

RDPAC Medical Affairs Subgroup's White Paper

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General Principle and Guidance of Medical Affairs

'Putting Patients First' is the Core Value of Medical Affairs, which is realized by non-promotional peer to peer communication and medical education that provides accurate and balanced information to healthcare professionals (HCPs) and/or medical communities at large with patients as the ultimate beneficiary.

Medical Affairs provides trusted and valued medical expertise and real world evidence that advances medical practice through partnership with HCPs and other stakeholders to ensure the safe and appropriate use of medicines for patients.

- Medical Affairs Personnel are medical experts and strategic leaders of pharmaceutical companies, are scientific partner of choice of HCPs and other stakeholders. Medical Affairs Personnel identify unmet patient, HCP, policymaker and payer needs, provide medical solutions across the whole patient journey, to advance clinical practice and improve patient outcomes.
- Medical Affairs Personnel participate clinical development and integrated evidence generation plan throughout the whole life cycle, generate, interpret and communicate accurate and balanced medical/scientific evidence to ensure HCPs and other stakeholders have sufficient information to make evidence based decision in elevating standard of clinical care, supporting regulatory decision and improving patients' access.
- Medical Affairs Personnel including Medical Science Liaisons (MSLs) practices are non-promotional in nature; all interactions with HCPs should be based on the principle of peer to peer medical/scientific exchange.
- Medical Affairs Personnel including MSLs' medical/scientific discussion with HCPs should be independent from commercial team. The content of the interactions with HCPs that contains cutting-edge medical/scientific information is primarily focused on disease and its management.
- Medical Affairs Personnel support patient centric activities including but not limited to disease awareness programs and patient education/support programs to improve the disease management.
- Medical Affairs activities should be planned and tracked with proper tools, the content of the interactions with HCPs should be documented within Medical Affairs team. Medical Affairs Personnel's performance should be properly evaluated by Medical Affairs function and should not directly link to any commercial target.
- Medical Affairs Personnel review and approve materials/programs that are intended for promotion, education, and distribution to HCPs and other stakeholders, or for training commercial personnel, according to RDPAC and individual company's Code of Conduct. The materials/programs that describe diseases and/or products must contain accurate and balanced information, and must be consistent with the package insert approved by National Medical Products Administration. Review decisions should be recorded and archived in an appropriate system.

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RDPAC: China Association of Enterprises with Foreign Investment R&D-based Pharmaceutical Association Committee