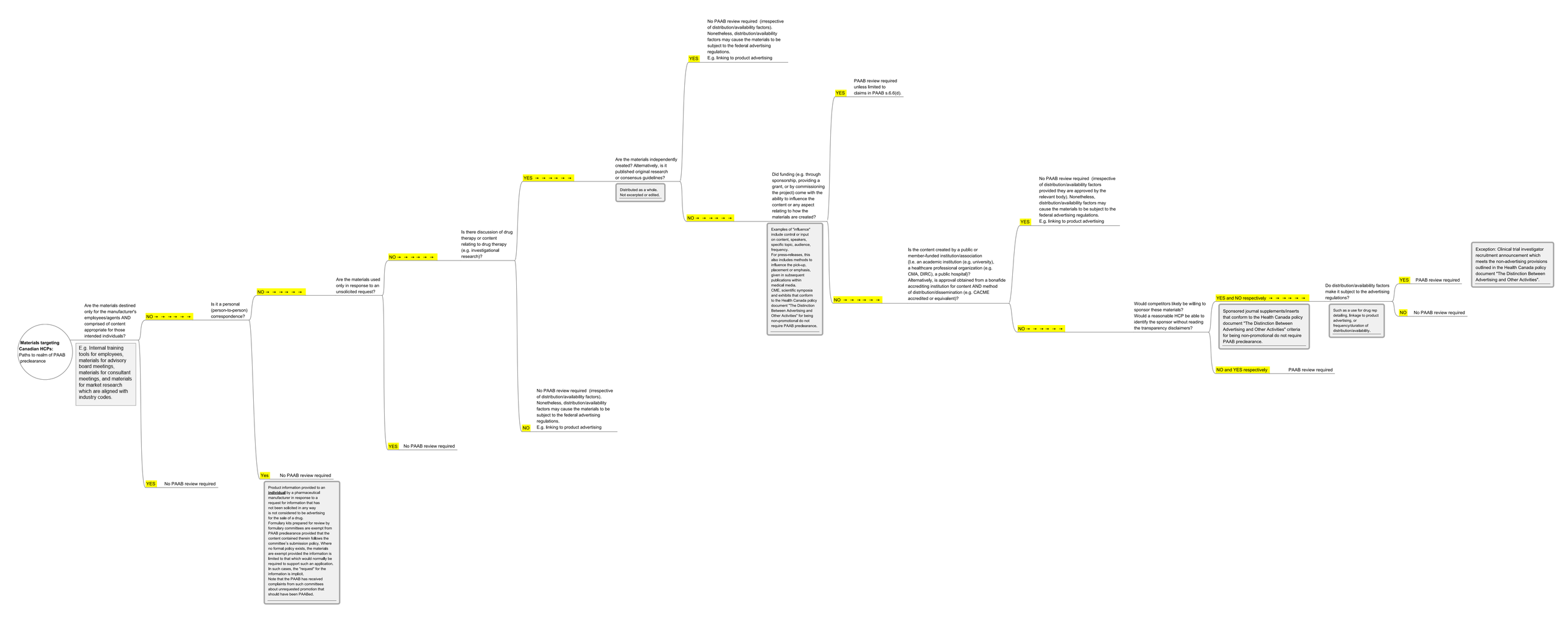
Materials targeting Canadian HCPs:
Paths to realm of PAAB preclearance
Are the materials destined only for the manufacturer's employees/agents AND comprised of content appropriate for those intended individuals?
NO → → → → → →
E.g. Internal training tools for employees, materials for advisory board meetings, materials for consultant meetings, and materials for market research which are aligned with industry codes.
YES No PAAB review required
Is it a personal (person-to-person) correspondence?
NO → → → → → →
Are the materials used only in response to an unsolicited request?
NO → → → → → →
Is there discussion of drug therapy or content relating to drug therapy (e.g. investigational research)?
YES → → → → → →
Are the materials independently created? Alternatively, is it published original research or consensus guidelines?
Distributed as a whole. Not excerpted or edited.
YES
No PAAB review required (irrespective of distribution/availability factors). Nonetheless, distribution/availability factors may cause the materials to be subject to the federal advertising regulations.
E.g. linking to product advertising
NO → → → → → →
Did funding (e.g. through sponsorship, providing a grant, or by commissioning the project) come with the ability to influence the content or any aspect relating to how the materials are created?
Examples of "influence" include control or input on content, speakers, specific topic, audience, frequency.
For press-releases, this also includes methods to influence the pick-up, placement or emphasis, given in subsequent publications within medical media.
CME, scientific symposia and exhibits that conform to the Health Canada policy document "The Distinction Between Advertising and Other Activities" for being non-promotional do not require PAAB preclearance.
YES
PAAB review required unless limited to claims in PAAB s.6.6(d).
NO → → → → → →
Is the content created by a public or member-funded institution/association (I.e. an academic institution (e.g. university), a healthcare professional organization (e.g. CMA, DIRC), a public hospital)? Alternatively, is approval obtained from a bonafide accrediting institution for content AND method of distribution/dissemination (e.g. CACME accredited or equivalent)?
YES
No PAAB review required (irrespective of distribution/availability factors provided they are approved by the relevant body). Nonetheless, distribution/availability factors may cause the materials to be subject to the federal advertising regulations.
E.g. linking to product advertising
NO → → → → → →
Would competitors likely be willing to sponsor these materials?
Would a reasonable HCP be able to identify the sponsor without reading the transparency disclaimers?
YES and NO respectively → → → → → →
Sponsored journal supplements/inserts that conform to the Health Canada policy document "The Distinction Between Advertising and Other Activities" criteria for being non-promotional do not require PAAB preclearance.
Do distribution/availability factors make it subject to the advertising regulations?
Such as a use for drug rep detailing, linkage to product advertising, or frequency/duration of distribution/availability.
YES PAAB review required
NO No PAAB review required
Exception: Clinical trial investigator recruitment announcement which meets the non-advertising provisions outlined in the Health Canada policy document "The Distinction Between Advertising and Other Activities".
NO and YES respectively PAAB review required
YES No PAAB review required
Yes No PAAB review required
Product information provided to an individual by a pharmaceutical manufacturer in response to a request for information that has not been solicited in any way is not considered to be advertising for the sale of a drug.
Formulary kits prepared for review by formulary committees are exempt from PAAB preclearance provided that the content contained therein follows the committee's submission policy. Where no formal policy exists, the materials are exempt provided the information is limited to that which would normally be required to support such an application. In such cases, the "request" for the information is implicit.
Note that the PAAB has received complaints from such committees about unrequested promotion that should have been PAABed.
YES No PAAB review required
NO
No PAAB review required (irrespective of distribution/availability factors). Nonetheless, distribution/availability factors may cause the materials to be subject to the federal advertising regulations.
E.g. linking to product advertising