Are there any commonalities in payer requirements and reimbursement pathways for medical devices in the DACH (Germany, Austria, Switzerland) region?

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- Germany – Inpatient
  - For the application of a new medical device in the inpatient sector only a CE mark is required.
  - The reimbursement pathway for a new medical device dependent on the available coding, targeting & coverage options.
  - For reimbursement pathways there are specific application procedures available – with a clear process & timing structure.

- Germany – Outpatient
  - For the application of a new medical device in the outpatient sector a positive reimbursement decision is mandatory.
  - Medical devices that are new, modified or controversial to existing comparator therapies may need to go through an appraisal process to be reimbursed.

- Austria – Inpatient/Outpatient
  - High-level clinical and economic evidence.
  - Clinical evidence is required for reimbursement decisions.
  - High randomized controlled clinical trials (RCT’s) were required and if "low" any kind of evidence including small single-arm evidence might be acceptable.

- Switzerland
  - There is no need to provide detailed clinical or health economic evidence during the application process.
  - The reimbursement fee of a new medical device depends on the available coding, targeting & coverage options.

- Austria – Extramural Outpatient
  - Submission by October each year.

Table 2: Commonalities between countries: Outpatient

<table>
<thead>
<tr>
<th>Item</th>
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<tbody>
<tr>
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<td>Timing determined</td>
<td>Submission by October each year</td>
<td>Submissions by given timelines</td>
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</tr>
<tr>
<td>Length of procedure</td>
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<td>1.5 - 2 years</td>
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CONCLUSION:

Despite varying reimbursement processes within the DACH region, there are important similarities between the clinical evidence requirements; especially when it comes to need reimbursement, the BAG will review the report form and advise the manufacturer if the product needs to go through the appraisal process to be reimbursed.

For the inpatient setting, the evidence requirements for clinical and health economic data are different between this analyzed countries.

- The lowest clinical evidence requirements are seen in Germany, while the highest are given in Switzerland (in the scenario of a full HTA submission).
- In terms of health economics the requirements are medium to low. A medium rating was given for Austria and Switzerland (in some scenarios); as a health economic analysis is required (e.g. cost comparison), and a low rating was applied to Germany as limited economic information (cost estimates/compares) needs to be submitted.

- The length of the application process is well defined in Austria and Germany and vague in Switzerland.

Main findings:

- Inpatient Setting
  - In the inpatient setting, the evidence requirements for clinical data are different between the analyzed countries.

- Outpatient Setting
  - In the outpatient setting, the evidence requirements for clinical and health economic data are significantly increasing in all countries analyzed.

Japan

- Clinical requirements are getting close to pharmaceutical methods whereas health economic evidence is requested in all DACH countries.

- The length of the reimbursement process is not clearly defined in all three countries.

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Figure 1: Reimbursement pathways for medical devices in Germany

- Germany – Inpatient
  - For the application of a new medical device in the inpatient sector only a CE mark is required.
  - The reimbursement pathway is of a new medical device dependent on the available coding, targeting & coverage options.

- Germany – Outpatient
  - For the application of a new medical device in the outpatient sector a positive reimbursement decision is mandatory.
  - Medical devices that are new, modified or controversial to existing comparator therapies may need to go through an appraisal process to be reimbursed.
  - The length of the reimbursement process is not clearly defined in all three countries.

Figure 2: Reimbursement pathways for medical devices in Switzerland

- The reimbursement fee of a new medical device depends on the available coding, targeting & coverage options.

- Switzerland
  - There is no need to provide detailed clinical or health economic evidence during the application process.

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