Complementary Medicines Australia submission to the Therapeutic Goods Administration Consultation:

Business process improvements supporting complementary medicines assessments pathways.

November 2017

To:
Complementary Medicines Reform Section
Complementary and OTC Medicines Branch
Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
complementary.medicine.reforms@health.gov.au

From:
Complementary Medicines Australia
PO Box 450
Mawson ACT 2606

Telephone: 02 6260 4022
Facsimile: 02 6260 4122
E-mail: carl.gibson@cmaustralia.org.au
Website: www.cmaustralia.org.au

Contents

Introduction

Complementary Medicines Australia (CMA) welcomes the opportunity to provide comment with regard to the TGA's consultation on the Business process improvements supporting complementary medicines assessments pathways.

CMA is committed to a vital and sustainable complementary medicines sector, and represents stakeholders across the value chain, including manufacturers, raw material suppliers, distributors, consultants, retailers and allied health professionals. The increasing consumer demand for complementary medicines has resulted in the industry becoming a significant pillar in preventative healthcare, both economically and as an employer. Over the last few decades the Australian complementary medicines sector has evolved into a major world class industry supporting domestic jobs, research, manufacturing and exports.

CMA notes that the TGA consulted already on the new pre-market assessment pathway for 'assessed listed medicines' earlier in 2017 and we re-commit our support for that pathway and acknowledge that this consultation expands on the application processes, timeframes and fees to support the new pathway, as well as revisions to business processes for new substances, and registered complementary medicines. We also note that the consultation process contains proposed enhancements to post market monitoring.

Overall, CMA believes that the proposals outlined in the consultation regarding application categories appear reasonable, but a great deal of the process will only become fully assessable once more details are known particularly around data requirements. We would also like to emphasis that the regulator should allow for flexibility in their criteria for overseas regulators, and that a great deal of caution needs to be exercised regarding the post market enhancement proposals.

Risk-based approach to regulating complementary medicines: three assessment pathways

CMA supports a risk-based approach, with the caveat that the level of risk is reflective of actual risk posed. In particular, we believe there needs to be a great deal of consideration when excluding indications from the first assessment pathway based on theoretically implied risk, rather than actual risk where the assessment would pass the reasonable consumer test.

Risk-based application categories for pre-market assessment pathways

Q: Do you agree with the proposed risk categories for new ingredients and medicines?

Q: Do you agree with the proposals for application categories to enable use of overseas regulatory reports?

CMA supports the proposal to undertake pre-market assessments: using reports from overseas regulators, or full *de novo* evaluations, or a mix of these evidence types. We agree with the proposed risk categories to provide greater flexibility in the pre-market evaluation of complementary medicines and are pleased that the regulator is developing risk commensurate categories that do not compromise upon quality and safety. However, CMA has some queries about the criteria for eligibility of overseas regulators and their reports. These are outlined in response to requirements in the following section.

CMA provisionally supports the application categories for each assessment type detailed in the consultation. We have a query, as the Listed Assessed 'LA' category represents a 'mixed' regulatory product where some aspects are self-assessed by the sponsor, and other aspects are pre-assessed by the regulator. The proposed LA categories refer only to assessment of the efficacy of the product. It is not clear in what context the assessment of the label or of manufacturing documentation occurs. Will it form part of the premarket assessment? Or, is it proposed that there will be a post-market mechanism similar to that for other listed medicines?

Requirements for pre-market submissions

Minimum data requirements

While this is a consultation concerning the business processes of the new applications types for new ingredients, listed medicines and registered medicines, the document does not contain the specificities about the data packages to be submitted for evaluation and states that this will be the subject of a separate consultation document. It is difficult to indicate support for these assessment pathways and the associated timeframes and fees in the absence of this information.

Further, the document describes a screening process of the minimum data requirements described in each category and states that the TGA states reserves the right to reject applications if those requirements are not met. In the absence of the specifics of the data requirements, it is difficult to determine how reasonable the proposed approach is and what impact this will have on applicants.

Therefore, support of many of the processes within this consultation will be dependent on further details regarding the required data packages.

Use of comparable overseas regulatory reports to support pre-market assessments

Q: Do you agree with the proposals for application categories to enable use of overseas regulatory reports?

CMA supports the consideration of overseas regulatory scenarios in the assessment of the suitability of ingredients and medicines for the Australian market. Whilst we are in favour the use of reports from overseas regulatory authority in premarket applications, there is a widespread concern that there would not be any overseas regulators and reports would meet the criteria described. If the number of comparable regulators or accepted reports from comparable regulators is minimal, the objectives to improve timeframes and business processes for the TGA evaluation areas are unlikely to be met. It will also funnel all new substance applications and listed assessed applications into the more expensive pathways. We propose that some of the criteria are re-examined for availability of flexibility to the regulator, without decreasing safety and quality considerations, and noting that the regulator will have the final ability to decide whether the overseas regulator or report is equivalent.

Q: Are the proposed criteria for determining the suitability of overseas regulators appropriate?

CMA agrees that appropriate criteria should be set to determine the suitability of overseas regulators. We have the following comments in relation to the criteria posed:

1. **International recognition of regulator.**

   The first criterion discusses using only 'internationally recognised regulatory authority'. What criteria or definition constitutes 'international recognition'? Would such a criteria be unnecessarily restrictive? Would it for example be a member of the International Coalition of Medicines Regulatory Authorities (ICMRA)? CMA proposes that it would be better to use instead use the term 'national regulatory authority' (NRA). The suitability of the NRA would be indicated the other remaining proposed criteria.

2. **Transparency.**

   The second criterion discusses that the regulator must have a transparent system for decision making processes such as risk assessment methodologies. Many of these processes are complex and not always fully described in publicly available documentation. CMA proposes that decision making processes should be considered acceptably transparent not only where it is obtainable publicly, but also if it is available on a regulator-to-regulator basis.

3. **Internationally accepted scientific standards and guidelines.**

   a. The third criterion discusses that the overseas regulator 'must' use 'internationally accepted scientific standards and guidelines'. No description of what constitutes international recognition is provided, or examples of scientific standards and guidelines. Presumably it is referring to standards and guidelines for complementary medicines. It is well known that the TGA regulates complementary medicines to a superior standard than any other overseas regulator. In many countries complementary medicines are regarded as foods, so technical reports are unlikely to meet the standards required for medicines. Therefore this criterion is unlikely to provide a useful reflection of the regulatory landscape. Noting that the TGA has provided that a list of overseas regulators will be under development for some time as the regulator gains a greater understanding, CMA proposes that the criteria is phrased in a way that provides greater flexibility as this understanding

is developed. In particular, so that information related to goods not currently regulated as medicines could still be eligible for submission if sufficient information is available.

b. Traditional medicine ingredients that are assessed on their basis of a long history of safe use is not accounted for in the criteria. Further, it is possibly excluded by criterion 3. As traditional medicines are often highly localized to particular regions, we think it is of particular importance that the knowledge of overseas NRAs are utilised as part of an assessment of ingredients based upon traditional medicines.

Overall, there is significant industry concern that there will be no comparable overseas regulators considered acceptable to the TGA by the proposed criteria. With this in mind, we believe that the criteria should be flexibly worded to allow for the TGA to consider individual cases when working with this complex environment of overseas regulation.

Q: Are the proposed criteria for determining the suitability of reports from comparable overseas regulators appropriate?

CMA agrees that appropriate criteria should be set to determine the suitability of reports from overseas regulators. We have the following comments in relation to the criteria posed in Stage 2:

1. **International equivalence**

   As referred to in item 3 above, we note that TGA regulates CMs to a higher standard than international counterparts and therefore notes there may need to recognise a level of flexibility in the 'comparability of the medicine or ingredient' in the criteria for regulatory reports: specifically, 'the formulation, route of administration and/or indications described in the comparable overseas regulatory report(s) must be equivalent to that being applied for'. For example, if it could be assessed that there is substantial equivalence to the formulation and indications. An example could be when an ingredient is traditionally prepared as a tea, it could be considered substantially equivalent if a water-only preparation was dried before tabletting. Another example is where an overseas medicine used for a Registrable indication is applied for via the intermediate (Listed Assessed) pathway, in this case a less-definitive indication should be considered substantially equivalent.

2. **Acceptable national guidelines or standards**

The second criterion provides that reports should be prepared using internationally accepted guidelines and standards, including but without being limited to 'the International Council on Harmonisation (ICH) or Organisation for Economic Co-operation and Development (OECD) guidelines; and pharmacopoeial standards such as the European Pharmacopoeia, British Pharmacopoeia and United States Pharmacopeia.'

Whilst we agree with the use of these guidelines and standards, it must be recognised that some national authorities will be using acceptable guidelines and standards for complementary medicine or food substances that are not necessarily used outside their own jurisdictions. To maintain flexibility in the face of uncertainty, CMA proposes that the criteria regarding international acceptance is reexamined to consider other possible acceptable circumstances.

3. **Minor redactions**

The third criterion provides that reports must be un-redacted. While we accept for functionality that reports should be primarily un-redacted, there is always the likelihood of minor redactions to protect privacy, confidential administrative details, etc. We propose that the criterion reflect that redaction is acceptable where it does not affect the usefulness of the report for its intended purpose.

4. **Applicability**

Overall, industry is concerned that while the TGA's proposed criteria are theoretically useful, they may not be achievable in real world circumstances due to the complexity of international regulation for complementary medicines and foods, which is different to the increasingly harmonised international approach for pharmaceutical medicines. If the regulator has a genuine commitment to using reports from overseas regulators for complementary medicines, the approach should be considered to provide the regulator sufficient flexibility to apply discernibly assess whether a report would be acceptable.

In summary, we believe more flexibility in the criteria would be beneficial to account for the realistic scenarios that the regulator will encounter when trying to account for international information to support the assessment of ingredients and medicines. As the assessments are all premarket, the regulator will still have premarket discretion over what is considered acceptable.

Sources of evidence for de novo assessments

Q: Is the proposed process for identifying alternate sources of evidence for *de novo* assessments appropriate?

Q: Are the individual criteria appropriate?

Q: On the basis of the above criteria, please propose other sources of evidence that you would like considered as acceptable for de novo assessment.

CMA believes that the increasing the sources of evidence for de novo assessment is appropriate, and strongly believe it will be the more regularly used process for complementary medicines due to the likely barriers of using overseas reports. The proposed sources of evidence for de novo assessments are: internationally recognised papers and articles about ingredients, internationally recognised traditional medicine pharmacopoeia, human use data, dietary exposure levels and epidemiological studies. We again query how 'internationally recognised' is defined and determined? The concern is whether this would unduly limit acceptable sources.

CMA agrees with the remaining proposed criteria, but due to the wide variability of proposed evidence sources, strongly suggests adding 'Where applicable, …' to the third and fourth criteria to allow for all proposed types.

We would also propose adding the consideration of safe, lengthy overseas permissible regulatory supply as a source of evidence. Recognising that the TGA currently only accept such data if there is an Adverse Drug Reaction (ADR) system in place, we believe that a long history of exposure via usage data could be taken into consideration as part of the safety evaluation even in the absence of a formal ADR system.

We note and support the intention to support the criteria for eligibility with the publication of a list of acceptable sources of evidence for applicants on the TGA website.

Business processes for pre-market assessments

Proposed pre-market assessment process

Q: Do you support the proposed assessment process and principles?

The TGA has proposed a phased approach to the assessment process, summarised below:

CMA supports the outlined descriptions for the 'pre-submission' and 'submission' phases. However, in the submission phase, the applicant will determine which category is appropriate based on the data requirements of the applicable category. Will there be the opportunity for an applicant to change category at the screening phase without incurring further fees (except where there is a difference payable for a higher category), if it is determined that it is not acceptable for one category but is acceptable for another? CMA supports that an applicant must be able to change category with **transference of the fee, not the forfeiting the initial fee** if the application is simply moving into a new category, particularly as the progression of the application is at the discretion of the TGA, particularly where the evaluator has the power to deem whether an overseas regulatory report is acceptable.

For the third 'screening' phase, we note that the minimum data requirements have not yet provided and therefore we cannot determine whether the data will be sufficiently unambiguous for the applicant to determine whether they have met the minimum data requirements for the category. If an application is determined to be ineffective and the application fee is forfeited, is this a decision made by a delegate under the Act, will there be appeal rights?

CMA provisionally supports the processes outlined in the 'evaluation' phase, noting that it is a complex process that requires testing through the pilot program. There are some questions about what kind of additional information will be requested, how vitally relevant the information will be to the decisions to

approve or reject the application, and what occurs if the type of information requested is unforeseen by the applicant and the information is not available? The Request for Information process must **only** be used for information that is directly required for approval of the application. Industry have expressed concerns that there are historical examples where information that is not essential to the application has been requested.

As an administrative matter on requests for information, we would seek to confirm whether extensions to requests for information could be provided in circumstances that require an extension.

CMA supports the processes outlined for the 'decision' and 'implementation' phases, assuming the appeal rights will be included in the final decision letter if an application is rejected.

Timeframes

Q: Are the timeframes for the individual application categories appropriate?

CMA believes the proposed timeframes are appropriate.

Fees

Q: Feedback on fee structure.

As referred to earlier in this submission, we expressed the concern that if applicants cannot meet the overseas report criteria that they will be automatically funneled into the higher fee structure, so we suspect the majority of applications will fall into the highest category.

CMA provisionally supports the proposed fee structure, dependent upon the release of the Cost Recovery Implementation Statement, and further detail about the minimum data requirements.

As described in other sections above, without knowing what the minimum data requirements will be, and whether labels and manufacturing data is assessed as part of this fee, it is difficult to provide further comment or support to this particular fee structure.

We note that the original estimates for the listed assessed pathway were approximately 50% ($7,000) of the existing proposed fee for LA category 3 ($15,160). We would be extremely concerned if there were a further increase in fees, as it reduces the accessibility of the new listed assessed pathway for all complementary medicine sponsors. It would also likely reduce the number of applications for more definitively worded permitted indications – if there is unlikely to be a distinctive effect upon the message to consumers – as it would not justify the large fee gap. In particular, there is a barrier for smaller sponsors to access the listed assessed pathway, and we query whether there is opportunities to level this barrier.

We understand from this document and seek to confirm that the less expensive 'generic' option will be available to smaller sponsors based on existing listed assessed medicines, in a manner similar to the codestock style arrangement for listed medicines.

Enhanced post-market compliance monitoring scheme for listed medicines

Q: Do you agree with the proposed approaches to target repeat offenders? If not, please outline other approaches that could be used to target this behaviour?

Q: Is the proposal to publish more information about compliance review outcomes appropriate?

Greater targeting of non-compliant sponsors

Members of Complementary Medicines Australia strive to run strong, viable businesses that aim to meet all compliance goals. Where compliance is aimed for and primarily achieved, they do not feel that the targeting is a fair or reasonable response. However, we recognise the need to reign in a very small number of individual sponsors who flaunt applicable provisions and affect the reputation of the industry and the regulator as a whole. Therefore we only support the targeting of the very small minority who blatantly and/or regularly behave contrary to appropriate regulation. This figure should be under 10% of all sponsors.

Central to any regulatory compliance debate is a discussion of the overall achievability of the regulations. In medicines regulation there is the need to achieve a balance between supply of medicines and information for consumers, and ensuring quality, safety, efficacy, and truthfulness in labelling and advertising. Where regulatory balance is achieved, there should be relative harmony between the regulator and the regulated industry.

It must be noted that industry already find the existing level of regulation tightly controlled in respect of the level of risk posed by listable medicines. There is also existing industry-wide and long-standing concern regarding shifting regulatory goal posts. It is not a reasonable request to have a high expectation of compliance where industry to keep up with moving goals that are frequently not known about until a Proposal to Cancel a medicine or an Advertising notice is received. There has been documentation of policy changes over time represented through various compliance notices.

The context in the consultation document for the enhanced post-market compliance monitoring is the result of post market audits carried out between 2014 – 2017. The document indicates that in 80% of reviews the TGA requested that compliance breaches were addressed. However, it is recognised that there are many minor or implied/perceived deficiencies in this bracket. It is not appropriate to target up to 80% of sponsors who are vastly conforming to the required regulations and ensuring the supply of safe, high quality medicines.

It is evident that there is a current sustained push to increase regulation over complementary medicines on many levels, under the umbrella of the MMDR reforms. There are concerns that many of the changes to indications, evidence, and advertising, both individually and 'synergistically', in combination with enhanced targeting of sponsors and public disincentives will negatively affect the overall regulatory balance. Proposed increases in regulation could represent significant challenges to the ability of industry to function in a regulatory landscape where balance is lost to overregulation.

The regulator may start seeing increases in non-compliance where the regulations become so difficult to meet that it is not possible for sponsors to meet every regulatory nuance that is provided for. The high level of minor or perceived/implied non-compliance levels already reported is to some extent a reflection of this effect.

The current proposed regulatory reforms, which introduce numerous regulatory changes within a short period, will require a sufficient period of transition and education. Sponsors with limited resources managing tens or hundreds of products cannot be reasonably be measured against a 100% compliance expectation within a highly changeable regulatory environment and a short timeframe.

We request that the regulator consider the genuine challenges, impacts, and realistic time scenarios involved. This is particularly important when considering changes to enhancing the post market monitoring scheme and the targeting of sponsors.

Categorising deficiencies

We strongly believe that if targeting of non-compliance is going to occur, that a revised discussion over what constitutes compliance and non-compliance and how this is perceived and measured, noting that compliance figures are a reflection upon both the industry and the regulator.

One effective way to reflect the reality of what is seen during post market reviews is to draw distinction between the kind of non-compliance that should elicit regulatory action (serious or safety breach), or the kind of non-compliance that requires guidance and education rather than punitive action (other deficiency). We note that for the purposes of GMP, audited deficiencies are categorised. CMA propose that compliance issues identified by Complementary Medicines and OTC Branch are separated into 'breaches' (Category A) and 'deficiencies' (Category B). Whilst it would not be practicable or reasonable for the regulator to determine intent, it is possible for the regulator to determine the nature and severity of compliance issues. Serious breaches (Category A) are likely only in the realm of 10% or less, and should likely include matters such as: the ingredient is not included in the permissible ingredients determination; the medicine is separate and distinct in a significant way; the medicine label has major deficiencies including potential safety issues; etc. Category B offences (minor deficiencies) could include: unacceptable font size on label; the label claim is inconsistent with the ARTG. The response to Category A problems would be more corrective and available for consideration of further targeting where there is a persistent problem. Whereas the response to Category B would primarily be educative and restorative.

Improved identification of non-compliant behaviours

Where a sponsor routinely withdraws a product from the ARTG and re-lists it, and has a significant history of non-compliant medicines, CMA supports the targeting of a sponsor for an increased level of post market scrutiny to a reasonable level. It is important that there is a level playing field for industry and that some sponsors should not be able to avoid review by cancelling a medicine. Such targeting should only occur where a cancelled medicine is genuinely in production and supply (noting that there are a number of ARTG entities without equivalent manufactured entities). However, CMA believes that all sponsors need to be treated fairly and equally at the administrative decision-making level, and that caution should be exercised by the regulator in that they are acting impartially, not seen to be participating in biased behaviour which is legally risky for the organisation.

Enforcing penalties for repeat non-compliance

While the preventative intent of enforcing penalties is understood, we don't believe it is something that can be fairly and consistently applied, and that it will create more regulatory problems than it will solve.

The consultation states that it would occur in circumstances where sponsors 'demonstrate a clear intent to circumvent their obligations under the Act'. This statement is referring to the determination of guilt/intent, which is quite a legally fraught thing to decide, and usually only done in a court of law. We would question whether this is an acceptable administrative government process.

Secondly, the organisational structure of sponsors should be given consideration, noting that regulatory staff will likely receive the blame in such circumstances even though marketing and other staff may be making important product decisions. It will create personal pressures upon individual regulatory staff who are more likely to leave organisations or change careers in the face of incredible work stresses, which will further reduce the availability of trained regulatory staff (refer to the discussion below under sponsor education). Frequently the best and most confident regulatory staff are those who have been in regulation for a considerable length of time - five or more years. Creating conditions that will cause significant stress and a high turnover of regulatory staff will only serve to increase non-compliance rates.

Publication of compliance review results

Regarding the current level of publication, in accordance with natural justice, before any publication occurs all rights of the sponsors must have been exercised beforehand, that is, that the time period for appeals and judicial review has passed before publication occurs.

The TGA is proposing to publish on the website, along with medicine and sponsor names:

- Specific claims that were not supported by the evidence provided;
- What actions the sponsor took;
- More detail about the reasons why a product was cancelled.

CMA does **not** support the publication of these confidential details. The publication of the regulatory affairs of other players within the therapeutic goods industry, or of the food industry etc, does not occur, and it represents an unfair and unreasonable targeting of the complementary medicine sector as well as the release of confidential commercial information. It must also be noted from a procedural fairness perspective that publishing details of reviews puts undue pressure upon sponsors to comply with aspects of these administrative law reviews even where they feel that unfair or unreasonable regulatory decisions are being proposed or made. Further, the 'naming and shaming' of breaches related to medicines in the TGA website will be unnecessarily alarming for the general public who are not familiar with the regulatory environment to understand the seriousness (or not) of the breaches. The only time it is appropriate to publish information about a medicine is where there is a safety issue that warrants a recall or other important safety precautions that a consumer should be aware of. Also given that is often the same sponsors who reflect a small segment of the market, repeatedly reporting the same deficiencies and breaches from the same sponsors will misrepresent the industry, and undermine consumer confidence in this class of medicines, and potentially undermine confidence in the regulator.

For the reasons above, publishing such details the regulator will create administratively unjust systems and create legal risk for its own organisation on a number of different levels.

Data linkages - permitted indications

The consultation has outlined a proposal to link permitted indications to other outcomes such as post market reviews and ingredients to identify trends with which to target category wide deficiencies. Whilst we support a level playing field, we believe such an approach must be taken with extreme precaution as the legislative requirement is that each sponsor must hold evidence to certify their claims, therefore each medicine must be considered individually as per natural justice. The regulator runs the legal risk of the delegate being seen to form their decision before the required processes have occurred.

CMA believes that the TGA's and industry's resources would be spent far more harmoniously and wisely on the development of evidence-based monographs for listable ingredients, as recommended by the MMDR review. Monographs are an extremely important issue for industry members.

Education and resources for product sponsors

Q: Do you have any views on the educative tools, including methods of delivery and locations of roadshows, to improve rates of compliance?

It should be noted that one of the greatest challenges to sponsors is the training of new regulatory staff. It is a long and complex process for regulatory managers that takes a minimum of 6 months for basic training and often 12-24 months before a relatively robust understanding and practical application of the complex regulatory scheme is approached. As regulatory staff hold a great deal of responsibility within an organisation, it is going to be most helpful to sponsor compliance if there are mechanisms available to new staff on an ongoing basis. The aim of educating and training staff is to empower their understanding of their regulatory accountabilities, in order that they can achieve compliance with relative ease, all inside the greater context of consumer safety. The beneficial by-product of increased understanding and skill could be less accidental errors, resulting in less regulatory action and less resources being mobilized by the regulator and the sponsors to achieve compliance.

Creating training materials is necessary and is also significantly enhanced by assessing the learner against the materials provides feedback as to whether the trainee is achieving competency and confidence. An example could be on-line, staged educational modules which deliver information and then assess understanding with multiple choice quizzes. This method is a common educational tool, which is modifiable over time and could be updated as legislation changes.

On-line platforms should not replace face-to-face opportunities, which also create the opportunity for strengthening harmonious working relationships. We believe that the current typical scheduling of roadshows in Sydney, Melbourne, Brisbane geographically captures a wide majority of sponsors and that an additional webinar is effective in capturing other sponsors, unless the TGA were to receive sufficient requests from other locations.

Of primary importance in the training of regulatory staff is the understanding of the operational perspective of the wider regulatory scheme. Education should not only focus upon the responsibilities of the sponsor but also the rights of the sponsor in regulatory decision making environment.

Summary

In the context of the wider reforms, CMA provides in-principle support for the proposed business processes as they relate to new substance applications, listed assessed medicines and registered medicines, subject to the provision of extra information, particularly the required minimum data requirements being made available.

Regarding proposed enhanced post-market monitoring, CMA recognises that there is a small handful of sponsors who disregard legislative accountabilities. The proposed solution - targeting of sponsors, applied penalties and public reports of post market activities, may or may not achieve the desired result, but could create discord between the regulator, the industry, and the perceptions within the community. We strongly believe it is necessary to focus on getting the reforms right, and educating and transitioning sponsors through the many, time-consuming changes, before assessing and implementing approaches to enhanced post market monitoring. We suggest a risk-based approach based upon a simple categorisation of the types of issues identified at post market review. Once it is established that a sponsor repeatedly commits 'serious offences', enhanced targeting and regulatory actions may be necessary under carefully considered and agreed upon circumstances.

CMA supports and has proposed educational tools that could enhance understanding and therefore improve compliance across the industry.

In response to the proposed content, please find a summary of CMA's comments on the elements of the proposed business proves reform.

In response to the consultation, CMA:

- Notes the inclusion criteria for overseas regulators and their reports is highly likely to be unachievable in the current form, and suggests re-examination for appropriate flexibility.
- Supports the broadening of the evidence base for *de novo* evaluations, noting that this will highly likely be the most used process.
- Queries the definition and necessity of the term 'internationally recognised' as it used throughout the document.
- Provisionally supports the pre-market assessment process, subject to several important details regarding the process outlined in that section.
- Supports the proposed timeframes for application categories.
- Provisionally supports the proposed fee structure, dependent upon the release of the Cost Recovery Implementation Statement, and further detail about the minimum data requirements and product assessments.
- Sees the need for targeted post-market assessments but maintains that a risk-commensurate approach needs to be adopted.
- Only supports publication of limited post market information, and only once all rights of appeal by the sponsor have been exercised.
- Suggests great caution must be exercised in proposing greater post market penalties and publication of sponsor information, and that this process should be put on hold while implementation of significant reforms is taking place.
- Suggests educational tools that will support all elements of the regulatory processes.

CMA is available to work with the regulator on specific considerations with the intention of stream-lining business processes.