted of confidential face-to-face interviews (either in person or via telecom) using the proprietary Psychmentation™ process developed by Medius International Inc. (MII) and validated over more than 200 global studies since 1994. Psychmentation™ focuses on creating an environment of trust and candor, so that participants may respond freely and openly. Questions are open-ended and designed to enable participants to address topics relevant to them rather than pursuing preconceived directions of inquiry.

Psychmentation™ is based on two well-established approaches to understanding phenomena: Grounded Theory and Motivational Interviewing. In Grounded Theory, understanding is built from the “ground up” rather than from preconceived theories. Motivational Interviewing focuses on the respondent as the primary resource for information and insight. Psychmentation™ adds proprietary advanced analytics to participants’ inputs in order to build a theory of how a phenomenon operates and to quantify the significance of various themes and issues.

Finally, the results represent participants’ *perceptions* of reality, recognizing that people will act on the basis of their beliefs rather than on strictly objective parameters.

DEMOGRAPHICS

A total of 7 senior Medical Affairs managers from major Canadian “branded” Pharma companies were interviewed. Companies were distributed between Ontario or Quebec headquarters. There were no segmentable differences on the basis of location. Interviews ranged from 45 minutes to one hour. They were all interviewed in real-time, face-to-face via videoconference.

RELIABILITY

Given the relatively small sample size, it was essential to report on themes and issues that had a high degree of consistency across the respondents. **As a result, this report presents only those outputs that had an 86% consistency level, i.e., they were mentioned as significant by at least 86% of participants.**

FOUNDATION PERCEPTIONS

Foundation perceptions are beliefs that are so strongly held that they form the “filter” through which people view a subject, experience or behaviour. Depending on the topic, foundation perceptions may or may not be present. In the case of Medical Affairs, there were two very significant foundation perceptions:

A CONSISTENT DISCIPLINE

Despite some internal variations in reporting structure from one company to another, participants saw Medical Affairs as a homogeneous and transferable discipline. While the demands on MA continue to evolve in parallel with changes in healthcare, MA already has an established set of qualifications, standards, activities, and responsibilities. Participants believed that any MA position could easily transition across different Pharma companies.

MA was consistently described as **the key liaison between internal and external stakeholders on the latest medical/scientific developments**. This was seen as a two-way street. For example, MA not only informs HCPs on new findings, it also informs Market Access on HCP priorities and decision drivers in order to better position new drugs. MA similarly provides feedback and insights to the marketing and sales organizations on how HCPs view new drugs. This feedback also informs the development of commercial literature, and so forth with a host of other internal activities. To quote one participant:

“Medical Affairs is the lynchpin that connects everything in Pharma”

This view of MA as a homogeneous and mature discipline has important implications for the selection, training, and career development of MA professionals. Historically, MA was seen as a potential advancement step for successful sales representatives. Study participants emphasized that this door, while still open for properly credentialed individuals, was increasingly being outsourced to a new generation of MA professionals. This topic is discussed in greater detail in the Major Themes and Key Issues section of this report.

THE COMMERCIAL CONUNDRUM

Pharma sales forces are increasingly constrained in the scope and content of their medical and scientific communication with HCPs. The information that they can communicate is tightly regulated and limited to monograph information, official updates of conference results, formulary changes, etc. This is the result of an ongoing commitment from Pharma to improve perception of its commercial influence on HCPs. With regulatory (PAAB) and Compliance restrictions, sales forces find themselves shifting their value proposition, at least in part, to an “agency” role, i.e., facilitating HCP access to programs and services offered by their companies.

Ironically, these restrictions come at a time when the volume of scientific information available through a host of sources, challenges HCPs to obtain accurate and balanced scientific information in a timely manner. This presents an excellent opportunity for Medical Affairs to fill the information gap with credible, balanced, honest information and discourse.

Sales forces increasingly and justifiably bring MA into the picture when discussions move beyond their limitations. Participants in this study expressed concern that Medical Affairs could be perceived by HCPs as part of the commercial process. They believed that the temptation to use MA for commercial support could prove irresistible, blurring the lines between business and scientific roles and ultimately undermining their credibility and effectiveness. To quote one participant:

“I’m already being asked to align my discussion with HCPs with topics that support the timing of commercial activities. This is a slippery slope”

MAJOR THEMES & KEY ISSUES

RECOGNITION & SUPPORT

Participants believed that there was strong recognition of the critical role of Medical Affairs from senior Leadership and Management within their respective organizations. This wasn't necessarily the case from all departments and levels, where education around MA's role was an ongoing process. Nevertheless, participants acknowledged that funding support was adequate, insofar as a financial case could be made for the resources.

METRICS

In our new data-driven world, metrics have become ubiquitous across industries, functions, and professions. Medical Affairs is no exception, and participants talked about the growing demand for metrics related to their day-to-day activities. These were seen as increasingly burdensome. More importantly, they reflected two trends. First, the need to justify investment with measurable outcomes. And, secondly, the need to ensure that MA was focusing its efforts and time on customer-facing activities. While customer centricity is a generally positive initiative, participants worried that it also reflected a tendency to put MA in a more influential role with respect to HCPs. This emphasis played into their concerns about navigating the channel between commercial and scientific roles.

NAVIGATING THE CHANNEL

Navigating the channel between commercial and scientific roles was the predominant concern for a majority of participants. Most spoke of the pressure to support the sales force. They worried that there would be a blurring of perceived roles among HCPs. This concern is not unfounded. In five recent private client studies using Psychmentation™ to hone in on key HCP value drivers in various specialties, MII found that both Sales Representatives and Medical Affairs Liaisons were increasingly perceived as part of Pharma companies' commercial efforts.

LIFE-CYCLE MANAGEMENT

Study participants believed that relying on Medical Affairs and MSL's for too long after a product launch ran a serious risk of compromising HCP's perception of MA's scientific integrity. With the exception of intervening medical/scientific developments, participants believed that six months to a maximum of one year post-launch was an appropriate timeframe for MA involvement. By that time, a new drug's characteristics should already have been integrated into the product monograph. They believed that using MA to support sales narratives was not a well-conceived use of MA resources. To quote one participant:

"Medical Affairs should be about 'Science unbranded' "

REACTIVE VS. ACTIVE APPROACH

Medical Affairs participants described two modes of their activity with HCPs:

1. **Reactive.** Product issues emerge and require information not on the monograph. MA is brought in (usually by Sales) to clarify or expand on product-specific medical/scientific questions.
2. **Active.** MA reaches out to HCPs with new information related to products or therapeutic areas, for feedback and discussion. HCPs are asked to give permission or "opt-in" prior to unsolicited contact by MA.

For most participants, the Active role required an even more judicious approach in order to avoid perceptions of commercial interest. They believed that the information brought to HCPs with this approach needed to be significant, objective, balanced, non-partisan and meaningful to their practices.

COMPETENCY MANAGEMENT / SELECTION VS CERTIFICATION

Medical Affairs was historically part of a career development path for successful sales representatives with a scientific background. As the role of Medical Affairs became ascendant in the overall company value proposition to HCPs, scientific credibility became a priority. In the absence of national or international external certification, companies began to focus on medical/scientific credentials as a substitute for certification.

Over the years, the credentials profile for MA has evolved. Today, there is a preference for advanced degrees with clinical backgrounds such as Pharmacy, Nursing, MDs (mainly in the US) and foreign-trained MDs. These are believed to have a better potential for effective interpersonal skills as a result of their clinical experience. PhDs in scientifically related disciplines, while more readily available, may not have an affinity for the interpersonal skills needed to interact successfully with HCPs.

In order of preference, the credentials preference in Canada is:

1. Doctorate in Pharmacy or Pharmacology
2. MSc in related clinical specialty
3. MD (foreign-trained)
4. PhD in related scientific specialty

On the subject of external professional certification, participants did not believe that this was necessary or of value for *existing* Medical Affairs staff. They believed that medical/scientific credentials, with their inherent credibility, would supersede any external certification in the minds of HCPs.

They did however believe, that external training and certification would be of great value as a *precursor* to hiring, by narrowing the field of candidates. Participants recommended offering Medical Affairs training and certification to those interested in developing the competencies necessary for a future career in MA.

By far the biggest skills gaps, according to participants, were in interpersonal, negotiation, and effective presentation skills. To quote one participant:

"In the hiring process, we now take scientific background as a given, and we screen and select on the basis of interpersonal skills"

GLOBAL AND LOCAL

The view of MA as a consistent discipline has important implications for training. While there isn't a standardized training and certification program, participants believed that most companies had managed to assemble a mixture of global and local, internally and externally sourced training that was nevertheless consistent across organizations. While the "mix" varied from company to company, participants believed that the end-result was the same; well-trained, technically competent Medical Affairs professionals.

This perception was derived from their interactions with professional colleagues at industry MA associations or from their experiences with former employers.

SKILLS TRAINING

Local training initiatives were important in developing skills that varied based on local culture. By far, the most frequently mentioned skill gaps in Medical Affairs were interpersonal, presentation, negotiation, convincing, needs assessment, and other communication skills. Even when selecting for these at the recruitment and hiring stages, there were still significant gaps in all the organizations represented by the study participants.

These gaps were exacerbated by the increasing HCP "face time" required of MA representatives. Some companies encouraged MA staff to attend training on these skills developed for the sales organization. There was some discomfort among participants at this approach because they felt that it risked "commercializing" MA. They believed that there was a need for MA-specific training in these skill areas.

GAP ANALYSIS

The following chart summarizes participants' perceived gaps in alignment of the Major Themes and Key Issues discussed above:

Aligned	Not aligned
Leadership support & funding	Metrics overload
HCP Focus	Commercial pressure
Science "Unbranded"	Compromised independence & credibility
Ethics and scientific independence	Certification for existing MA staff
Compliance	Technical training
"Soft skills" training	"Sales" training of soft-skills
Certification for prospective MA candidates	

RECOMMENDATIONS

The following recommendations emerged directly from participants:

- Fund appropriately, even without ROI, as part of risk management
- Ensure scientific independence to preserve credibility and avoid confounding with commercial objectives
- Limit MA presence post-launch to reasonable timeframe (6 mo. – 1 year)
- Metrics should be related to relevant MA competencies and objectives, not to commercial goals
- Consider local external training for "soft skills" that is specific to MA
- Training and certification of external MA candidates would be an important time-saver and produce better hiring outcomes.

SUMMARY & CONCLUSIONS

Medical Affairs is in a period of ascendance with respect to its role and contribution to Pharma's overall value proposition. Participants were concerned with the potential to co-opt MA into commercial processes and objectives. They believed that this confounding of roles would diminish MA's ultimate value with HCPs. Medical and scientific post-graduate credentials have become a substitute for external certification. Such certification is now seen as redundant, except for those wishing to be considered for an MA position, i.e., external candidates. Medical and scientific credentials are no guarantee of the soft-skills essential to effective communication, in fact, they are often the opposite. The biggest training need was for MA-specific programs in communication, negotiation, presentation, etc.

AFTERWORD FROM LEGITIMED INC.

The results of this study underscore deep & wide frustration around value-positioning of MA internally which can lead to 'forced collaborations' with other internal groups in order to secure ('fight') for resources. There was congruence around the need for MA to better 'sell its why' internally to ensure proper positioning (avoid commercial bias) and secure appropriate resources (budget) to deliver on the expanded and sometimes delicate mandate of bridging the Pharma-Academic divide.

Many see the role of MA as essential to "generate data [including real word evidence (RWE)] on functional patient outcomes that support the value of new drugs" and to drive "dissemination of this information so it receives the scrutiny and feedback from external stakeholders required to advise future strategies." While this speaks to their current skill set, there were clear needs expressed for enhanced training around business acumen; understanding both the practice and business of medicine; articulating the interconnectedness of the entire healthcare system and refined soft-skills training to effectively translate evidence into real-world implications.

The participants acknowledged that the MA function differs with the complexity of the therapeutic areas of interest as well as the scale of the commercial organizations. Nonetheless, hard skills around scientific knowledge appeared common to all but soft-skills, namely foundational communication skills, were recognized as gaps. While there was congruence around the need for standards, 'certification' was deemed most beneficial as pre-qualification for prospective MSL candidates or as ad-hoc training. Interest was expressed in continuous channels of communication and collaboration across industry to advance the collective value proposition of Medical Affairs.



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