**Additional file 6: An analysis of Strengths, Weaknesses, Opportunities and Threats of the current HMs registration system at the Bahraini drug regulatory authority**

**Table 1**

**Perceived Strengths, Weaknesses, Opportunities and Threats in the current HMs registration system at the Bahraini drug regulatory authority, with participants’ quotes**

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| --- | --- |
| Strengths (internal conditions) | Participants quotes  |
| Motivation of the regulatory authority to improve making it a trustworthy authority  | *“We are aiming to be number one regulatory authority in the Gulf, so we are always trying* *to improve our procedures, our system, going over old policies and advance them” (KI3)* |
| Transparency and honesty of the review procedure  | *“We make sure that we are transparent as much as possible, this is very important to gain* *public trust” (KI8)* |
| Existence of committee for scientific assessment | *“The final decision for approving medicines are made by the scientific committee, this has* *the advantage of ensuring the availability of experienced staff and discuss issues that may* *not be tackled by only one reviewer” (KI1)* |
| Availability of guidelines and SOPs  | *“We have guidelines, we follow our own SOPs, we have registration requirements that are* *clear, these helps a lot, they help us carryout the registration procedure consistently* *“(KI8)* |
| Availability of an electronic system  | *“Having an electronic system to register and track applications, to record decisions of* *applications and you, this provide better handling for information and saves time” (KI6)* |
| Weaknesses (internal conditions) | **Participants quotes** |
| Lack in the organisational structure and hierarchy | *“I think that the organisational structure could be improved to give a higher authority to* *certain positions. For example, the structure needs to be more hierarchal, there is still* *some gaps in the structure of the different departments of the Pharmaceutical Product. I* *think it is better to have one manager for each department, like for HPs, medicines,* *renewals and so on, like this I think it is easier for reviewers to reach their managers* *instead of having one manager for all departments” (KI2)*  |
| Lack of training in HMs regulations  | *“We do have financial resources but it is very restricted and for all employees under all* *departments in the NHRA not specifically for Pharmaceutical Product department. And* *what happens is that the [names another department in the NHRA] takes the most of the* *training being a newly established department that needs improvements. How can I* *improve the authority without continuous training and continuous knowledge about what is* *happening in the regulatory aspects worldwide?” (KI3)* |
| Extreme lack of human resources | *“The extreme limitation in staff is becoming a serious problem, it’s causing us a hard time* *finishing deadlines on time, because you have so much work to do, the type of work we do* *needs time, you can’t rush things. We need more staff, that’s for sure” (KI4)* |
|  Opportunities (external conditions) | **Participants quotes** |
| Independent authority  | *“We are independent from the MOH, so the production of new policies and guidelines* *doesn’t require the MOH approval and the long process of approving policies. Internally* *at least we can produce our own policies and guidelines and the MOH can’t intervene with* *this” (KI8)* |
| Working in collaboration with regional and international agencies  | *“Cooperation with international authorities is very important, we have several* *collaborations with agencies for example the WHO, which also have many competent* *followers, and we are growing along with the global advancements of these followers”* *(KI2)* |
| Expand through GCC cooperative efforts  | *“Being part of the GCC and during our communications with the GCC countries for central* *registration, we learn that certain guidelines must exist which will make our life easier”* *(KI6)* |
| Threats (external conditions) | **Participants quotes** |
| Poor funding resulting in lack of significant regulatory procedures  | *“We need experts on pharmacovigilance, more staff and connections with referenced* *countries and hotlines, and more importantly, we need a full team and a guideline to start* *with, this all needs more money” (KI1)* |
| Open market  | *“When consumers do not find what they need from the market they would easily order HMs* *online and who knew what these products include they might’ve contained banned and* *dangerous substances, these are not tested” (KI5)* |
| Increased number of substandard and counterfeit HMs | *“Unsafe HMs are incredibly increasing all over the world, many products we received did* *not meet the required quality or safety, we need to be very careful with herbs and very* *thorough in our review” (KI4)* |

*GCC* Gulf Cooperation Council, *HMs* herbal medicines, *HPs* health products, *MOH* Ministry of Health, *SOPs* Standard Operating Procedures, *WHO* World Health Organisation

Additional file 6: Data from the analysis of interview transcripts on Strengths, Weaknesses, Opportunities and Threats of the current HMs registration system at the Bahraini drug regulatory authority