EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Risk indicators for Shortages (Manufacturing and Quality)

NAME OF MEDICINAL PRODUCT -	Application number: EMEA/ / / Authorisation number: EU/ /
Active substance - **Pharmaceutical Form** -	☐ Chemical ☐ Sterile ☐ Biological
Supply Chain Risk Factor Evaluation	

Nr.	Item	Yes	No	Comments
1	There is only a single manufacturer of the API registered			
2	There is only a single manufacturer of Finished Product registered			
3	Location of the Manufacturing Site(s) cause any concern? [i]			
4	One or more manufacturing sites have a marginal level of GMP compliance or are subject to increased inspection surveillance. (link to EudraGMDP and potentially risk based classification) [ii]			
5	There is a high product concentration at the finished product manufacturing site[iii]			
6	End to End Manufacturing process has long lead/holding times and/or extended supply chain;			
7	Manufacturing methods are complex, with capacity bottle necks in production;			

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Nr.	Item	Yes	No	Comments
8	The manufacturer has had previous problems with quality defects and/or recalls.			
9	The manufacturer has had previous problems with supply.			
10	The medicinal product would meet the criteria of critical[iv]			
11	A design/device feature of the medicinal product could potentially prohibit switching patients.			

Recommendation, when applicable, on specific items that could be covered in next GMP inspection arising from this evaluation.	

Please record below the name, organisation and telephone number of a contact person

Name: _____

Organisation: _____

Telephone Nr.: _____

Notes

[i] This may be based on a general concern that there is a potential for future disruption in the supply due to the geographical location of the manufacturing facility, or source of plant or animal materials.
[ii] This should be based on what is in the marketing authorisation application and checking EUDRAGMP during the assessment and ideally liaising with the inspectorate. EMA will follow up for CAP's
[iii] This could be completed by EMA
[iv] Based on classification criteria for critical medicinal product agreed by CHMP