New models are needed to optimise the management of new medicines

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Abstract: Countries struggling to fund new premium priced medicines with ever increasing prices. In addition, substantial savings as medicines lose their patents. This requires co-ordinated approaches. Models are being developed centring on three pillars: pre-launch including horizon scanning; peri-launch including P & R/ risk sharing; post-launch including assessing effectiveness. This will continue to enable access to safe, effective and affordable medicines.

Introduction: Countries are struggling to fund new premium priced medicines with ever increasing prices. In addition, substantial savings as medicines lose their patents. This requires co-ordinated approaches. Models are being developed centring on three pillars: pre-launch including horizon scanning; peri-launch including P & R/ risk sharing; post-launch including assessing effectiveness [1,2]. This will continue to enable access to safe, effective and affordable medicines.

Methodology: Desk research of regulatory and other relevant policy documents as well as a thorough and extensive literature search in peer-reviewed databases.

Results: Models to optimise the use of new medicines are being developed. These centre on three pillars: pre-launch activities including horizon scanning with a specific focus on unmet needs, drugs' expected place in therapy, drugs' preliminary budget impact and forecasting (including medicines likely to lose their patents); peri-launch activities including P & R assessment and assessments of risk sharing arrangements; post-launch activities include assessing the effectiveness and safety of new medicines in routine clinical care [1,2]. Pre-launch activities to agree the number of potential patients for new cancer medicines resulted in hospitals staying within budget [3]; and health authorities that had instigated activities pre-launch saw limited excess bleeding with dabigatran [3]. Risk-sharing arrangements have increased access to new medicines; however, concerns with their confidential nature and administrative burden [2,3]. Qualitative and/or quantitative approaches are also being developed to better value (new) medicines. There is also growing use of patient level data post launch, e.g. studies highlighted concerns with dabigatran prescribing in Spain and anti-obesity medicines in Sweden. Long-term follow-up studies have shown greater effectiveness of ciclosporin vs. tacrolimus for transplants despite the rhetoric.

Conclusion: Stakeholders in the health care field are working together and developing methods to increase funding for new valued medicines whilst restricting their use where there are concerns to optimise resource use. This will (need to) continue to enable access to safe, (cost-) effective and affordable medicines.

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