Medicines and Healthcare products Regulatory Agency

24 April 2017

Agency's Risk Appetite Statement

Issue/ Purpose:

Attached is the Agency's Risk Appetite Statement which sets out how we balance risk and opportunity in pursuit of achieving our objectives of promoting and protecting public health.

The statement forms a key element of our governance and reporting framework and is set by the Corporate Executive Team (CET) and approved by the Audit & Risk Assurance Committee (ARAC) on behalf of the Board, which also reviews the statement annually.

Summary:

Overarching statement

We are not averse to taking risks; our risk appetite varies across the activities of the Agency and our approach is based on judgement and circumstances of each potential intervention and an assessment of its impact. This means we will not seek to intervene in all situations, rather we prioritise in terms of risk, perceived benefits and cost in a consistent and transparent way, choosing the most appropriate course of action. We accept that there are some irreducible risks, for example it is recognised that no medicine is entirely without risk. Our role is to balance those risks against the potential benefits. Similarly, in our inspection work, we will balance the closure of an inadequate factory with the implications for patients of a loss of supply of their medication.

Resource implications: N/A

EU Referendum implications: N/A

Timings: N/A

Action required by Board:

The Board is recommended to approve the Agency's Risk Appetite Statement.

Links: N/A

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Which of the five themes in the Corporate Plan 2013/2018 does the paper support? All

If relevant, which Business Plan strategic activity does it support? All

CET Sponsor: Jon Fundrey

Agency Risk Appetite Statement

Introduction

This statement sets out how we balance risk and opportunity in pursuit of achieving our objectives of promoting and protecting public health.

It forms a key element of our governance and reporting framework and is set by the Corporate Executive Team (CET) and approved by the Audit & Risk Assurance Committee (ARAC) on behalf of the Board, which also reviews the statement annually.

One of our fundamental roles is to manage risk – we manage the risks of the products that we are regulating and we assess them against the benefits for patients and public health. However, that balance is not always clear cut, and whilst known risks can be reviewed against benefit, unknown risks (that may only become apparent later) cannot. The negative consequences of regulatory risk tolerance in allowing drugs onto the market that turn out to be unsafe are obvious, but the potential for adverse effects on public health owing to the absence of new drugs or withdrawal of products because of regulatory risk-aversion is less apparent, but nevertheless real.

We also assess and manage risks to the Agency itself. The Agency distinguishes between those risks which are operational in nature and as such within our control (such as information security, business continuity or safety issues with a regulated medicine or device) and those external risk factors (such as Brexit or the risk of an economic downturn) which are not directly within our control but which nevertheless must be identified and considered to address those risks we can influence.

The Agency also recognises that there will be uncertainties about which it has no knowledge but which may impact on its risk appetite. Our horizon scanning will contribute towards developing mitigating actions.

Overarching statement

We are **not averse** to taking risks; our risk appetite varies across the activities of the Agency and our approach is based on judgement and circumstances of each potential intervention and an assessment of its impact. This means we will not seek to intervene in all situations, rather we prioritise in terms of risk, perceived benefits and cost in a consistent and transparent way, choosing the most appropriate course of action. We accept that there are some irreducible risks, for example it is recognised that no medicine is entirely without risk. Our role is to balance those risks against the potential benefits. Similarly, in our inspection work, we will balance the closure of an inadequate factory with the implications for patients of a loss of supply of their medication.

External/Regulatory

We are therefore relatively **averse** to risks to our statutory objectives created by those who we regulate failing to meet the standards required by law as explained in our codes of practice and guidance. We act in an appropriate manner. Our decisions are based on expert judgement of our highly qualified staff supplemented by expert external advice as necessary. We also place reliance on other parties such as Notified Bodies. Our judgment is also influenced by the circumstances of use of

the product. However, we have a more **open** appetite for taking well managed risks where innovation and change create opportunities for discernible benefits to public health and clear improvement in our ability to achieve our objectives e.g. improved technologies, areas of high unmet medical need. The extent of our risk taking is heavily dependent on the expertise of our staff who informs the judgements we make.

We carefully assess any possible conflicts of interest in our work to ensure that our decision making is based on scientific excellence whilst free of potential or perceived bias.

Operational

In acknowledgement of the growth and operational maturity of our regulatory functions, we maintain a **cautious** risk appetite towards sustaining appropriate operational processes, systems and controls to support delivery but adopt a more **open** appetite for the development and enhancement of these systems.

We are heavily reliant upon information and data to be able to operate as an effective risk-based regulator. The accidental or deliberate wrongful disclosure of sensitive or restricted information has the potential to erode trust, damage our reputation and ultimately prevent us from being able to function. As such we have a **minimalist** appetite for such risks.

On occasions we can be **hungry** in our approach; for example, when we decided to invest heavily in the Clinical Practice Research Datalink (CPRD) as we saw the significant potential benefits for public health, and in our intention to build on the increasing development of Artificial Intelligence (AI) tools to assess the data we are provided with and hold.

Financial

As a Government Trading Fund, reliant on generating our income from our regulatory and other trading activities and governed by the requirements of *Managing Public Money* we are **minimalist** in our appetite for financial risks. We are content to invest where there is a good business case but will not be willing to undertake speculative high-risk activities.

Fraud

We are **averse** to the risks of fraud and fraudulent behaviour and will maintain appropriately robust controls and sanctions to maximise prevention, detection and deterrence of this type of behaviour. We will avoid wherever possible having multiple layers of controls, ensuring they are proportionate to the risks.

Legal

Where we are working with relatively untested legislation we are willing to adopt a **cautious** risk appetite to achieve our statutory objectives and to determine the extent of our powers and our own jurisdiction and this will be based on the likelihood of legal challenge against the Agency, its success and impact. We take account of the particular circumstances – if there is a significant risk to public health we are prepared to adopt a more forceful position. We use and are informed by the Government Legal Department's levels of risk descriptors.

We would not knowingly behave in an illegal, unreasonable or irrational way, or any other way, which would be likely to give rise to a successful judicial review. Such risks would include our regulatory

risks (e.g. enforcement action resulting in fines) and professional liability risks (e.g. where the Agency acts contrary to its legal obligations).

Reputational

We rely on our reputation in order to influence and secure the engagement of the regulated community, industry participants and key stakeholders such as patients, customers, the general public and healthcare professionals. The support of these parties is essential to achieving our objectives and so we hold a strong commitment to being seen as a proportionate and respected authority within the regulatory arena and retain an overall **cautious** risk appetite with regard to our reputation. However we are prepared to take a stance which may be opposed by some of our audience where we believe it is necessary for the achievement of one or all of our statutory objectives.

Appetite	Descriptions
Averse	Avoidance of risk and uncertainty in achievement of key deliverables or initiatives is paramount. Activities undertaken will only be those considered to carry virtually no inherent risk.
Minimalist	Predilection to undertake activities considered to be very safe in the achievement of key deliverables or initiatives. Activities will only be taken where they have a low degree of inherent risk. The associated potential for reward/pursuit of opportunity is not a key driver in selecting activities.
Cautious	Willing to accept/tolerate a degree of risk in selecting which activities to undertake to achieve key deliverables or initiatives, where we have identified scope to achieve significant reward and/or realise an opportunity. Activities undertaken may carry a high degree of inherent risk that is deemed controllable to a large extent.
Open	Undertakes activities by seeking to achieve a balance between a high likelihood of successful delivery and a high degree of reward and value for money. Activities themselves may potentially carry, or contribute to, a high degree of residual risk
Hungry	Eager to be innovative and choose activities that focus on maximising opportunities (additional benefits and goals) and offering potentially very high reward, even if these activities carry a very high residual risk.