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## Drug substitution safety should be ensured, says Stockholm Network report

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Maria Bailey

While switching patients from one medicine to another may not be risky in itself, the way in which it is being done raises safety and equity concerns, says a new report, Patient Safety and Comfort– The Challenges of Switching Medicines, from the European think-tank Stockholm Network.

Innovative treatments for chronic illnesses make more patients dependent on medicines, which have to be taken for a long time. This is one reason why the consumption of prescription drugs across the world is growing rapidly. Estimates suggest, for example, that spending on them in the US is expected to almost double by 2017.

National healthcare systems are coming under increasing financial pressure, with governments implementing cost-cutting schemes including the substitution of prescribed medicines. However, this process leaves many patients at the mercy of local regulations that decide which medicines are prescribed and define opportunities for their substitution. The report's authors believe that transparency of this process should be improved.

They are also concerned that drug substitution may not always be safe for patients, particularly in the case of biosimilars, which are more complex than conventional medicines. Whether they should be regulated in the same way as conventional generic drugs remains to be seen, and the current uncertainty complicates matters for both doctors and patients.

The report analysed substitution policies in Canada, Spain, Sweden, the UK and the US, all of which are committed to cap rises in pharmaceutical spending. The authors found that almost 90% of hospitals in the US have established drug switching practices within their pharmaceutical formularies. Similar, but different in every country, practices are also on the rise in Sweden, the UK and Spain.

At the same time, the report's authors found that regulators in the surveyed countries paid more attention to switching policies for biological medicines and biosimilars than to those for chemical drugs. The automatic substitution within this class of substances in many European countries is either attributed to prescribing doctors or prohibited.

The report contains recommendations for healthcare regulators and policy makers to ensure effective and safe drug switching policies, including:

- patients should be warned about any replacements of their medications, and their advantages and disadvantages should be explained clearly. If there is a disagreement, patients should be able to either appeal against the switch decision or be allowed to make a co-payment and receive the original medication;
- the benefits and risks of substitution need to be better understood at all levels of medical practice, and this information should be made available to patients;
- healthcare practitioners and policymakers should be fully aware of the fact that biosimilars are different from conventional generic drugs and should be treated differently. This difference should be clearly explained in regulations, guidelines and educational materials; and
- drug substitution practices should be different for patients who are on a medication for a short period and those who require prescribed medicines over long periods. An effective, safe and comfortable prescription regime should be established for the latter group, and substitution should only take place with the prescribing doctor's consent after the consultation with the patient.

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<http://www.scripintelligence.com/policyregulation/Drug-substitution-safety-should-be-ensured-says-Stockholm-Network-report-297539?autnID=/contentstore/scrnews/codex/1cc33962-787f-11df-a60b-c5f200628e27.xml>