Statens legemiddelverk
*Norwegian Medicines Agency*

Nordisk ministerråd

# Better access to medicines for children in the Nordic area: Possibilities for closer collaboration and joint policy?

## SUMMARY


- Several important medicines for children are not marketed in the Nordic countries. The limited market in each Nordic country probably contributes to the fact that important medicines for children are taken off the market or never marketed at all. A coordinated Nordic collaboration in this area could contribute to making the Nordic region a more attractive market and thereby ensuring stable access of a broader selection of important medicines for children
- **The main objective** of this project was **to explore the possibilities for closer Nordic collaboration** to ensure better access to authorised and marketed products for children in our countries
- **The main conclusion** is that there is a clear potential for closer collaboration between the Nordic medicines authorities related to medicines for children; Both product specific, case-by-case collaboration, but also at a more overarching, strategic level. The opportunities within a joint policy and potentially a more proactive role of the Nordic medicines authorities should be further explored.
- Our regulatory system and procedures are complex. None of the existing Nordic structures are suited to directly implement any such 'cross-product/cross-discipline' collaboration. The network that has been established through this project could serve as a starting point for collaboration and should be further strengthened and operationalised.
- A 12 month pilot is recommended to collect experience based on product- and procedure specific cases, to further identify collaborative elements.
- To implement a more structured and closer collaboration within the Nordic NCAs, resources will be needed accordingly, as well as entrenchment within and between our organisations.


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## Abbreviations

| | |
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| CMS | Concerned member state |
| CP | Centralised procedure |
| DCP | Decentralised procedure |
| EEA | European Economic Area |
| EU | European Union |
| MA | Marketing authorisation |
| MAA | Marketing authorisation application |
| MAH | Marketing Authorisation Holder |
| MP | Medicinal product |
| MRP | Mutual Recognition Procedure |
| MS | Member State |
| NCA | National Competent Authority |
| NOMA | Norwegian Medicines Agency |
| PI | Product information |
| RMS | Reference member state |
| RUP | Repeat Use Procedure |

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# 1. INTRODUCTION

## 1.1 Background, problem statements

Many paediatric medicines are not marketed in the Nordic countries. This applies both to products used in primary healthcare and in hospital care, and in particular for medicines intended for the youngest children. Examples are low-strength tablets and oral liquids.

Most member states (MS) have in place various exemption schemes to compensate for the lack of marketed products. These exemptions serve an important role, but extensive use of such schemes creates various challenges, both for healthcare professionals, and for the children and their guardians. Bringing to the market medicines licenced in the Nordic countries would ensure (better) control of product quality, more predictable availability, facilitate prescribing and better possibility of price regulation. It also ensures access to product information (PI) in national languages, as well as adherence to requirements for product life-cycle follow-up and regulatory maintenance. From a clinical perspective this would enable safer use of medicines in children, reduce the need of manipulations and off-label drugs use and support better compliance.

The decision to apply for marketing authorisations (MA) and to market the products lies completely with the individual pharmaceutical companies. The reasons behind the limited availability of many important paediatric medicines are complex and differ between products. One of the main reasons is low estimated profit, alternatively, too many elements of uncertainty connected to the profit estimation. The MAA process requires both economic and technical investment, and this is often more or less independent of any expected sales volume and price. The assembly of proper documentation on quality, safety, efficacy, PI etc can be costly and the application procedure is often resource demanding. Another cost is the fees associated with an application. Children are also a relatively small patient group regarding medical use, and many medicines are used for a shorter period. Several MS have policies in place to keep prices down. Low sales volumes, especially in combination with low prices, significantly increase the risk for a product not being marketed. Consequently, smaller markets such as those in the Nordic area are generally more affected by such availability issues than larger countries.

These challenges are often seen for older, off patent, medicines, but are also relevant for new medicines: The Paediatric Regulation (2006/1901) requires companies to research and develop new MPs for children in EU/EEA, but do not oblige the companies to market their paediatric products in all countries. A recent study* showed that 29%–50% of the new paediatric-relevant formulations approved in the EU since the implementation of the Regulation were not marketed in the Nordic countries. Thus, despite being developed, licenced and available in some parts of Europe, access to such MPs in the Nordic area is hampered and consequently, the treatment options are limited for our youngest population. The Regulation opens for further incentives by MS to support availability of MPs for children. Collaboration initiatives within the Nordic area are options that should be explored, to facilitate authorisation and marketing processes for such products.

**: Lepola P et al. (2020) Does the EU's Paediatric Regulation work for new medicines for children in Denmark, Finland, Norway and Sweden? A cross-sectional study. BMJ Paediatrics Open; Dec 30;4(1):e000880. doi:10.1136/bmjpo-2020-000880*

## 1.2 Main objective and interim goals

The main objective of this project has been to explore the possibilities for closer Nordic collaboration to ensure better access to authorised and marketed MPs for children in our countries. A long-term objective could be to establish collaboration within identified relevant areas and enable the Nordic area to potentially serve as one common market for such MPs.

The interim goals:

- To establish dialogue between the Nordic NCAs regarding the limited availability of MPs for children
- To identify common challenges in obtaining authorised and marketed paediatric MPs, and evaluate potential forms of collaboration to solve these
- Where/if collaboration seems appropriate, propose a plan/strategy for this

The main elements in the project were: A preparatory NCA survey, a workshop, an MAH survey, and overall network building.

# 2. DELIVERABLES AND ACTIVITIES

## 2.1 Project organisation

The project has been led by Norway (NOMA). National contact points were identified, and NCA representatives from Denmark, Finland, Iceland, Sweden and Norway were involved, covering different areas of expertise, *e.g.*, regulatory, paediatric, shortages, legal, and pricing. The Nordic project group counted 17 participants in total. One face-to-face workshop and two virtual meetings were arranged for the full group. The primary focus of this project was on the involvement of the national regulatory authorities. However, input from other stakeholders was ensured.

## 2.2 NCA survey on current practice

Prior to the workshop, a survey to map the current situation was distributed to each national contact point. The purpose of the survey was twofold: Firstly, to raise awareness and start preparations and discussion within each MS prior to the workshop. Secondly, for the organisers of the workshop to obtain an impression of current practices within each MS, enabling identification of topics to be further elaborated during the workshop and potential areas for collaboration.

MS were asked to provide information about which measures and/or incentives, if any, were currently being used to facilitate the MA process and marketing of critical paediatric MPs. Further, MS should specify to what extent such measures and incentives are being used, and which are considered most effective. They were asked to comment whether they believe a closer Nordic collaboration could be useful, and if so, which areas would have the most potential. They were also asked to identify obstacles (legal and other) to a closer Nordic collaboration.

The main outcomes of the survey demonstrated that most MS already use various incentives and tools to facilitate the MA process and marketing of critical MPs. Overall, incentives and tools are used on a case-by-case basis, depending on the specific situation and the challenges it represents. No MS has measures in place specifically targeted to critical paediatric formulations. For most MS, there seems to be limited systematic approach and lack of clear decision-making process at national level. It is difficult for MS to draw a general conclusion on which measures are most effective. Depending on the situation, it will vary whether regulatory or economic tools are deemed the most appropriate and effective.

Regarding existing areas of collaboration, the common Nordic Product Information (PI) is the most widely used. The use of accelerated Mutual recognition procedures (MRP) to facilitate obtaining MAs in new MS is used actively by some MS. Accelerated procedural timelines in Decentralised procedures (DCPs) was also mentioned.

Regarding obstacles for (further) Nordic collaboration, the lack of existing contact points between MS and appropriate structures within MS to handle these cases in a systematic approach was considered most important. Furthermore, there is currently no common objective and/or prioritisation across the Nordics that would facilitate collaboration. There also seems to be limited systematic use of incentives within each MS, leading to insufficient experience and understanding of which incentives are the most attractive and efficient. Appointing dedicated contact points at MS level was seen as a prerequisite to enhance collaboration. Furthermore, optimising and facilitating for common Nordic PI and making available industry guidelines for the use of accelerated MRP Repeat Use procedure (RUP) was mentioned.

For relevant new MPs that either have been applied for or have obtained MA through CP, collaboration to evaluate the joint Nordic need/ market potential was suggested as useful, ahead of the dialogue with the MAH to promote and facilitate marketing in the Nordics. For desired MPs with an existing national MA in one or more EU MS, but not in the Nordic MS, it was suggested to appoint one Nordic MS as point of contact with the MAH, on behalf of all Nordic MS. The aim would be to streamline communication and negotiation with the MAH, on behalf of the group of MS. This could turn out to be a resource efficient way of work sharing between the Nordic MS. It was suggested to discuss further at a Nordic level in which situations and to what extent deviations from standard documentation could be considered acceptable. Such an understanding could be useful when several MS have an unmet need for the same product and are in contact with an MAH.

Overall, the survey indicated that a closer Nordic collaboration was considered beneficial by all MS, as the Nordic market combined is larger and more attractive to the MAHs.

## 2.3 Nordic Workshop

A workshop was held in Oslo on 20th-21st October 2022, with attendees from all five Nordic authorities. In total, 26 participants attended the whole or parts of the workshop, including five specifically invited external stakeholder participants for the first day. The second day was for authority participants only.

The first day focused on the current situation, problem statements and challenges as seen from different stakeholder perspectives: clinical, industry and regulatory. Two pan-European pharmaceutical industry associations (EfPIA and Medicines for Europe) were invited to present the current situation and challenges from their perspective. A paediatrician presented the current situation and challenges faced in a paediatric ward due to unavailability of paediatric MPs and formulations. Reflections on the regulatory challenges, in particular on roles and remits, were given by NOMA. Further, the preliminary results from the MAH survey performed by NOMA were presented (see 2.4.), as well as a few relevant ongoing national and Nordic

activities related to electronic PI and alternative financial models, initiatives potentially important for paediatric MPs.

The second day started with presentations by each NCA on their current practice and experience related to authorisation and availability of paediatric formulations. This was followed by specific case studies on how certain availability challenges have been solved or could have been solved better. The rest of the day was allocated to the exchange of experiences and discussion to agree whether there is interest in further collaboration to improve the situation in the Nordics. As there was a clear agreement in support of this, the discussion moved to identification of potential areas of collaboration. Action points and discussion items to take back home for further discussion and entrenchment at national level were identified. A follow-up web meeting to provide input from internal discussions in each MS was agreed.

## 2.4 MAH survey

There is limited knowledge of which facilitation measures MAHs consider most relevant. Strategies for business plans differ between companies and can also differ within a company, for example between national offices or between products. Consequently, there is probably no "one-size-fits-all" solution.

As part of this project, a survey was conducted among MAHs on various regulatory measures. The purpose was to gain a better understanding of the industry's view on different measures and their impact on the industry's willingness to apply for MAs, willingness to market and willingness to keep products on the market. A questionnaire was sent to all MAHs with at least one MA in Norway. The questions were related to all phases in the life cycle of a product, including questions on how to facilitate new MAAs, how to get products marketed and how to avoid marketed products being withdrawn. The recipients of the survey were asked to keep small products, such as MPs for children, in mind when answering the questions.

Responses from around 70 companies were received, representing a substantial portion of the total market share. It is clear from the responses that price and sales volume, and predictability thereof, are important factors when developing business plans for new products. It can also be concluded that there is no clear common opinion on which measures and incentives are the most attractive and effective. For example, some companies prefer waived fees whereas others prefer simplified regulatory procedures. Thus, it might be important to make use of all available measures and incentives.

## 2.5 Established dialogue

Through this project, a framework for dialogue between the Nordic medicines agencies has been established. Contact persons with relevant expertise were appointed by each NCA. Representatives from all countries have participated throughout the project period. It has been agreed that further dialogue, both product specific and on broader strategic discussions, should involve the full Nordic group of participants. For some countries, paediatric mailboxes serve as technical contact points.

# 3. CHALLENGES AND POSSIBILITIES

The following reflections on challenges and potential solutions have been identified during this project:

## 3.1 Different authorisation routes imply different possibilities and limitations

Most innovative products are authorised through the centralised procedures (CP), whereas the majority of generic, off-patent, products are authorised via decentralised procedures (DCP) or, more seldom, purely nationally. Products authorised through CP obtain an MA in all EU/EEA MS. However, even though each MS has an MA, the MAH decides in which MS the product will be marketed. For products authorised via DCP, the applicant is free to choose which MS are included in a procedure, *i.e.*, where the product potentially will be authorised. Again, once national MAs are granted, the decision regarding marketing of the product is in the remit of the MAH.

Fewer MS involved in a procedure means that it might be easier to agree on regulatory flexibilities. On the other hand, an MS with an unmet medical need might not be included in the procedure.

Consequently, the options available for Nordic collaboration at authority level will differ depending on the authorisation route.

## 3.2 Potential regulatory measures to obtain an increased number of marketed products

There are several potential measures that can be used as incentives for MAHs to apply for MAs, to market their products and to keep them marketed. These measures are currently used nationally to different degrees and could potentially also be used in procedures that involve several, or all, Nordic MS. It is reasonable to believe that an aligned and joint Nordic approach on such measures could facilitate a common Nordic strategy from pharmaceutical industry perspective.

Open dialogue with MAHs is essential to establish appropriate incentives in order to increase the likelihood of products being marketed and kept on the market. Incentives and opportunities should be communicated and transparent to MAHs.

### 3.2.1 Prioritised procedure

For DCPs, *i.e.*, European marketing authorisation procedures involving several MS, the applicant needs to find a Reference Member State (RMS) who has the main responsibility for assessing the application. For several years, there has been restrained capacity in the European NCAs for accepting RMS responsibilities. This is a general problem, which means that a clear prioritisation of RMS tasks, including prioritising RMS requests for important paediatric products, is important. Procedures for new MAAs are assigned a time slot in accordance with available resources at the RMS. As a result, the start of a procedure is in many cases several months after the applicant's first contact with the RMS. There is no guarantee to receive a start of procedure date within a certain period. One incentive to obtain MAAs for an important MP is to provide a prioritised time slot, *i.e.*, start of procedure.

### 3.2.2 Expedited procedural timelines

The formal timelines as defined in the legislation is different for the different MAA procedures (National procedure, CP, DCP, MRP). A typical DCP procedure takes at least a year including clock-stop. Many MS offer expedited procedural timelines for important MPs. Policies for when to apply this differs between MS.

One extreme example of an accelerated procedure is the "zero-days-procedure" (accelerated MRP Repeat Use Procedure, based on an authorisation already issued in another MS) where an MA is issued immediately after start of procedure. Approaches in-between standard procedures and "zero-days-procedure" are also possible using accelerated assessment. If several MS are involved in such a procedure, all NCAs need to agree on the shortened timeline. Expedited procedural timelines may act as an attractive incentive for companies when applying for an MA.

### 3.2.3 Fee reduction/exemption

NCAs charge fees for regulatory applications, for example for new MAAs and variations (changes) to MAs. Fees are determined on a national basis and each MS has their own systems and rates. The fees can be charged on a one-time basis or annual basis. Many MS also have the option to grant exemptions from fees and this can be used as an incentive for companies to apply for new marketing authorisations, *e.g.* for needed products with low profitability.

### 3.2.4 Price and reimbursement negotiations

Each MS has its national system for how, and by whom, prices and reimbursements are determined. Consequently, flexibility and possibilities for deviations and exemptions also differ between MS. Acceptance of a higher price is a relevant incentive to obtain critical products on the market, and can also be used to keep certain products on the market, *e.g.* for products risking being withdrawn due to low profitability.

Due to the somewhat different structures in each country, collaboration within the price and reimbursement area will be challenging. Still, it could be possible to explore principles to align policies in the Nordic MS.

### 3.2.5 Accepting deficient documentation and deviations from guidelines

MAHs are required to keep the dossier up to date, in accordance with current requirements and practice. Maintaining the dossier and keeping this up to date is a resource demanding activity, and in some cases, this is not always fulfilled. This is especially true for products with low profitability that in turn might have a low focus from the MAH's side. As a result, many older products have a dossier that do not fulfil current regulatory requirements for an MAA. Updating a dossier to current requirements and standards can be very resource demanding and costly. Consequently, any request from an NCA to update the dossier could potentially result in the withdrawal of an application or withdrawal of a product from the market.

For critical products, the risk of not having the product on the market should be balanced against the risk of such suboptimal documentation.

### 3.2.6 Facilitate multilingual packages

There is a legal requirement to have packages and product information (PI) in each national language. For small markets such as the Nordic ones, this is associated with manufacturing challenges and costs. The use of multilingual packages, *e.g.* common Nordic packages, is currently a legal opportunity. However, this possibility could be used more often, and MAHs should be encouraged to do so. The introduction of electronic PI fully replacing paper leaflets is currently discussed at the European level and will require legislative changes. Pilots on e-PILs in products for hospital use are currently in place in Luxembourg/Belgium, Iceland, and the Baltic states, *e.g.* Latvia.

### 3.2.7 Foreign language packages

In some MS, the national language requirements can be exempted for certain products, *e.g.* hospital products, and for a certain time period. For example, English packages and leaflets can be considered

sufficient in some situations. Such exemptions can facilitate for MAHs and manufacturers and act as an incentive to place products on smaller markets.

### 3.2.8 Common Nordic public call for needed products

Most MS have unmet needs for certain medicinal products, and they use different methods to communicate such needs to industry - if communicated at all. NOMA has published on their website a "call for needed products"; a list that includes active substance, formulations, strengths and other relevant information. The published list serves several purposes: One is to communicate the needs in a transparent manner to the public and industry. Another is to give all companies the same possibility to engage in listed products, since exemptions from standard requirements may be considered for these products. It is important to avoid unequal treatment of companies in situations where exemptions might be given, thus leading to unequal competition.

One potential measure that could be evaluated is a common Nordic call for needed products. Such a joint list of 'needed product' could serve as a tool for exchange of information between MS, but also, if public, as a direct tool for MAHs to consider a broader market.

## 3.3 Differences between the Nordic countries could influence measures and perceived needs

Despite being considered similar, the Nordic countries have different structures that might impact both the need for, and the ways to, collaborate within the medicines area. A relevant example is the structure of the pricing and reimbursement bodies, being outside or within the medicines authorities, as separate entities or within governmental structures. Such discrepancies could complicate close collaboration on pricing and reimbursement strategies. Additionally, national legislations might limit possibilities for joint strategies: Up-front discussion and agreement with MAHs on pricing ahead of an MAA, indicated as an attractive incentive by some MAHs, would not be possible in some countries.

There might also be differences between countries to which extent the lack of available authorised and marketed products is perceived as a problem. Facilitating access to and reimbursing unlicensed products would reduce the urgency of having these products authorised and marketed. The degree of national pharmaceutical compounding varies between Nordic MS, and such regular compounding strategies could potentially 'mask' the need for authorised and marketed products for children. Although such strategies are indeed important tools to compensate for the lack of authorised products, it is important to be aware how these differences between countries could affect the perceived problem.

In addition, although our medical traditions in treating children are to a large degree aligned, differences in treatment guidelines do exist also between our countries. This could have a negative impact on any facilitation measures as needs and perceived suitability of products might differ between countries. Clinical collaboration and dialogue to align treatment guidelines would increase the likely market thus also the potential of any facilitation measures.

Finally, any limitations in 'information sharing policies' based on national regulations should be identified and considered, as transparency and exchange of information between NCAs will be a prerequisite for optimal collaboration.

## 3.4 Exchange of information between countries on ongoing procedures

Currently, there is limited and unsystematic collaboration between the Nordic MS related to MAAs. Improved systems for a closer dialogue between authorities at the start of, and during, procedures could potentially facilitate joint decision making and aligned policies.

One MS (Sweden) has agreed to systematically flag to MAHs to include Iceland as CMS when a request for acting as RMS for a new MAA is received. This reminder is included in the response letter template but not actively followed up. It is currently unknown to which degree such initiatives have been efficient. Systematically encouraging MAHs to include Nordic MS in a procedure, if possible and relevant, could be applied by all Nordic MS. The concept of 'always' considering the entire Nordic market should be conveyed when in dialogue with the MAHs.

It is vital that potential opportunities to access markets in the Nordic countries are transparent and integrated into the application process.

## 3.5 Identify 'needed products' in collaboration with clinical communities

Any proactive or accommodating approach by NCAs (either towards other Nordic NCAs or towards MAHs) regarding critical products for children would imply some degree of 'unmet need assessment'. This includes estimating to what degree there is a need for a specific product, and whether it would trigger a 'national-only initiative' or a 'Nordic approach'. Close dialogue with the paediatric clinical community would be essential to identify needed products. Existing Nordic/Scandinavian clinical professionals' structures could be helpful in identifying needs. Dialogue within the Nordic paediatric clinical communities on harmonising treatment approaches would be important in some cases, to possibly reduce the need for country-specific products.

## 3.6 Complexity of the landscape and stakeholders involved

It was decided from the start of the project that initial focus would be limited to national regulatory authorities. Although acknowledged that several non-government stakeholders, *e.g.* pharmaceutical industry and wholesalers, have important roles, there was a need at this stage to focus on collaboration between medicines authorities in order to have an efficient and candid discussion with concrete outcomes. However, input from the perspective of pharmaceutical industry and the paediatric clinician community was ensured during the workshop.

A broader dialogue with all stakeholders in the supply chain, both at national and Nordic level, is recommended to further investigate challenges and potential solutions.

## 3.7 Existing initiatives and structures potentially relevant for Nordic collaboration to increase access to medicines for children

Some areas of Nordic authorities' collaboration and initiatives are in place:

- WGEMA (Working group on exchange of information in the medicines area) under the umbrella of the Nordic Council of Ministers (various workstreams)

- Nordisk Lægemiddelforum (NLF, Nordic Pharmaceuticals Forum): collaboration on supply of hospital pharmaceuticals for the Nordic countries. A framework on joint tendering and price negotiations is currently in place between DK, IS and NO.
- FINOSE is an established collaboration between FI, NO and SE within the HTA area.
- The Nordic NCAs have established the Nordic Package Group. A joint guideline and Q&A on Nordic packages, to assist companies in creating common Nordic packages aiming for a single Nordic market, already exists Guideline on nordic packages (lakemedelsverket.se). A common Nordic approval procedure for packages has also been established.
- Recently, initiatives (national and European) are established related to antimicrobial resistance (AMR) challenges and availability of essential antimicrobial products, involving *e.g.* public health institutions and NCAs. Paediatric formulations are central in this discussion. Related to this topic is an initiative exploring alternative financial models for small but essential products.

In the continuation of this project, it should be considered how to optimise dialogue with and make the most out of these existing structures where relevant.

## 3.8 Regulatory mindset and role perception

**Risk assessment:** NCAs assess documentation on quality, safety and efficacy aspects during approval of MPs, to a certain degree depending on the type of application and procedure. Some requirements are legal, but most of the assessment is based on EU guidelines. A final benefit-risk evaluation is performed where the clinical benefit is assessed against clinical risk. For low profit, but critical products, MS can consider deviations from guidelines in order to increase the MAH's interest to apply for an MA. This is especially relevant for older products where the documentation might not be up to date. For such products, the overall risk assessment should also include the availability aspects, and requirements in guidelines should be weighed against the risk of not having the product authorised and available.

**Role perception:** The role of the NCAs is traditionally defined as reactive rather than proactive. The core responsibility of an agency is to issue MAs for MPs based on a positive risk-benefit analyses. It is regarded as an industry initiative and responsibility to develop suitable products, and to decide where and when to apply for an MA.

It is evident that for areas with an unmet medical need, such as for paediatric medicines, this current model and split of responsibilities is not working satisfactorily for patients. One of several ways to improve this situation is for authorities to take a more proactive role with the overall goal to obtain MAs for unmet needs. Nordic MS have, to a smaller or larger extent, experience in acting in a proactive manner by initiating direct dialogue with industry for unmet medical needs. Impartiality would have to be safeguarded.

The discussion on the regulatory mindset, specifically of what lies within the remit of the authorities, is an overarching discussion. Whether such an expansion of role is considered beneficial may also depend on national contexts and discourses. However, future collaboration would need a certain degree of alignment on this issue.

Risk assessment and role perception are high-level topics, not only relevant to availability of paediatric products but considered essential for the overall discussion on access to products with a limited market.

# 4. CONCLUSIONS AND RECOMMENDATIONS

There is currently no established systematic collaboration between authorities to obtain an increased number of paediatric medicines on the Nordic market. However, it is clear from this project that there is an interest and potential to develop a more systematic collaboration.

The project has shed light on the multifaceted aspects of obtaining products authorised and marketed. As expected, the matter is complex by nature. Still, the potential for Nordic collaboration seems to be evident. Further dialogue is essential at all levels of our organisations and with relevant stakeholders. The overall aim is to make progress on potential practical measures, to implement collaboration and to obtain authorised and available relevant medicines for all children in the Nordic area.

## 4.1 Recommendations:

Closer collaboration between the Nordic NCAs to facilitate MAs and marketing of paediatric products is wanted, should be possible, and needs to be further explored.

### 4.1.1 Structural:

- There is a need for 'Paediatric Contact Points' in all MS, for ad hoc product specific questions and ongoing procedures. This group should aim for regular meetings, not 'ad hoc' only. The group established from this project serves as a starting point.
- The contact points could pave the ground for a broader 'Nordic Paediatric Forum', for both product and procedure specific questions and for general discussions.
- Appropriate structures to enable fit-for-purpose information flow within NCAs is a prerequisite for optimal functioning of such forum and must be ensured.
- A formal role within, or linked to, existing Nordic collaborations is recommended.

### 4.1.2 Collaborative:

- New relevant MAAs should be flagged between MSs
- MAHs should be encouraged to include other Nordic MS in any relevant procedure
- Open dialogue should be undertaken to explore potential alignments regarding requirements and principles for deviations or 'pragmatic approaches', *e.g.* regarding limited dossiers, old documentation, faster procedures etc.
- Systems for sharing information on need for specific products in different Nordic MSs should be put in place, potentially also a common 'list of missing products' for paediatrics, and/or joint public list of unmet needs / 'call for needed products'
- Information sharing on relevant withdrawal notifications and shortages should be improved
- Closer dialogue with the "Nordic Package Group" should be initiated, to increase awareness of challenges related to common Nordic packages
- A pilot should be run (min 12 months) to collect experiences based on specific products and procedures

### 4.1.3 Strategical:

- Any first initiatives should be feasible and realistic. In the longer run, joint approaches should be resource-saving and facilitating, both for industry and for the authorities. The work to enable such collaborative structures should therefore be prioritised, including allocation of resources.
- Entrenchment within the national organisations is essential to ensure implementation of measures proposed or agreed, in particular due to the diversity of expertise and decision-making structures potentially involved within the NCAs.
- Continued dialogue with all stakeholders (industry, clinical community, wholesalers, supply chain organisations, HTA bodies etc.) is important in any follow up of this project, to further explore the Nordic collaborative potential.

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*Participants in this project:*

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|---|---|
| *Siri Wang* | *Norwegian Medicines Agency* |
| *Andreas Sundgren* | *Norwegian Medicines Agency* |
| *Suzanne Gordon* | *Norwegian Medicines Agency* |
| *Guri Wilhelmsen* | *Norwegian Medicines Agency* |
| *Sameer Kohli* | *Danish Medicines Agency* |
| *Louisa Exner* | *Danish Medicines Agency* |
| *Nanna Borup Johansen* | *Danish Medicines Agency* |
| *Ann Marie Tötterman* | *Finnish Medicines Agency* |
| *Minna Myllyntausta* | *Finnish Medicines Agency* |
| *Johanna Kristiina Kaste* | *Finnish Ministry of Social Affairs and Health* |
| *Hanna Varakas* | *Finnish Medicines Agency* |
| *Jana Rós Reynisdóttir* | *Icelandic Medicines Agency* |
| *Hrefna Gudmundsdottir* | *Icelandic Medicines Agency* |
| *Elin Ingibjorg Jacobsen* | *The National University Hospital of Iceland* |
| *Elin Kimland* | *Swedish Medicines Agency* |
| *Oscar Ljungberg* | *Swedish Medicines Agency* |
| *Kristin Karlsson* | *Swedish Medicines Agency* |