INTRODUCTION TO ENVIRONMENTAL CRITERIA IN NORDIC TENDERS

Inter-Association Initiative, Pharmaceuticals in the Environment

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Sofie Pedersen, Senior Sustainability Specialist, spe@amgros.dk

ENVIRONMENTAL IMPACTS THAT CHALLENGE OUR HEALTH

Higher temperatures are spreading new diseases

Adverse impact on rights to health and a healthy and sustainable environment

Eight billion people means scarce resources and pressure on supplies

Pharmaceutical residues lead to increasing antimicrobial resistance with 5 million deaths per year

HOW WE CAN MAKE A DIFFERENCE

Climate
Reduce energy consumption in supply chain

Responsible Business Conduct
Respect human rights and environment

Circular Economy
Minimize waste by reducing comsumption and increasing recycling

Medicine Residues in Wastewater and Antimicrobial Resistance
Reduce overuse in treatment and pharmaceutical residues in wastewater

Manufacturing

Distribution and Storage

Prescription and Treatment

AWARD CRITERIA TO COMBAT AMR

ANTIBIOTICS ARE AMONG THE MOST ESSENTIAL MEDICINES HOWEVER, AMR IS A SILENT PANDEMIC

- Antimicrobial resistance (AMR) is one of the top global public health and development threats.
- It is estimated that bacterial AMR was directly responsible for 1.27 million global deaths in 2019 and contributed to 4.95 million deaths (The Lancet).
- Overuse, misuse and pharma residue in waterwater from manufacturing led to AMR
- Infections are becoming increasingly difficult, if not impossible to treat

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WE ARE DEVELOPING AWARD CRITERIA TO COMBAT AMR

The Nordic countries are developing common criteria to prevent bacterial AMR from manufacturing of antibiotics

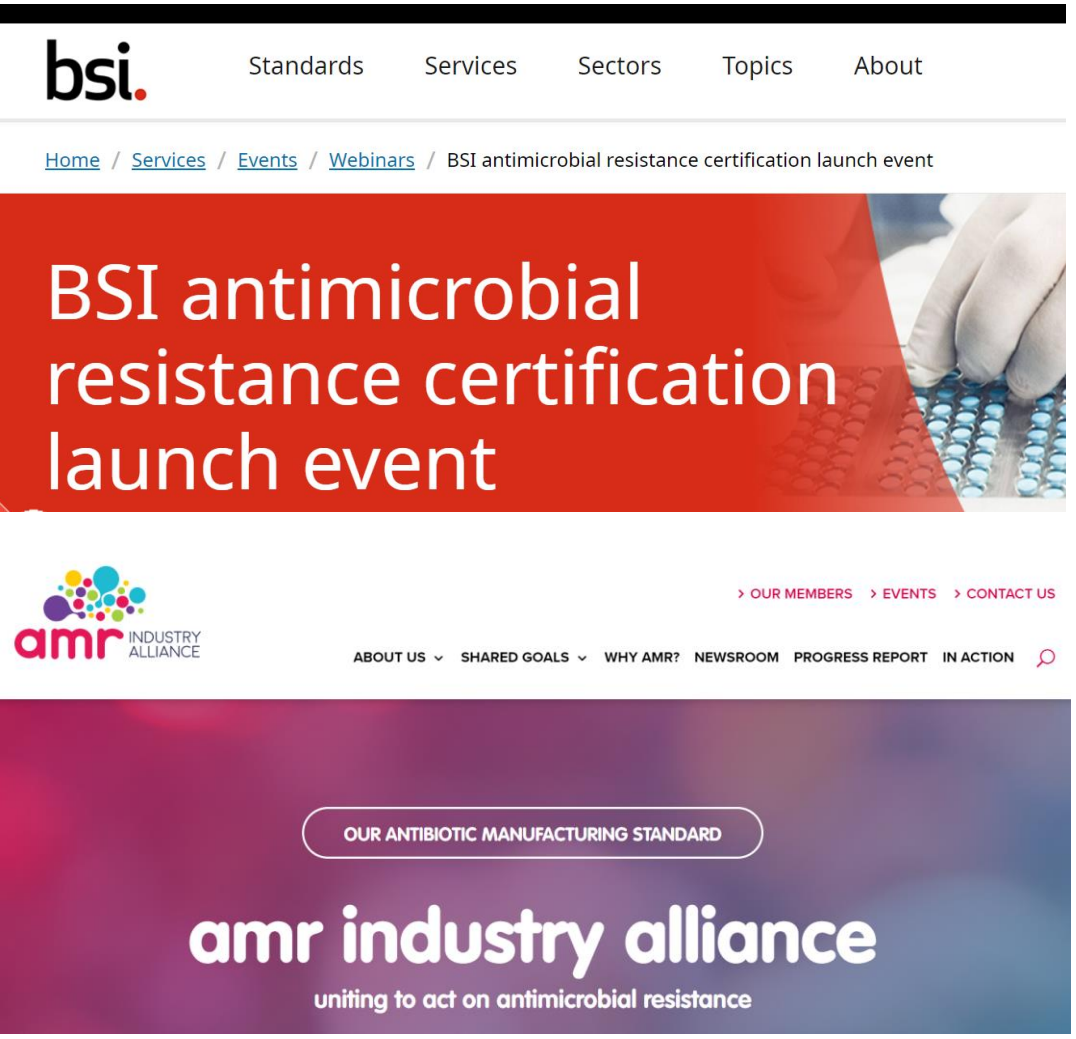
The criteria are based on the standard of AMR Industry Alliance og British Standard (BSI)

We prefer criteria based on an international standard – with a certification scheme:

- A request from the suppliers – operating globally
- Reduces administrative burden and transition costs
- Increases quality of documentation

Link to Joint Nordic Tender (Lægemidler nordisk fællesudbud): https://levportal.amgros.dk/Udbudsoversigt/Sider/Udbud.aspx

WE PROMOTE DEVELOPMENT OF INTERNATIONAL STANDARDS



Courtney Soulsby, Global Healthcare and Lifesciences Director, BSI

Courtney Soulsby works as a Global Director for the healthcare and life Sciences sector team for BSI (British Standards Institution). Working to understanding market challenges and future needs of the healthcare sector, Courtney works with key clients and industry partners to develop holistic solutions, strategies and programs. Courtney has worked with pharmaceutical industry and their supply chain for over ten years – with a deep understanding the issues with regulation, environment and sustainability concerns, compliance, and other risk exposures when manufacturing medicines.

Steve Brooks, AMR Industry Alliance

Steve Brooks currently serves as an Advisor to the Antimicrobial Resistance Industry Alliance (AMRIA), and chairs the AMRIA Manufacturing Work Group. Steve has many years of pharmaceutical industry experience. Steve led Pfizer's Global EHS organization from 2007-2018 during which time he assumed responsibility for Business Resiliency and Environmental Sustainability for the company. In his Pfizer role, Steve was also responsible for monitoring and where appropriate, seeking to influence the external environment on EHS matters of importance to Pfizer and/or to the biopharmaceutical industry. In this capacity, Steve was a committee member of relevant trade associations and other organizations, including the AMRIA, where he played important roles especially in areas at the intersection of the environment and public health. Steve has been an advisor to the AMRIA since 2019.

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TIMELINE

Meetings in NLF working group
2022, autumn

Dialogue meetings with the industry
2023, June

Embedding in national procurement organisations
2023, autumn

Deadline for tenders
2024, April 30th

Criteria development
2023, spring

Consultantion with industry
2023, ending ultimo August

Published joint Nordic tenders
2024, March

Start of agreement
2025, April 1st

Criterion A – AMRIA Antibiotic Manufacturing Standard	
Criterion	Information to tenderer
The Supplier is compliant with the AMRIA Antibiotic Manufacturing standard or similar manufacturing standard that combats antibiotic resistance throughout the supply chain. **To achieve the highest score, the compliance to the standard this must be certified by an independent third party or the certification process must be initiated.**	Enter answer option. The purpose of the criterion is to achieve the least possible environmental impact in the manufacturing processes of the products and to prevent antibiotic resistance as a result of the production of the offered product. Documentation must be provided upon request. Compliance to the AMRIA standard can be evidenced by independent third-party certification, accredited by BSI, through program Antibiotic Resistance Manufacturing certification program by BSI – or similar program/standard. Find more information here. See the standard set by AMRIA and BSI here: https://www.amrindustryalliance.org/antibiotic-manufacturing-standard/

	Answer option
A	The supplier is compliant to AMRIA Antibiotic Manufacturing Standard or similar standard that combats antibiotic resistance throughout the whole supply chain, and this is certified by an independent 3rd party or certification process has started.
B	The supplier is compliant to AMRIA Antibiotic Manufacturing Standard or similar that combats antibiotic resistance throughout the whole supply chain, but only part of the supply chain is certified by an independent third party or certification process has started. (Specify which part of the supply chain is certified).
C	The supplier is compliant to AMRIA Antibiotic Manufacturing Standard or similar standard that combats antibiotic resistance throughout the whole supply chain, but this has not been certified by an independent third party and no certification process has started.
D	The supplier is compliant to AMRIA Antibiotic Manufacturing Standard in part of the supply chain and this has been certified by a independent third party or certification process has started. (Specify which part)
E	The supplier is compliant to AMRIA Antibiotic Standard in part of the supply chain, but this has not been certified by an independent third party and no certification process has started. (Specify which part)
F	N/A

Criterion B – PNEC		Answer option	
Criterion	Information to tenderer		
The offered product should be produced by API manufacturer and finished product manufacturer who has implemented measures for managing and/or treating wastewater from production of offered product to achieve the predicted-no-effect concentration (PNEC) of the active ingredient.	Enter answer option. The PNEC value and the source of the PNEC value utilized in the wastewater treatment of the API manufacturer and finished product manufacturer must be specified to be awarded the highest score. Measures for achieving the PNEC must be specified in an agreement with any third-party manufacturer. Documentation must be provided upon request. Further information on PNEC values: https://www.amrindustryalliance.org/wp-content/uploads/2023/02/AMR-Table-1-Update-20230222_corrected.pdf PNEC can be active pharmaceutical ingredient specific PNEC-ENV or PNEC-MIC (lowest value). If an antibiotic is not listed in the table, read-across to a similar antibiotic based on chemical structure or mode of action can be made. Alternatively, based on a statistical assessment of all available data, a default PNEC in the absence of both a PNEC-ENV and PNEC-MIC of 0.05 µg/L can be leveraged as a target. When available, a compound specific PNEC-ENV, PNEC-MIC or the lowest of both values should be used. If no data are available, a default PNEC of 0.05 µg/L should be used.	**A**	Both API and finished product manufacturers have implemented measures for achieving PNEC. (Specify which PNEC-value is used and the source)
		B	Only the API manufacturer has implemented measures for achieving the PNEC. (Specify which PNEC-values are used and the source)
		C	Only the finished product manufacturer has implemented measures for achieving the PNEC. (Specify which PNEC-values are used and the source)
		D	N/A

Criterion C+D – SOPs for wastewater and waste	
Criterion	Information to tenderer
The product offered should be produced by an API manufacturer and a finished product manufacturer who have standard operating procedure(s) to minimize the amount and concentration of active substance in wastewater.	Enter answer option. Procedure(s) for wastewater must be specified in the agreement with any subcontractor in order to fulfill the criterion. The standard operating procedure(s) must be documented on request. The purpose of the criterion is to achieve the least possible environmental impact when producing the offered product.
The product offered should be produced by an active substance manufacturer and a finished product manufacturer who have standard operating procedure(s) for handling, processing, and depositing waste to eliminate or minimize emissions of active substances into the environment.	Enter answer option. Procedure(s) for handling, processing and depositing waste must be specified in the agreement with any subcontractor in order to fulfill the criterion. The standard operating procedure(s) must be documented on request. The purpose of the criterion is to achieve the least possible environmental impact when producing the offered product.

	Answer option wastewater	Answer option waste
1	Both API and finished product manufacturers have standard operating procedure(s) for minimizing active substance in wastewater.	Both API and finished product manufacturers have standard operating procedure(s) for handling, processing, and depositing waste.
2	Only the API manufacturer has a have standard operating procedure(s)s for minimizing active substance in wastewater.	Only the API manufacturer has standard operating procedure(s) for handling, processing, and depositing waste.
3	Only the finished product manufacturer has standard operating procedure(s) for minimizing active substance in wastewater.	Only the finished product manufacturer has standard operating procedure(s) for handling, processing, and depositing waste.
4	N/A	N/A

NEXT STEP

- Common criteria for preventing antibiotic resistance in manufacturing in more European countries
- Using BSI and AMR Industry Alliance Manufacturing Standard and certification as award criteria - or in time minimum requirement
- All suppliers are certified according to the standard – both finished goods and API

WE REDUCE PACKAGING WASTE

Using common environmental award criteria in tenders

WE INCORPORATE PACKAGING CRITERIA INTO OUR TENDERS

Objective:

- Reduce the amount of packaging
- Increase reuse and recycling of packaging
- Increase the share of recycled and bio-based packaging materials.

Why:

Common requirements across markets - at the request of the suppliers

- Reduces administrative burden
- Ensure quality

https://www.regioner.dk/rfi/services/rfi-nyheder/2023/oktober/nordiske-kriterier-for-mere-baeredygtig-emballage/

A ‘LIBRARY’ OF AWARD CRITERIA

1. Reduce material consumption

    1.1 Reduce material

    1.2 Weight and material information

    1.3 Environmental burden of packaging (Annex A)

    1.4 Minimize metal use

2. Design for recycling

    2.1 Limit variety of plastic types

    2.2 Increase recyclability

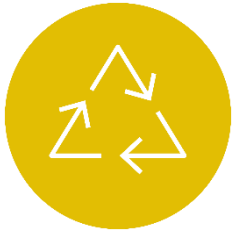
    2.3 Document recyclability

    2.4 Avoid labels that harm recyclability

3. Recycled or sustainably sourced material content

    3.1 Reduce the environmental burden of plastic packaging material

    3.2 Avoid deforestation from unsustainable card-board.



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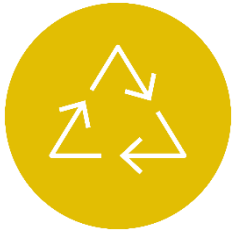
EXAMPLE: REDUCE MATERIAL CONSUMPTION

No.	Level	Criteria	Documentation
1.1 *Reduce material*	***Basic***	**Competition criterion** It is considered positive that, at contract start, the proposed packaging has been minimised in terms of weight and volume in accordance with the ten performance criteria in EN 13428 or similar during the contract period.	Completion of Annex A in EN 13428, stating which of the ten performance criteria are met.
	Advanced	**Minimum criterion** At contract start, the proposed packaging must be minimised in terms of weight and volume in accordance with the ten performance criteria in EN 13428 or similar.	Declaration of conformity with EN 13428.
	Spearhead	-	-



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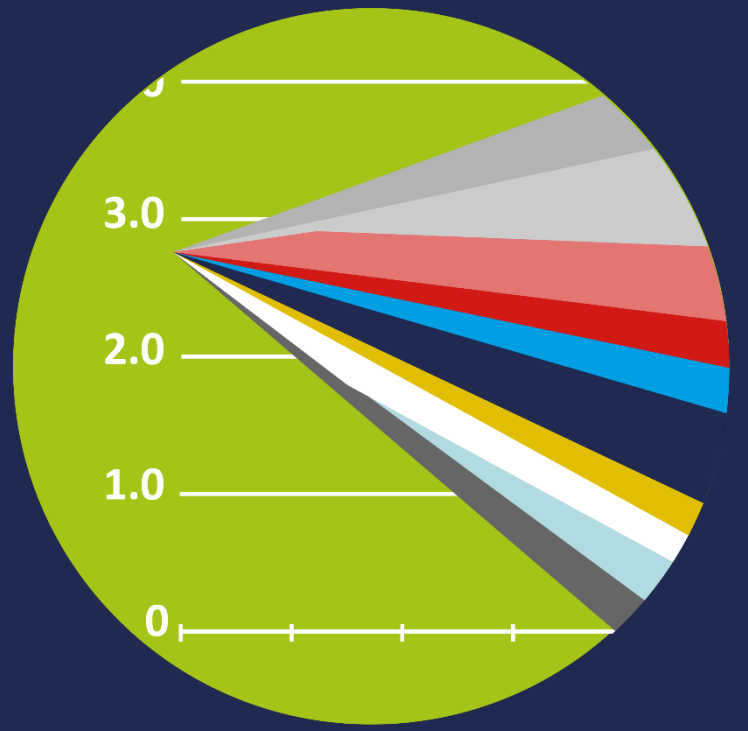
NEXT STEP – REDUCING CARBON FOOTPRINT

In 2024-25, we will develop strategies and pilot projects for carbon reductions:

- The Danish regions and Amgros will have common environmental award criteria for Last mile transport
- Environmental award criteria for energy efficiency in manufacturing of medicinal products
- A common Nordic / EU pack with e-leaflets




THANK YOU