An Roinn Sláinte
Department of Health

2023

The Mazars Report

STAKEHOLDER SUBMISSION

The Department of Health is holding a public consultation to give stakeholders the opportunity to provide feedback on the recommendations of the Mazars Report on the governance of Ireland's drug pricing and reimbursement system.

Your views are very important to us, and we will carefully assess all feedback received. Feedback will be used to inform the implementation of recommendations from the Report.

Please note: The focus of this survey is the recommendations made in the Mazars Report. We welcome responses to all questions, and there will be an opportunity at the end to provide any additional general comments.

The feedback from your consultation will be used to assist the work of the Mazars Implementation Working Group. Any information you provide will be held securely and will not be published, subject to legal requirements under Freedom of Information (FOI) legislation or where you are responding on behalf of an organisation, in which case the name and type of organisation will be published in the Summary of Stakeholder Involvement Report.

The closing date for the public consultation is:

5pm, 16 June 2023.

Instructions for submitting feedback

- The Mazars Report is available at www.gov.ie
- Please combine all feedback from your organisation into one submission. We request that you supply a name and contact number for a designated representative from your organisation in case we need to verify the authenticity of your contribution.
- When referring to a specific section of the Report, please include the section and page number that you are commenting on.
- Please do not paste other tables into the boxes already provided – type directly into the box as it expands.
- Please spell out any abbreviations that you use.

You can email or post a completed form to us

Mazars Implementation Working Group
Department of Health
Block 1, Miesian Plaza
50-58 Lower Baggot Street
Dublin
D02 XW14

mazarsworkinggroup@health.gov.ie

Data Protection Privacy Notice – The Mazars Implementation Working Group

The Department of Health is committed to protecting the rights and privacy of individuals in accordance with Data Protection legislation.

Within the Department, this project is being operated by the Mazars Implementation Working Group, who can be contacted at mazarsworkinggroup@health.gov.ie.

Purpose of Project

The purpose of this project is to seek submissions relating to the Mazars Review of the Governance Arrangements and the Resources currently in place to support the Health Service Executive reimbursement and pricing decision-making process. Submissions will inform the work of the Implementation Working Group.

The type of personal information we collect

To deliver this project, we are collecting and processing the following personal data:

- Names and email addresses.

How we receive the personal information

The personal information processed in this project is provided to us directly by you in the submission to the Implementation Working Group.

Lawful processing

Under the General Data Protection Regulation (GDPR), the lawful basis we rely on for processing this information are:

a. We need it to perform a public task.
b. We have a legitimate interest.

Your submission will inform the work of the Implementation Working Group addressing the Health Service Executive's drug pricing and reimbursement process. As a stakeholder in this process, your submission provides valuable insight to the group on the process.

How we store your personal data

Your information is securely stored on the Department's shared drive, with access restricted to specific team members only.

This information will be retained only for as long as is necessary for the specified purpose for which it was collected. The intended retention period for this data is five years, following which, the information will be securely destroyed in accordance with the Department of Health's obligations under the National Archives Act.

This information will not be subsequently used for any purposes other than the original reason for which it was collected. Your information will not be processed outside of the EEA.

How we share your personal data

In some instances, personal information held by the Department is shared with other Departments/Agencies to enable the Department to perform its functions. In such cases the disclosure is made in a manner consistent with the original purpose for which the information was provided.

In this instance, there will be no further sharing of your personal data.

Your data protection rights

Under data protection law, you have rights including:

- Your right of access - You have the right to ask us for copies of your personal information.
- Your right to rectification - You have the right to ask us to rectify personal information you think is inaccurate. You also have the right to ask us to complete information you think is incomplete.
- Your right to erasure - You have the right to ask us to erase your personal information in certain circumstances.
- Your right to restriction of processing - You have the right to ask us to restrict the processing of your personal information in certain circumstances.
- Your right to object to processing - You have the right to object to the processing of your personal information in certain circumstances.
- Your right to data portability - You have the right to ask that we transfer the personal information you gave us to another organisation, or to you, in certain circumstances.

Please contact us at dpo@health.gov.ie if you have a query in relation to data protection.

Right to make a complaint

You have the right, if you are unhappy with how we have delivered on our obligations, to make a complaint at any time to the Data Protection Commission.

You can contact the DPC by webforms on their website www.dataprotection.ie

31st May 2023

Contents

About your organisation

Please provide your organisation's name and contact details below.

IPPOSI – the Irish Platform for Patient Organisations, Science, and Industry

Derick Mitchell, CEO & Laura Kavanagh, Research & Advocacy Manager

Please briefly summarise the purpose of your organisation.

IPPOSI is a patient-led, multi-stakeholder platform which aims to put the patient voice at the centre of health policy and health innovation.

Recommendations

The Mazars Report made 17 recommendations which could be considered to improve the governance arrangements of Ireland's drug reimbursement process:

Ownership of the process

1. The HSE must ensure that it assumes full responsibility for all documentation and communications relating to the process. These communications should only originate either from the HSE website or from appropriate HSE employees.

Transparency and representation

2. The HSE should introduce an application tracker on its website which details when an application is received and whether the application is progressing through the process.
3. Lack of information should be addressed by fully documenting the process and ensuring this is readily available to the process stakeholders through the HSE website, which should define the actors in the process and their roles, the pathways for an application, the possible outcomes, and timelines.
4. The HSE should consider whether opening part of the HSE Drugs Group meeting to the public is appropriate for the Irish process.
5. All applications should continue to receive clinical input as required. However, the rationale for seeking clinical input or not should be documented for all applications to improve governance in this area.
6. Consideration should be given to having a representative from the pharmaceutical industry on the HSE Drugs Group.

Timelines and process efficiency

7. Introduce indicative timelines for completing the process steps to increase transparency for the stakeholders.
8. The HSE should introduce decision points within the process based on information quality, pricing, and timelines that would require the process to end where an applicant was unable to meet process requirements and would be necessitated to resubmit an application later when the issue had been resolved.

Negotiations

9. The HSE should consider limiting the number of times that pricing negotiations can be reopened and the length of time that can be dedicated to those negotiations in order to improve efficiency in the process.
10. Consideration should be given as to when is the most appropriate time in the process to engage in pricing negotiations or whether it is more appropriate to engage in pricing negotiations external to the process.

Patient involvement in the process

11. The Corporate Pharmaceutical Unit (CPU) should receive patient submissions instead of the National Centre for Pharmacoeconomics (NCPE). It should also be made clear where these patient submissions will be considered i.e. at the HSE Drugs Group evaluation stage.
12. The introduction of a patient liaison team would facilitate more active participation by patient groups in the process and would confirm the HSE's commitment to patient participation in the process.

Monitoring and review of the process

13. It would be prudent to introduce an independent review process which would assess a sample of applications on an annual basis to understand if the applications are adjudicated in line with the process and whether the decisions made in relation to the applicants are consistent.
14. An SLA between the HSE and the NCPE should be put in place.

Resourcing

15. Resource gaps identified in the NCPE and the NCCP TRC should be fully reviewed and addressed. As detailed in the report, the resource gaps equate to: 8 WTE for the NCPE, a dedicated administrative resource and a pharmacist in the NCCP TRC.
16. In the CPU, there is a requirement for legal support for pricing negotiations. At present the CPU does not have access to this support. Further, we have identified a requirement for specialist negotiation training for the CPU team as they are not trained negotiators. The recommendation is to fill the above three gaps.
17. The HSE must ensure that there are appropriate staff succession plans in place in each of the actor organisations within the process.

You are invited to provide your feedback on each of these recommendations. If you do not wish to provide feedback on certain items, this will not affect the consideration of any feedback you do provide on other items.

For each item, it would be appreciated if you give thought to:

1. The merits of the recommendation,
2. How best to implement the recommendation,
3. The effects of the implementation of the recommendation.

Ownership of the process

Please provide your feedback on **recommendation 1**: The HSE must ensure that it assumes full responsibility for all documentation and communications relating to the process. These communications should only originate either from the HSE website or from appropriate HSE employees.

The HSE should lead on the development of a process description document to publicly communicate the process and its various stages. This should include the stages at which the patient experience is considered. Patient representatives should be involved in the drafting of this document to ensure that the process is communicated in a way which is understandable and comprehensive.

During this development, the HSE would be minded to gather from patient representatives the key pitfalls from a patient perspective in relation to the process and its various stages, with a view to keeping the process description document a 'live' document for future revisions to the process. The HSE should make provision for the regular review of the process. It should also make provision for the independent audit of the process.

There should be single point of entry on the HSE website for stakeholders seeking to access documentation about the process. This digital entry point should be widely communicated, and it should be readily identifiable from the web menu options.

There should be a single point of contact within the HSE for stakeholders seeking to obtain documentation about the process, or submit queries about aspects of the process, or to request updates on the status of the process. This contact point should be widely communicated, and it should serve as a responsive and informed liaison with stakeholders.

Transparency and representation

Please provide your feedback on **recommendation 2**: The HSE should introduce an application tracker on its website which details when an application is received and whether the application is progressing through the process.

There is currently no way for patients to track the progress of an application through the system.

The HSE should urgently seek to implement an application tracker. The tracker should detail:

- **The date an application is submitted to the HSE CPU**
- **The status of the application within the overall process e.g rapid review submitted to the NCPE or under review by the NCPE or NCPE review completed**
- **The date an application is scheduled for review by the HSE Drugs Group**
- **The date an application is reviewed by the HSE Drugs Group**
- **The date an application receives a recommendation from the HSE Drugs Group, and the positive or negative details of that recommendation**
- **The date an application is scheduled for review by the HSE SLT**
- **The date an application is reviewed by the HSE SLT**
- **The date an application receives a final decision, and the positive or negative details of that recommendation, and in the case of a positive recommendation, the approved indications**
- **The date the application is listed on the reimbursement list**

For rare diseases, the tracker should indicate whether the application has been reviewed by the Rare Diseases TRC and it should provide details of the Rare Diseases TRC determination.

To ensure accessibility for patients and the public, the tracker should at all times include the name of the product under application, the details of the company making the application, and the details of the therapeutic area.

The tracker should be searchable by product name, by therapeutic area, by status (received, scheduled for review, under review, with recommendation, decision), and by time (more than 180 days, less than 180 days). A list of applications (without a searchable function) is not a tracker.

All web content must be clearly written and made accessible using Web Content Accessibility Guidelines WCAG 2.1 AA compliance.

Please provide your feedback on **recommendation 3**: Lack of information should be addressed by fully documenting the process and ensuring this is readily available to the process stakeholders through the HSE website, which should define the actors in the process and their roles, the pathways for an application, the possible outcomes, and timelines.

The HSE should provide a process description document to publicly communicate the process and its various stages. In addition to a process description document, the HSE should regularly publish a range of documents pertaining to the various stages of the process (see bullet points below). This two-pronged approach will allow patients and members of the public to have 1) a theoretical understanding of the process and 2) an overview of the practical application of the process.

- **The agenda of the HSE Drugs Group should be published 14 days in advance of the meeting. The agenda should contain the list of applications due to be considered at that meeting.**
- **The time lag for publishing minutes of the HSE Drugs Group should not exceed 6 weeks. The current time lag is in the range of six months.**
- **The agenda of the HSE SLT (the items relating to drug reimbursement) should be published 7 days in advance of the meeting. The agenda should contain the list of recommendations from the HSE Drugs Group due to be decided upon at that meeting.**
- **The decisions of the HSE SLT should be communicated publicly within 2 weeks of the meeting.**

The information gathered during the horizon scanning part of the process should also be made publicly available. This allows patients and members of the public to prepare for applications coming down the tracks which are of interest to them or to their community.

Please provide your feedback on **recommendation 4**: The HSE should consider whether opening part of the HSE Drugs Group meeting to the public is appropriate for the Irish process.

The consideration given to patient evidence during the process is largely unknown. To address this shortcoming, patients who have submitted evidence in relation to an application should be invited to make a short presentation – either via pre-recorded video or in-person at the start of the relevant HSE Drugs Group meeting. The latter allows for the HSE Drugs Group members to have the opportunity to ask questions of the patient representatives. At a minimum, this portion on the

HSE Drugs Group meeting should be public. This approach mirrors the approach taken by NICE and SMC where meetings are open to the public.

A patient partnership team (or patient liaison team) should be established within the HSE CPU to facilitate this engagement between the patient community and the HSE Drugs Group.

This team should be responsible for collecting patient submissions and for presenting this patient information to the HSE Drugs Group members in instances where a patient representative is not available to attend the HSE Drugs Group meeting.

This team should ensure that the Drugs Group indicates in its recommendation how patient submissions have been considered, and the team should communicate the Drug Group's considered opinion to the relevant patient groups.

Please provide your feedback on **recommendation 5**: All applications should continue to receive clinical input as required. However, the rationale for seeking clinical input or not should be documented for all applications to improve governance in this area.

Like patients, clinicians with an interest in a particular application (because of how it relates to their speciality) should be able to submit a written submission to the HSE Drugs Group. This submission should be considered in the final decision, and details on how it has been considered should be included in the final recommendation to the HSE SLT.

In the case of rare disease applications where a negative recommendation is likely, the Rare Disease TRC should be required to review the application to ensure that clinical and patient evidence is given the full weight it deserves. Consideration should be given to running the work of the Rare Disease TRC parallel to the work of the NCPE, like the NCCP does, rather than wait to later in the process when the application is with the HSE Drugs Group.

The experience of using Clinical Advisory Groups (CAGs) by the NCCP TRC should be considered for use in the mainstream reimbursement process.

In a recommendation report, the rationale for seeking clinical input (or not) should be clearly documented. This explanatory note should be included (in full) in the public minutes.

Please provide your feedback on **recommendation 6**: Consideration should be given to having a representative from the pharmaceutical industry on the HSE Drugs Group.

Examples from other jurisdictions demonstrate that industry representatives can be involved in the process. When recommendations and decisions are being formulated, it is likely that this representative can share 1) the impact on the specific application, but 2) the impact on the pharmaceutical market more broadly. They may also be able to provide information on the status of applications in other countries, or the types of similar applications coming down the pipeline in the future. Industry representative with a medical, regulatory, or clinical science background may also be able to provide valuable insight into clinical trial data. Conflicts of interest can be declared as per current HSE Drugs Committee procedures.

To start with, perhaps a representative with previous understanding of the industry (now retired or consulting or with an umbrella association) could be co-opted onto the HSE Drugs Group as a participating but non-voting member.

Please provide your feedback on **recommendation 7**: Introduce indicative timelines for completing the process steps to increase transparency for the stakeholders.

The introduction of indicative timelines would be a welcome addition for patients and their representatives. The current lack of information available on which applications have entered the system and where they are at within that system is very frustrating.

The practice of making HSE Drugs Group agendas publicly available 14 days before the meeting (and the HSE SLT agendas publicly available 7 days before the meeting) would also be a strong step towards making the process more transparent.

Greater efforts also need to be made to publish the recommendations of the HSE Drugs Group and the decisions of the HSE SLT in a timely manner. Patients with an interest in a particular medicine should not have to hear about the outcomes of applications from 1) the media 2) the industry 3) the 'grapevine'. It is also worth nothing, that the industry applicant hears confidentially from the HSE Drugs Group about the outcome of their application, rather than the information being made part of the public record.

Timelines and process efficiency

Please provide your feedback on **recommendation 8**: The HSE should introduce decision points within the process based on information quality, pricing, and timelines that would require the process to end where an applicant was unable to meet process requirements and would be necessitated to resubmit an application later when the issue had been resolved.

Breaking down the process into more manageable chunks with specific requirements which need to be met to advance to the next stage of the process seems reasonable.

The specific requirements identified for each stage would need to be realistic, and co-developed with stakeholders (patients, clinicians, industry and topic experts), rather than worked up internally.

The decision to require an applicant to resubmit an application at a later date should be made by the HSE Drugs Group and publicly documented in the minutes, with the rationale for the decision clearly detailed.

Negotiations

Please provide your feedback on **recommendation 9**: The HSE should consider limiting the number of times that pricing negotiations can be reopened and the length of time that can be dedicated to those negotiations in order to improve efficiency in the process.

In the interests of the patient community, we are not sure that we could ever approve a process change which would obligate the HSE Drugs Group to provide a recommendation (either positive or negative) to the HSE SLT based on an arbitrary number of pricing renegotiations.

Negotiations are frustrating for all involved in the process, but are unfortunately part of the process, unless we find a better way to set pricing, for instance, by measuring the outcomes delivered for patients based on real-world data.

Please provide your feedback on **recommendation 10**: Consideration should be given as to when is the most appropriate time in the process to engage in pricing negotiations or whether it is more appropriate to engage in pricing negotiations external to the process.

No comment

Patient involvement in the process

Please provide your feedback on **recommendation 11**: The Corporate Pharmaceutical Unit (CPU) should receive patient submissions instead of the National Centre for Pharmacoeconomics (NCPE). It should also be made clear where these patient submissions will be considered i.e. at the HSE Drugs Group evaluation stage.

The role of the patient across the process requires more consideration, and ideally a meeting with all patient organisations and representatives can be called to make some concrete suggestions which will improve the experience for all. The consideration of patient evidence and patient experience across the process is particularly confusing, and this issue needs to be addressed through dialogue with the patient community.

One tool in use for capturing the patient perspective is the patient submission form. However, the purpose and timing of patient submission are not clearly understood. From our observation, as patient submissions are not considered as part of the NCPE assessment process, it would seem appropriate that these submissions are received elsewhere in the process.

It is worth noting that the current patient submission process is described as a challenge by many in the patient community. Small patient organisations and informal groups do not have the resources or expertise to engage in this part of the process. Some of the larger patient member organisations who have participated in this part of the process estimate that it has taken them more than 200hours to collect the necessary evidence and data from their patient groups, without any feedback on its consideration. For this to make sense, the HSE Drugs Group must detail in its minutes how due regard is given to the patient submissions in its final decision. The system as a whole also needs to provide patient representatives with education and training on what evidence can best support the assessment of applications.

The patient submission rarely meets the criteria of scientific evidence for HTA, and it therefore not considered by the NCPE as part of the assessment process. If we aim to have a medicines assessment and reimbursement process which is centered around the patient, we must build into the process a number of elements of capturing the patient experience.

The role of NCPE is to consider clinical efficacy, comparative efficacy, and clinical benefits and outcomes. In carrying out this function, the NCPE (and HIQA as part of its HTA function) needs to develop generic measures to assess the patient experience. Questions arise around how this experience can be gathered, assessed and weighted, but whereas these questions are challenging, this does not mean that this experience should be excluded. Using systematic methodologies, assessment teams should be required to gather evidence about the patient experience as part of their assessment.

The lack of infrastructure in Ireland to collect information about patients with different conditions is a challenge. We know little about their current treatments, the efficacy of these treatments, the

side effects of these treatments, and the outcomes resulting from these treatments. We need a digital health information management system which allows us to capture this data and this data must inform the assessment and reimbursement process. Persons working within this process must develop the business cases to secure funding from the Department of Public Expenditure, and push for this infrastructure to be put in place, urgently and comprehensively.

In Ireland the assessment of clinical efficacy typically ends at the point of reimbursement. This is not a modern system. We need to be able to rely on real-world data to tell us how patients are responding to certain treatments, which patients are responding to certain treatments, and which treatments are not delivering as promised. We need to be able to remove treatments which are not delivering from our reimbursement lists to free up resources for new treatments which may offer better outcomes.

In 2019, IPPOSI published a Charter on Patient Involvement in the Medicines Assessment and Reimbursement Process. There are many elements included in the Charter which could improve the way patients are involved across the process. For instance, the involvement of patients in the horizon scanning part of the process, and the publication of this information among patient communities, could help patient organisations prepare their evidence for applications coming down the tracks. Another example is the involvement of patients in the preparation of early access schemes or managed access protocols (where typically only clinicians are consulted).

Please provide your feedback on **recommendation 12**: The introduction of a patient liaison team would facilitate more active participation by patient groups in the process and would confirm the HSE's commitment to patient participation in the process.

The patient liaison team should rather be a patient partnership team, and part of the remit of this team should be to collect written patient submissions and to facilitate the presentation of these submissions to the HSE Drugs Group (either by organising for the patient representatives to present themselves in person or by presenting the submissions on behalf of patient representatives). This team should ensure that the Drugs Group indicates in its recommendation how patient submissions have been considered, and the team should communicate the Drug Group's considered opinion to the relevant patient groups.

The patient liaison team should provide training on 1) the assessment and reimbursement process in general and 2) the patient submission part of the process. Ideally, trainings should be co-developed with patient organisations and co-facilitated with patients who have experience of the assessment and reimbursement process.

Monitoring and review of the process

Please provide your feedback on **recommendation 13**: It would be prudent to introduce an independent review process which would assess a sample of applications on an annual basis to understand if the applications are adjudicated in line with the process and whether the decisions made in relation to the applicants are consistent.

An independent audit of the process is a strong recommendation. We ask that patient representatives are included in the audit/review team. The perspectives of the patient

representatives involved in the audit/review team should be given a special section within the final audit/review report.

In selecting applications for audit, we ask that these are randomly selected, with consideration given to ensuring that they represent a variety of therapeutic areas and a variety of therapeutic products.

Please provide your feedback on **recommendation 14**: An SLA between the HSE and the NCPE should be put in place.

The recommendation seems a reasonable one.

Resourcing

Please provide your feedback on **recommendation 15**: Resource gaps identified in the NCPE and the NCCP TRC should be fully reviewed and addressed. As detailed further in the report, the resource gaps equate to: 8 WTE for the NCPE, a dedicated administrative resource and a pharmacist in the NCCP TRC.

The recommendation seems a reasonable one.

Please provide your feedback on **recommendation 16**: We have identified the requirement for legal support for pricing negotiations for CPU. At present the CPU does not have access to this support on a consistent basis. Further we have identified a requirement for specialist negotiation training for the CPU team as they are not trained negotiators.

The recommendation seems a reasonable one.

Please provide your feedback on **recommendation 17**: The HSE must ensure that there are appropriate staff succession plans in place in each of the actor organisations within the process.

The recommendation seems a reasonable one.

General feedback

If you wish to provide feedback on Ireland's pricing and reimbursement process beyond the recommendations of the Mazars Report, please do so here.

NOTE: **In line with commitments to transparency, communication and dialogue, the full membership of the Mazars working group should be published, and work plans and progress reports should be also published in a comprehensive and timely manner to allow for feedback and stakeholder engagement.**

The HSE SLT are the ultimate decision-maker, however in the absence of a National Director for Patient Engagement or Patient Partnership, we underline that there is no key decision-maker who is truly capable of reflecting the patient perspective on the HSE SLT. While this is a broader point, we think that it is time for a rethink of how the patient voice is represented within the HSE SLT more generally.

The unmet needs of the rare disease community in Ireland cannot be a secondary consideration. A solution for rare disease applications and the role of the Rare Disease TRC is given little consideration in the Mazars report. Given that the Joint Oireachtas Health Committee Report on Evaluating Orphan Drugs laid the groundwork for the commissioning of the Mazars review, it is somewhat out-of-sync that the review itself does not advance government policy in this area. The TRC was established to address a serious concern within the process, namely the poor consideration of rare disease applications. The Rare Disease TRC must be given a more visible and timely role and they must be required to give a decision on each rare disease application which receives a negative recommendation. As mentioned above, the work of the Rare Disease TRC might be better initiated at the NCPE part of the process. Resources must be allocated to support this TRC.

The issue of remuneration for the important work which patient representatives on the HSE Drugs Group and on the Rare Disease TRC requires immediate rectification. The review of application documentation is an arduous task and requires technical skill. The time offered by these patient representatives must be valued. Remuneration scales in other jurisdictions provide a guide as to how to resolve this. The draft Patient Voices Partners (PVP) policy recently produced by the Department of Health is unlikely to adequately address this issue.

The HSE should annually (i.e by December 2024) produce a public report on the performance of the process in the preceding 12 months (i.e. for the period Jan-Dec 2023). This report should include the number of applications pending within the process which are under 180 days, under one year, in under 18 months, in under two years, in under three years, in under four years etc.

The Mazars recommendations are the norm in many European Member States, and they are unlikely to deliver a broader reform of the assessment and reimbursement process in terms of how we plan for an increasing number of applications, and an increasing number of personalised/innovative medicines applications. The process by which applications are assessed and reimbursed in Ireland is in need of reform if Irish patients are to access new innovations on par with their European counterparts.

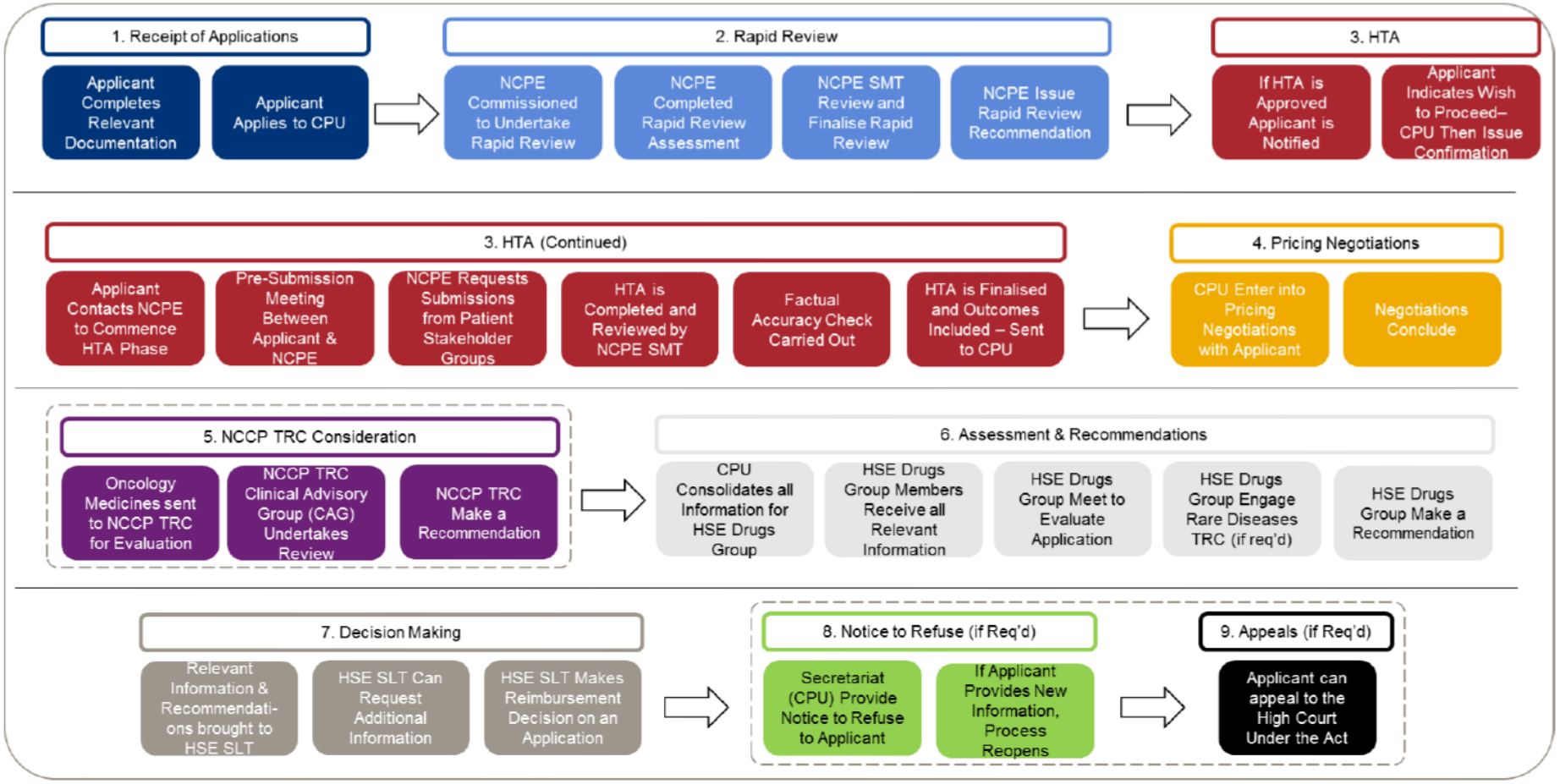
This reform process needs to be informed by a multi-stakeholder advisory panel comprising of patients, clinicians, industry and topic experts. This advisory panel should work in partnership with the Department of Health and the HSE to prepare a national strategy to ensure sustainable access to innovation for the next 10/20 years. The reform process should review how neighbouring countries have addressed access and affordability challenges in their own markets. A forward-looking approach is a necessary next step to ensure that we future-proof our system today for the challenges of tomorrow. It should also prepare Ireland for changes at the EU level, including the consideration of joint clinical assessments, and it should develop an assessment and reimbursement process which relies on and takes advantage of digital health information management systems. The reform process should also focus on designing a unique route for rare disease innovation to ensure that the most vulnerable in our patient community have timely access to life-changing and often life-saving therapies.For more information on our work in this space, please refer to:

- IPPOSI EU consultation response to HTA, Jan 2022
- IPPOSI EU consultation response to the revision of the general pharmaceutical legislation, Dec 2021
- IPPOSI EU consultation response to the revision of the rules on medicines for children and rare diseases, July 2021

- IPPOSI recommendations for the renegotiation of the agreement between IPHA and DoH, May 2021
- IPPOSI Access to Medicine Digital Discussion Report, Sept 2020
- IPPOSI EU consultation response to the pharmaceutical strategy, Sept 2020
- IPPOSI Charter for Patient Involvement in Medicines Assessment and Reimbursement, Feb 2019
- IPPOSI consultation response to the NCPE patient submission template, May 2018
- IPPOSI/MRCG Drug Iceberg Report 2.0, Feb 2018
- IPPOSI/MRCG Drug Iceberg Report 1.0, Aug 2017

The Process

The below image illustrates Ireland's medicines pricing and reimbursement process.



Thank you

Thank you for taking the time to give us your views on the Mazars Report.

Please return your form to us by email or post.

You can email the completed for to mazarsworkinggroup@health.gov.ie

Or

Print the consultation form and **post** the completed form to:

Mazars Implementation Working Group
Department of Health
Block 1, Miesian Plaza
50-58 Lower Baggot Street
Dublin
D02 XW14

If you have any questions on this document, you can contact the Working Group by email at: mazarsworkinggroup@health.gov.ie

Please ensure that your return your form to us by **5pm, 16 June 2023.**