Position Paper

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Assessment Reports - A Tool for Regulatory Reliance

Introduction

Reliance is an act whereby a regulatory authority (NRA) in one jurisdiction may take into account and give significant weight to – i.e. totally or partially rely upon - evaluations performed by another regulatory authority or other trusted institution in reaching its own decision. The relying authority remains responsible and accountable for decisions taken, even when it relies on the decisions and information of others[1]. According to a 2019[2] WHO survey on reliance, access to information, including unredacted assessment reports promotes an understanding on what was reviewed, a rationale for decision making and promotes confidence and trust.

IFPMA supports the concept of reliance[3] and recognises the facilitating role which assessment reports can play. Our members have found that there can be assumptions and misunderstandings on what type of information can be provided and the true scope of any redactions. There is no one size fits all definition of an unredacted assessment report due to differing laws and practices by NRAs globally. Within this paper we outline our overall position.

Overall Position[4]

- We believe that public assessment reports are valuable as they provide key insights into the rationale of the regulatory decision-making process. Where available, these reports should be the primary source of information to support regulatory reliance.
    - We encourage all NRAs to produce meaningful publicly available assessment reports, supporting the benefit-risk decision making for major approval decisions. A procedure involving the marketing authorization holder must be put in place to ensure appropriate redaction of personal data and commercial confidential information, in line with the national legislation. The sharing of such documents will facilitate reliance, especially as WHO seeks to expand the pool of reference NRAs and institutions who can be relied upon.
- We encourage NRAs that are seeking to implement regulatory reliance procedures to use public assessments reports which are already routinely produced by many agencies and institutions. Public assessment reports provide a detailed summary of the basis of the regulatory decision. For example, the European Public Assessment Report (EPAR) contains in practice very few redactions, which have been reviewed and accepted by the EMA during the redaction process and is therefore very informative.

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[1] WHO (2016), Good Regulatory Practices Guidance
[2] WHO (2019), Reliance - WHO survey on outcomes
[3] IFPMA (2019), Considerations for effective regulatory reliance – an Industry perspective
[4] For further information on this topic you can refer to IFPMA's FAQ's on Assessment Reports

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- NRAs should establish regulatory reliance procedures based on what is actually possible for reference NRAs to provide, recognising that assessment reports vary across different jurisdictions due to national legislation that determines what type of information can be provided.
    - In the absence of a public assessment report, or if the relying NRA requires more detail to take informed decisions on an abridged review, the relying NRA may require sight of confidential documents such as unredacted assessment reports or questions and answers exchanged between the reference NRA and the applicant during review. Ideally, these documents should be provided directly from NRA to NRA, via a secure platform to safeguard confidentiality and intellectual property. A prerequisite for the exchange is that NRAs have in place the necessary bilateral Memorandum of Understanding and confidentiality agreements to safeguard confidential information from entering the public domain and to prevent such information being used inappropriately to assess a product from another company. The company should always be informed about the sharing of information. If NRAs are unable to exchange reports, companies may provide these with the agreement of the regulator, on a case by case basis.
- We believe that the provision of assessment reports to support regulatory reliance should speed up and not slow down approval process in comparison to a conventional review, thus enabling patients to have faster access to new treatments as a result.
- We believe that only **one** assessment report from one agency being relied upon should be requested and supplied. Provision of reports from multiple NRAs who arrived at the same approval decision and for the same conditions of use for the product is not value added, because it is not providing any additional information to inform the decision.